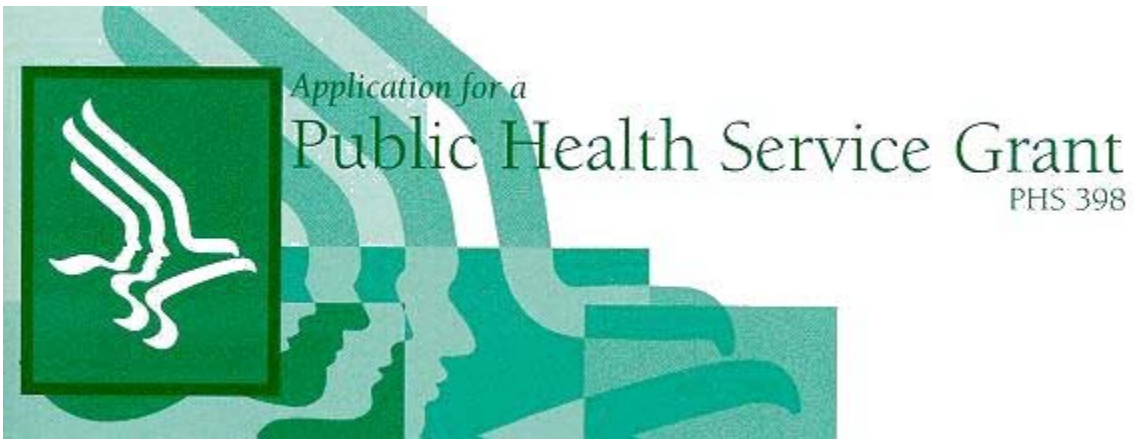

U.S. Department of Health and Human Services

Public Health Service

Grant Application (PHS 398)

Instructions for PHS 398
Rev. 05/2001

Form Approved Through 05/2004
OMB No. 0925-0001

**********IMPORTANT CHANGES AND REMINDERS**********

IMPORTANT CHANGES

INVESTIGATORS SHOULD BOOKMARK THIS WEBSITE AND CHECK IT FOR UPDATED INSTRUCTIONS AND POLICY INFORMATION PRIOR TO SUBMISSION OF APPLICATIONS.

FORMAT AND AVAILABILITY

The PHS 398 grant application instructions are available in electronic PDF format. The Table of Contents includes direct links to specific sections of the document, and text searches are possible using the "binocular" icon. Moreover, the revised format includes dynamic website links and cross-references, which enable readers to easily navigate through sections the document. The PHS 398 forms have been modified to enable the fields to be filled in directly using Adobe Acrobat Reader software. **Note: Documents can be saved only if you have obtained Adobe Acrobat.**

APPLICATION FORMS

NOTE: All Form Pages and Format Pages have been renumbered.

Form Page 1: Face Page
Items for Social Security Number and Organizational Code have been eliminated.

Human Subjects Research box (Item 4) has been modified as follows:

- 4a: No/Yes check boxes for "Research Exempt"
- 4b: Human Subjects Assurance Number
- 4c: No/Yes checkboxes for Phase III Clinical Trial

Modular Budget Format Page: Budget Justification Page for Modular Research Grant Applications.
A format page and specific instructions for preparing Modular Grant Applications are provided.

Biographical Sketch Format Page:
A ***standardized format*** for the Biographical Sketch (maximum of four pages for each key person) will be used for all (modular and other) research grant applications. A format page, including a sample biographical sketch, has been developed.

Resources Format Page:
A format page has been developed. See Section I, Item 7.

Checklist Form Page:
Assurances and Certifications. This section has been updated to include Research on Transplantation of Human Fetal Tissue; Women and Minority Inclusion Policy; Inclusion of Children Policy; Research Using Human Pluripotent Stem Cells; Non-Delinquency on Federal Debt; Recombinant DNA; and for STTR only, Certification of Research Institution Participation. See Section III. G, "Assurances and Certifications."

Facilities and Administrative (F&A) costs.
This section includes spaces to calculate F&A costs for the initial year through the entire budget period. (F&A costs were formerly referred to as Indirect Costs for some types of applications.)

Other Support Format Page:
A ***standardized format*** for the Other Support information will be used for all (modular and other) research grant applications. Do NOT submit Other Support information with the application. NIH staff will request this information at an appropriate time after peer review. See Section III-B.

Appendix Material:
Applicants may ONLY include manuscripts that have been *accepted* for publication. Manuscripts submitted for publication may no longer be included. See Section I-9.

INSTRUCTIONS

HUMAN SUBJECTS RESEARCH

Specific instructions regarding the use of human subjects in research, including new format pages for Women and Minority Inclusion enrollment and reporting and instructions regarding inclusion of a Data and Safety Monitoring Plan for clinical trials. Information about inclusion of women, minorities, and children are no longer part of the 25-page limit of the Research Plan. See Section I-8, Item e.

SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) GRANT PROGRAMS

PHS 398 Application Forms and Instructions incorporate the SBIR and STTR Grant Programs. See instructions in Section VI.

REMINDERS

- Type size and format specifications must be followed or the application will be designated as incomplete and will be returned to the applicant organization without peer review.
- Prepare a succinct Research Plan. There is no requirement for applicants to use the maximum allowable pages allotted to the Research Plan (Items a-d).
- Required Education in the protection of human research subjects (submitted prior to award.) See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

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FOREWORD

The PHS 398 instructions contain information for preparing applications for:

Public Health Service (PHS) Research Grants

Research Career Awards

Institutional National Research Awards (Training Grants)

Small Business Innovation Research (SBIR) Grants

Small Business Technology Transfer (STTR) Grants

The PHS 398 is required for all new, revised, competing continuation, and supplemental research grant, research training grant, and cooperative agreement applications. It is formatted according to the following sections:

Section I: Specific instructions for completing the application

Section II: General information on submitting the application

Section III: Definitions, assurances, and other relevant information

Section IV: Information pertinent to research career awards

Section V: Information pertinent to institutional training grants

Section VI: Instructions for submitting SBIR and STTR applications

Section VII: Grant application forms in editable PDF format.

The PHS 398 grant application instructions and interactive forms will be available in electronic PDF format. Form pages are available separately on the NIH Web Site (http://grants.nih.gov/grants/funding/phs398/phs398.pdf).

Investigators are encouraged to bookmark this website for future submissions and for instructions on submitting just-in-time other support information.

THESE INSTRUCTIONS AND APPLICATION FORMS (revised 05/2001) SUPERSEDE ALL PREVIOUS EDITIONS. Applicants should give careful attention to the instructions, because an application that fails to meet the PHS requirements will be grounds for the PHS to return the application without peer review. A properly prepared application will facilitate the administrative processing and peer review that must occur before an award can be made.

While the instructions are generally applicable, many grant programs have additional, specific instructions. Applicants should contact an official (See Section II-C, "Interactions Before Submission", p.33) of the PHS awarding component (Institute, Center or other unit) to obtain the most current information and instructions.

GRANTS INFORMATION

The Division of Extramural Outreach and Information Resources is the central source for general information about NIH extramural research and research training programs, funding mechanisms, the peer review system, and application procedures. The NIH Grants Information Web site (http://grants.nih.gov/grants/oer.htm) provides a repository of helpful information. Additional information can be obtained by e-mailing your request to: GrantsInfo@nih.gov or by calling (301) 435-0714.

GRANTS POLICY STATEMENTS

The PHS Grants Policy Statement is a compilation of the salient features of policies and various policy issues regarding the administration of PHS grant awards – other than NIH. This publication is generally available in institutional offices of sponsored research. If not available, a copy may be obtained from the NIH Web site.

The NIH Grants Policy Statement serves as the term and condition of award and is a compilation of the salient features of policies and various policy issues regarding the administration of NIH awards. This publication is generally available in institutional offices of sponsored research. If not available, a copy may be obtained from the NIH Web site.

NIH GUIDE FOR GRANTS AND CONTRACTS

The NIH Guide for Grants and Contracts, a weekly electronic publication, contains all NIH requests for applications (RFAs) and program announcements (PAs), RFAs and PAs from other PHS agencies, and vital information about NIH and PHS policies and procedures. The NIH Guide is also available on the NIH Web site at http://grants.nih.gov/grants/guide or via LISTSERVE e-mail. For instructions to subscribe, visit http://grants.nih.gov/grants/guide/listserv.htm.

The PHS estimates that it will take approximately 40 hours to complete this application for a regular research project grant. This estimate does not include time for development of the scientific plan. Items such as human subjects and vertebrate animals are cleared and accounted for separately. Therefore, these items are also not part of the time estimate. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance office, 6705 Rockledge Drive MSC 7974, Bethesda, MD 20892-7974, ATT: PRA (0925-0001). **Do not send applications or any materials related to training or career award applications to this address.**

I. PREPARING YOUR APPLICATION

A. INTRODUCTION

Read all of the instructions thoroughly prior to preparing your application.

These instructions pertain to applications for research project grants. Use the additional instructions and sample pages included in sections IV, V, or VI of this document when applying for Research Career Awards, Institutional National Research Service Awards or Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Awards.

When applying for other specialized grants or cooperative agreements, request additional instructions from the appropriate PHS awarding component. Phone numbers for contacting these awarding components are listed in Section II-C, "Interactions Before Submission" (p.33). For further assistance, contact:

GrantsInfo
National Institutes of Health (NIH)
E-mail: GrantsInfo@nih.gov
Phone: (301) 435-0714.

REQUESTS FOR APPLICATIONS/ PROGRAM ANNOUNCEMENTS

If you are responding to a specific request for applications (RFA) or program announcement (PA) published in the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/index.html), the *Federal Register* (http://www.access.gpo.gov/nara/index.html), or other public media, then it is important that you contact the issuing PHS component for additional instructions. The instructions in the RFA or PA may differ from the general instructions, and they supersede the general instructions. Many RFAs incorporate On-Time (Just-in-Time) procedures. Thus, it is important for applicants planning to respond to RFAs to review the instructions in the announcements carefully. Each RFA and PA contains contact information under INQUIRIES in addition to information specific to the RFA or PA.

AUTHORIZATION

The PHS requests the information described in these instructions pursuant to its statutory authorities for awarding grants, contained in Sections 301 (a) and 487 of the PHS Act, as amended (42 USC 241a and 42 USC 288). Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the PHS' ability to review an application and to monitor the grantee's performance.

B. GENERAL INSTRUCTIONS

Read and follow the instructions carefully to avoid delays, misunderstandings and possible return of applications. Prepare the application single-sided and single-spaced, and stay within the one-half inch margin limitations indicated on the form and format pages. The print must be clear and legible. Use standard size, black letters that can be clearly copied.

In preparing the application, use English and avoid jargon. If terms are not universally known; then, spell out the term the first time it is used, with the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

FORMAT SPECIFICATIONS

Observe type size and format specifications throughout the application, or the application will be returned without review. See frequently asked questions FAQs (http://www.format.nih.gov/FAQ/FAQ.htm) for additional information related to format requirements. The application must be clear, readily legible, and conform to the following four requirements:

1. The height of the letters must not be smaller than 10 point; Helvetica or Arial 12-point is the NIH-*suggested* font.
2. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi;
3. No more than 6 lines of type within a vertical inch;
4. Margins, in all directions, must be at least ½ inch.

Applicants should check the type size using a standard device for measuring type size, rather than relying on the font selected for a particular word processing/printer combination. Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be readily legible. The type size used throughout the application must conform to all four requirements. **Small type size makes it difficult for reviewers to read the application; consequently, the use of small type will be grounds for the PHS to return the application without peer review.** Adherence to type size and line spacing requirements is also necessary so that no applicant will have an unfair advantage, by using small type, or providing more text in their applications.

Do not use photo reduction. Prepare all graphs, diagrams, tables, and charts in black ink. The application must contain only material that reproduces well when photocopied in black and white. Glossy photographs or other materials that cannot be photocopied must be submitted in five collated sets as appendices (see Section I-9, Appendix; p. 28.)

You may substitute computer-generated facsimiles for government-printed forms; however, they must maintain the exact wording and format of the government-printed forms, including all captions and spacing. **Deviations from the font size specifications and page limitations will be grounds for the PHS to reject and return the entire application without peer review.**

PAGE LIMITATIONS AND CONTENT REQUIREMENTS

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in NIH solicitations, internet Web site addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an Internet site as it could compromise their anonymity.

Observe the page number limitations given in Table 1. Only in cases involving interdependent multiple subprojects (e.g., Program Projects and Multi-Center Clinical Trials) will the PHS accept applications that exceed the page number limitations. However, specific page number limits may apply to each subproject. For information pertaining to page number limits for such projects, contact the awarding component to which the application may be assigned. (See Section II-C, "Interactions

Before Submission" p.33.) The page number limitations may also be different for other specialized grant applications. For information regarding page number limitations, request and follow the additional instructions for those applications.

TABLE 1. PAGE LIMITATIONS AND CONTENT REQUIREMENTS

Section	Page Limit	Content
Introduction - Revised applications - Supplemental applications	 3 1	See Instructions (p.16)
Research Plan - Sections a-d - Sections e-i	25* (*Some exclusions for competing continuation applications) none	Text plus all figures, charts, tables, and diagrams
Biographical Sketches	4	No more than four pages for each key person
Literature Cited	none	Complete citations, including titles and all authors
Appendix	none	No more than 10 publications (including *accepted* manuscripts); photographs (include a copy in the Research Plan); questionnaires; and other materials that do not photocopy well.

Note: Failure to comply with the formatting and page specifications will be grounds for the PHS to reject and return the entire application without peer review.

The Division of Receipt and Referral has the responsibility to make the final determination of legibility and authority to return applications. Questions should be directed to the Division of Receipt and Referral, Center for Scientific Review, (301) 435-0715.

C. SPECIFIC INSTRUCTIONS

1. FACE PAGE

Note Some fields on the Form Pages are pre-set to auto calculate. In these cases, a zero will appear until actual data are entered.

(FORM PAGE 1, PDF FORMAT)

Note: Character length restrictions noted on the face page must be followed.

ITEM 1. TITLE OF PROJECT

Do not exceed 56 characters, including the spaces between words and punctuation. Choose a title that is specifically descriptive, rather than general. A new application must have a different title from any other PHS project with the same principal investigator/program director. A competing continuation or revised application should ordinarily have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title. A supplemental application must have the same title as the currently funded grant.

ITEM 2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS (RFA) OR PROGRAM ANNOUNCEMENT (PA)

Check "Yes" if the application is submitted in response to an RFA or a PA, and identify the number of the RFA or the number and title of

the PA. For RFAs only, attach the RFA label or a facsimile, including the RFA number, to the bottom of the face page of the original application. The RFA label is under the general mailing label, following the checklist and personal data pages. In addition, identify grant applications such as for the Research Career Award, Academic Research Enhancement Award (AREA), Institutional National Research Service Award, and AIDS research. Any special instructions in the RFA must be followed when preparing the application.

ITEM 3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

New Investigator. Check "Yes" in the "New Investigator" box *only* if the principal investigator has not previously served as such on any PHS-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory/developmental grant (R21), or research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research career (K01, K08, K22, and K23). **If the Principal Investigator/Program Director is not a new investigator, check "No."** Current or past recipients of Independent Scientist and other nonmentored career awards (K02 and K04) are not considered new investigators.

Item 3a. Name of Principal Investigator/ Program Director

Name the one person responsible to the applicant organization for the scientific and technical direction of the project. A supplemental application **must** have the same principal investigator/program director as the currently funded grant. **PHS staff conduct official business only with principal investigators and institutional officials.**

Item 3b. Degree(s)

Indicate up to three academic and professional degrees or other credentials, such as licenses (e.g., R.N.)

Item 3c. Position Title

Provide the academic or professional title of the principal investigator/ program director. If more than one title, indicate the one most relevant to the proposed project, such as Professor of Biochemistry, Chief of Surgical Service, or Group Leader.

Item 3d. Mailing Address

Provide complete information (including room number, building, and street address) necessary for postal delivery. All written communications with the principal investigator will use this address. For electronic mail, enter the appropriate e-mail address.

Item 3e. Department, Service, Laboratory, or Equivalent

Indicate your organizational affiliation, such as department of medicine, materials research laboratory, or social sciences institute.

Item 3f. Major Subdivision

Indicate your school, college, or other major subdivision, such as medical, dental, engineering, graduate, nursing, or public health. If there is no such subdivision, enter "None."

Item 3g. Telephone and Fax Numbers

Provide a daytime telephone number and, if available, a fax number.

ITEM 4. HUMAN SUBJECTS

(See Section III-A, "DEFINITIONS"; p. 35)

No Human Subjects

Check "No" if activities involving human subjects are not planned at any time during the proposed project period. The remaining parts of Item 4 are then not applicable.

Human Subjects Involved

Check "'Yes" if activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution. "Yes" should be

checked even if the research is exempt from regulations for the protection of human subjects (See Exemption Categories; p. 21).

Item 4a. Exemptions from Human Subjects Regulations

Check "Yes" if the activities proposed are designated to be exempt from the regulations. Insert the exemption number(s) corresponding to one or more of the six exemption categories isted in Section I, 8.E (p.21) under "Exempt Human Subjects Research." If the proposed research corresponds to one or more of the exempt categories then the remaining parts of Item 4 of the Face Page are not applicable.

Note: Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research may result in delays in the review of an application or the return of the application without review. The PHS will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan. In doubtful cases, consult with the Office for Human Research Protections (OHRP) Department of Health and Human Services by accessing their website http://ohrp.osophs.dhhs.gov/ for guidance and further information.

Human Subjects Activities Not Exempt from Regulations

Check "No" if the planned activities involving human subjects are not exempt, and complete the remaining parts of Item 4.

Item 4b. Human Subjects Assurance Number

If the applicant organization has an approved Federal Wide Assurance (FWA), Multiple Project Assurance (MPA), Single Project Assurance (SPA) Number or Cooperative Project Assurance Number on file with the OHRP (http://ohrp.osophs.dhhs.gov/) that covers the specific activity, insert the number in the space provided.

Insert "None" in Item 4b if the applicant organization does not have an approved assurance on file with OHRP. **Do not insert the human subjects assurance number of any collaborating institution in the space provided.** In this case, the applicant organization, by the signature on the face page, is declaring that it will comply with 45 CFR 46 and proceed to obtain a human subjects assurance (see http://ohrp.osophs.dhhs.gov.)

Note: NIH no longer requires IRB approval and certification of the proposed research prior to NIH peer review of an application (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html). As part of the peer review process, the peer review group carefully considers protections from research risk. The peer review group will assess the adequacy of safeguards of the rights and welfare of research participants based on the information in the application. See "Research Plan, *Item e.*, Human Subjects Research; (p. 17.)

Following NIH peer review, applicants and their institutions will be notified of the need for review and certification for the proposed research by an OHRP- Registered Institutional Review Board (IRB). See http://ohrp.osophs.dhhs.gov to register an IRB. The certification of IRB approval from an official signing for the applicant organization must then be sent to and received by the Grants Management Office identified in the notice requesting IRB certification. This IRB certification must include: the PHS application number, title of the project, name of the principal investigator/program director, date of IRB approval, and appropriate signatures. You may also use optional Form 310, "Protection of Human Subjects" to provide IRB certification (see http://ohrp.osophs.dhhs.gov/humansubjects/assurance/as-fm310.htm.)

Any modifications in the Research Plan section of the application, required by the IRB, must be submitted with the follow-up certification. It is the responsibility of the principal investigator/program director and the applicant organization to submit the follow-up certification.

When a year will have elapsed between the initial IRB review date and the anticipated award date, awarding unit staff shall require re-review by the IRB and certification prior to award.

Item 4c. NIH-Defined Phase III Clinical Trial

Check "Yes" or "No" to indicate whether the project is an NIH-Defined Phase III clinical trial. See Section III-A, "DEFINITIONS" (p. 35) for

definitions of clinical research and Phase III clinical trial. Phase III clinical trials require a Data and Safety Monitoring Board. See Data and Safety Monitoring Plan (p.26).

ITEM 5. VERTEBRATE ANIMALS

Check "No" if activities involving vertebrate animals are not planned at any time during the proposed project period. The remaining parts of Item 5 are then not applicable.

Check "Yes" if activities involving vertebrate animals are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution,

Item 5a. IACUC Certification.

NIH policy requires the submission of Institutional Animal Care and Use Committee (IACUC) approval when animal studies are involved.

Note: The certification of IACUC approval must be submitted with the application or within 60 days after the application receipt date. Otherwise, the application will be considered incomplete and deferred to the next review cycle.

Enter the date of approval by the IACUC in the space provided, if the applicant organization has an Animal Welfare Assurance.

If the IACUC review is unavoidably delayed beyond the submission of the application, enter "Pending" in the box requesting IACUC approval date. A follow-up certification of IACUC approval from an official signing for the applicant organization must then be sent to and received by the Scientific Review Administrator of the scientific review group (SRG). The name and address of the Scientific Review Administrator of the SRG will be sent to the principal investigator/program director and applicant organization as soon as possible after the receipt date, usually within 6 weeks. To avoid delays in review, send the follow-up information directly to the Scientific Review Administrator.

The follow-up certification must include: the PHS application number, title of project, name of principal investigator/program director, institution, Animal Welfare Assurance number, date of IACUC approval, and appropriate signatures.

Any modifications of the Research Plan section of the application, required by the IACUC, must be submitted with the follow-up certification. It is the responsibility of the principal investigator/program director and the applicant organization to submit the follow-up certification.

Item 5b. Animal Welfare Assurance

Enter the Assurance number of the applicant organization in Item 5b if the applicant organization has an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). See http://grants.nih.gov/grants/olaw/olaw.htm.

Insert "None" in Item 5b if the applicant organization does not have an approved Animal Welfare Assurance on file with OLAW. **Do not insert the Animal Welfare Assurance of any collaborating institution in the space provided**. By inserting "None" and, by the signing on the face page, the applicant organization is declaring that it will comply with PHS policy regarding the care and use of animals by establishing an IACUC and submitting an Animal Welfare Assurance and certification of IACUC approval when requested to do so by OLAW.

ITEM 6. DATES OF PROPOSED PERIOD OF SUPPORT

Request no more than 5 years of support. To select an appropriate beginning date for a new application, consult the review and award schedule in Table 2, Receipt, Review, and Award Cycles. For a competing continuation application, choose a beginning date immediately following the termination date of the current period of support. **Submit a supplemental application only for a period within the current period of support.** (A supplement may not extend beyond the parent award period.) Make the ending date of the

supplement's first budget period coincide with the ending date of the budget period that is to be supplemented, regardless of the supplement's beginning date. If requesting supplemental funds for the future years of a currently funded grant, make the future years' budget periods coincide with those of the currently funded grant.

PHS awarding components may not always be able to honor the requested start date. No commitments or obligations should be made until confirmation of the actual start date by the awarding component.

ITEM 7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD.

Be sure to read the instructions for Modular Grant Applications (p.13) to determine if the application should be submitted in this format. All amounts requested in Items 7 and 8 and on the budget pages must be in U.S. dollars.

Item 7a. Direct Costs Requested for Initial Budget Period.

Enter the direct costs from Form Page 4 or the "Modular Budget Format Page." For budget requests of $500,000 direct costs or more for any year, see specific instructions in Section I-4 (p.10).

Item 7b. Total Costs Requested for Initial Budget Period

Enter the sum of the total direct costs from Form Page 4 or the "Modular Budget Format Page" and the Facilities and Administrative costs for the initial budget period, as calculated on the Checklist Form Page.

ITEM 8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT.

Item 8a. Direct Costs Requested for Proposed Period of Support.

Enter the direct costs from Form Page 5 or the "Modular Budget Format Page."

Item 8b. Total Costs Requested for Proposed Period of Support

Enter the sum of the total direct costs from Form Page 5 or the "Modular Budget Format Page" and the Facilities and Administrative costs for the proposed period of support, as calculated on the Checklist Form Page.

ITEM 9. APPLICANT ORGANIZATION.

Name the one organization that will be legally and financially responsible for the conduct of activities supported by the award. **If the NIH-assigned Institutional Profile File (IPF) number is known, insert it in Item 9; otherwise, leave it blank.**

ITEM 10. TYPE OF ORGANIZATION

Check the appropriate box. See Section III-A, "DEFINITIONS;" (p. 35)

ITEM 11. ENTITY IDENTIFICATION NUMBER, DUNS NUMBER, CONGRESSIONAL DISTRICT.

Enter the number assigned to the applicant organization by the Department of Health and Human Services for payment and accounting purposes. If a number has not yet been assigned, enter either (1) the organization's Internal Revenue Service employer identification number (nine digits). or (2) the words "Applied for" to indicate that the organization does not have an EIN but has applied to the local office of the IRS for one. An individual's social security number is not appropriate for this item. If a Dun & Bradstreet (DUNS) number is available, it should also be entered. The DUNS number is a nine-digit identification code assigned by Dun & Bradstreet. Also, enter the number of the Congressional District.

ITEM 12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE

Name the applicant organization administrative official to be notified if an award is made. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the administrative official.

ITEM 13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION

Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or

grant application, including the applicable Federal regulations. For electronic mail, enter the appropriate e-mail address.

ITEM 14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE

An original signature, in ink, is required. "Per" signatures are not acceptable. Date of signature must be included.

ITEM 15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE.

An original signature, in ink, is required. "Per" or "For" signatures are not acceptable. Date of signature must be included. ***In signing the application face page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application.*** The applicant organization is responsible for verifying the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

ASSURANCES/CERTIFICATIONS

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Definitions are provided in the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/policy.htm) and in Section III. G. Assurances and Certifications (p.43) of these instructions.

- Human Subjects
- Research on Transplantation of Human Fetal Tissue
- Women and Minority Inclusion Policy
- Inclusion of Children Policy
- Research Using Human Pluripotent Stem Cells
- Vertebrate Animals
- Debarment and Suspension
- Drug-Free Workplace
- Lobbying
- Non-Delinquency on Federal Debt
- Research Misconduct
- Civil Rights
- Handicapped Individuals
- Sex Discrimination
- Age Discrimination
- Recombinant DNA and Human Gene Transfer Research
- Financial Conflict of Interest (except Phase I SBIR/STTR)
- Certification of Research Institution Participation (STTR only)

NOTICE OF PROPRIETARY INFORMATION

When the application contains information that constitutes trade secrets; or information that is commercial or financial; or information that is confidential or privileged, the information must be identified by asterisks (*) and page number in the Research Plan. The information is furnished to the Government in confidence with the understanding that it shall be used or disclosed only for evaluation of this application; provided that, if a grant is awarded as a result of, or in connection with, the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

2. DESCRIPTION, PERFORMANCE SITES, AND KEY PERSONNEL

(FORM PAGE 2, PDF FORMAT)

NOTE: Do not insert additional pages between Form Page 1 and Form Page 2.

DESCRIPTION

Instructions for this section are on Form Page 2.

Note: Do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the project description will be entered into an NIH database (CRISP) and will become public information.

PERFORMANCE SITE(S)

Indicate where the work described in the Research Plan will be conducted. If there is more than one performance site, list all the sites, including V.A. facilities and foreign sites, and provide an explanation on the Resources Format page of the application. One of the sites indicated must be the applicant organization or be identified as off-site in accordance with the conditions of the applicant organization's negotiated Facilities and Administrative (F&A) agreement. This information must agree with the F&A information on the Checklist Form Page of the application. State if a consortium/contractual arrangement is involved with one or more collaborating organizations for the conduct of a portion of the work described in the Research Plan. If a performance site is participating in research using human subjects, it is the responsibility of the applicant organization to assure that the performance site complies with the regulations in 45 CFR Part 46.

KEY PERSONNEL

Key personnel are defined as all individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. **Consultants should also be included if they meet the definition of "key personnel."**

Start with the principal investigator. All other key personnel should be listed in alphabetical order, last name first. For each individual provide: name, organization (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project. Use additional pages as necessary.

3. RESEARCH GRANT TABLE OF CONTENTS

(FORM PAGE 3, PDF FORMAT)

Provide the page number for each category listed on the Table of Contents. Consecutively number pages throughout the application. Place page numbers at the bottom of each page. **Do not include unnumbered pages and do not use suffixes, such as 5a, 5b**.

BUDGET INSTRUCTIONS FOR NON-MODULAR GRANT APPLICATIONS

Applicable only to R01, R03, R15, and R21 applications.

Budget instructions for research grant applications requesting more than $250,000 direct costs per year.

(USE FORM PAGE 4 AND FORM PAGE 5, PDF FORMAT)

NOTE: If the proposed budget is $250,000 or less per year, skip items 4 and 5 that follow, use the 'Modular BudgetFormat Page' only and follow the specific Budget Instructions for Modular Grant Applications (p.14).

4. DETAILED BUDGET FOR INITIAL BUDGET PERIOD

(FORM PAGE 4, PDF FORMAT)

BUDGET REQUESTS OF $500,000 DIRECT COSTS OR MORE FOR ANY YEAR

An NIH applicant planning to submit an investigator-initiated new (type 1), competing continuation (type 2), competing supplement or

any amended/revised version of the preceding grant application types requesting $500,000 or more in direct costs for any year is advised that he or she must contact Institute or Center program staff before submitting the application. A cover letter must be sent with the application identifying the staff member and NIH Institute or Center who agreed to accept assignment of the application. If unsure which Institute or Center to contact, call the Division of Receipt and Referral,CSR, NIH at (301) 435-0715. This policy does not apply to applications submitted in response to RFAs. However, an application submitted in response to an RFA must be responsive to any budgetary limits specified in the RFA.

Each item listed in the budget must be clearly justified on Form Page 5. All amounts must be in U.S. dollars. List only the direct costs requested in this application. Do not include any items that are treated by the applicant organization as Facilities and Administrative (F&A) costs according to a Federal rate negotiation agreement, except for those F&A costs included in consortium/contractual costs.

For a supplemental application, show only those items for which additional funds are requested. If the initial budget period of the supplemental application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

FOREIGN JUSTIFICATION

For projects with a foreign component, explain and justify on Form Page 5 or, for Modular Applications, on the "Modular Budget Format Page." For a definition of a substantial foreign component, see Section III. A (p. 35).

PERSONNEL

Name. Starting with the principal investigator, list the names of all applicant organization employees who are involved on the project during the initial budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff.

Role on Project. Identify the role of each individual listed on the project. Describe their specific functions under Justification on Form Page 5. Provide budget narrative for ALL personnel by position, role, and level of effort. This includes consultants and any "to be appointed" positions.

Type of Appointment/Months. List the number of months per year reflected in an individual's contractual appointment to the applicant organization. PHS staff assume that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50 percent time, identify with an asterisk (*) and provide a full explanation under "Justification" on Form Page 5. Individuals may have split appointments, for example for an academic period and a summer period. For each appointment, identify and enter the number of months on separate lines. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for that period.

Percent of Effort on Project. For each individual at the applicant organization, list the percent of each appointment to be spent on this project.

Institutional Base Salary. An applicant organization may choose to leave this column blank. However, PHS staff will require this information prior to award. See Section III-A, "DEFINITIONS" (p. 35).

Salary Requested. Enter the dollar amounts for each position for which funds are requested. The salary requested is calculated by multiplying the individual's institutional base salary by the percent of effort on this project. Explain under "Justification" on Form Page 5 if a lesser amount is requested (e.g., endowed position or institutional sources.)

Some PHS grant recipients are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award. For

guidance on current salary limitations, see the *NIH Guide for Grants and Contracts* on the NIH grants Web site or contact your office of sponsored programs.

Fringe Benefits. Fringe benefits may be requested, in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.

Totals. Calculate the totals for each position and enter the subtotals in each column where indicated.

The applicant organization and its subcontractor(s) may omit salaries and fringe benefits for individuals from copies of the application that are available to non-Federal reviewers. In such cases, replace the numbers with asterisks. You must show the subtotals. Provide one copy, for use only by PHS staff, with the asterisks replaced by the salaries and fringe benefits.

Special Instructions: Joint University and Department of Veterans Affairs Appointments

Individuals with Joint University and Department of Veterans Affairs Appointments may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. Signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the Department of Veterans Affairs (VA); and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work.

Consultant Costs

Whether or not costs are involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who serve on external monitoring boards or advisory committees to the project. Describe the services to be performed on Form Page 5 under "Justification." Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

Equipment

List each item of equipment separately and justify each purchase on Form Page 5.

Supplies

Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized. If animals are to be purchased, state the species and the number to be used.

Travel

Itemize travel requests and justify on Form Page 5. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested.

Patient Care Costs

If inpatient and/or outpatient costs are requested, provide the names of any hospitals and/or clinics and the amounts requested for each on Form Page 5.

State whether each hospital or clinic has a currently effective DHHS-negotiated research patient care rate agreement and, if not, what basis is used for calculating costs. If an applicant does not have a DHHS-negotiated rate, the PHS awarding component can approve a provisional rate. Indicate, in detail, the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both inpatient and outpatient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site.

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be

lower at the start or during the course of the project, plan budget(s) accordingly.

Provide specific information regarding anticipated sources of other support for patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of General Clinical Research Centers.

ALTERATIONS AND RENOVATIONS

Itemize, by category and justify on Form Page 5, the costs of essential alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs. Costs for alterations and renovations are not allowed on grants made to foreign organizations.

OTHER EXPENSES

Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission in lieu of salary. Justify costs on Form Page 5.

CONSORTIUM/CONTRACTUAL COSTS

Each participating consortium/contractual organization must submit a separate detailed budget for both the initial budget period (Form Page 4) and the entire proposed project period (Form Page 5).

Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including Facilities and Administrative (indirect) costs. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs.

When Facilities and Administrative (F&A) costs are requested by a consortium organization, enter the F&A costs in the F&A cost category for each supplementary budget. Provide the F&A cost base and rate. Leave the direct cost category blank.

For the applicant organization budget, list the sum of all consortium/contractual costs (direct and F&A). Insert additional page(s) after Form Page 5, numbering them sequentially. (Do not use 5a, 5b, 5c, etc.)

5. BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT

(FORM PAGE 5, PDF FORMAT)

Enter the totals under each budget category for all additional years of support requested. Identify with an asterisk (*), and justify any significant increases or decreases from the initial year budget. Also, justify budgets with more than a standard escalation from the initial to the future year(s) of support.

BUDGET INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS

Research grant applications requesting up to $250,000 direct costs per year

(USE THE MODULAR BUDGET FORMAT PAGE; OMIT FORM PAGE 4 AND FORM PAGE 5)

NIH requires a Modular Budget Format (http://grants.nih.gov/grants/guide/notice-files/not98-178.html) for all research grant applications requesting up to $250,000 direct costs per year. **DO NOT COMPLETE FORM PAGE 4 AND FORM PAGE 5.** If an application requesting $250,000 or less contains Form Page 4 and/or Form Page 5, the application will be returned to the applicant organization without peer review.

Applicants must request total direct costs in modules of $25,000, reflecting appropriate support for the project. There will be no future year escalations. A typical modular grant application will request the same number of modules in each year.

There is no form page for the budget of modular grant applications. Follow the format on the "Modular Budget Format Page." At the top of the Budget Justification Page for Modular Research Grant Applications, enter (a) the total direct costs requested for each year and (b) the total direct cost requested for the entire project period.

Personnel. List **all** personnel, including names, percent of effort and roles on the project. No individual salary information should be provided. Since the modules should be a reasonable estimate of costs allowable, allocable, and reasonable for the proposed project, applicants must use the current salary cap when estimating the number of modules. With the significant flexibility to rebudget and the ability to carry forward unobligated balances, funds generally should be available to cover any modest increase in the legislatively imposed salary cap.

Consortium/contractual costs. Provide an estimate of total costs (direct plus facilities and administrative) for each year, rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made. List all personnel, including percent of effort and roles on the project. No individual salary information should be provided. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount.

Provide an additional narrative budget justification for any variation in the number of modules requested.

NIH may request (prior to award) additional budget justification in exceptional circumstances. For further information, see http://grants.nih.gov/grants/funding/modular/modular.htm and http://grants.nih.gov/grants/funding/modular/modular_review.htm.

6. BIOGRAPHICAL SKETCH

(**FORMAT PAGE, PDF FORMAT**)

There is no form page for the biographical sketch. Follow the instructions on the "Biographical Sketch Format Page." This section must contain the biographical sketches of all **KEY** personnel including consultants following the order as listed on Form Page 2.

Use the sample format on the "Biographical Sketch Format Page" to prepare this section for **all** (modular *and* other) grant applications.

Note: The Biographical Sketch may not exceed four pages. Items A and B may not exceed two of the four-page limit.

Complete the educational block at the top of the format page, and complete sections A, B, and C.

A. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

B. Selected peer-reviewed publications or manuscripts in press (in chronological order). Do not include manuscripts submitted or in preparation.

C. Research Support. List selected ongoing or completed (during the last three years) research projects (federal or non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of principal investigator identified above.

This information will be used by the reviewers in the assessment of each individual 's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.

OTHER SUPPORT INFORMATION

NOTE: Information on other support beyond that required in the biographical sketch, should NOT be submitted with the application. Failure to comply with this requirement will be grounds for the PHS to return the application without peer review. "Other support" information is required for all applications that are to receive grant awards; however, NIH will request

complete and up to date "other support" information from applicants at an appropriate time after peer review. The Institute's scientific program and grants management staff will review this information prior to award.

7. RESOURCES

(FORMAT PAGE, PDF FORMAT)

There is no "Form Page" for resources. Follow the sample format and instructions on the "Resources Format Page" when completing information on resources available for the project. If there are multiple performance sites, then resources available at each site should be described.

8. RESEARCH PLAN

There is no Form Page for the Research Plan. The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative, and avoid redundancies. Organize *Items a-d* of the Research Plan to answer these questions:

1. What do you intend to do?
2. Why is the work important?
3. What has already been done?
4. How are you going to do the work?

INTRODUCTION (REVISED OR SUPPLEMENTAL APPLICATIONS ONLY)

All revised (amended) and supplemental applications must include an Introduction. Do not exceed three pages for revised applications or one page for supplemental applications.

REVISED APPLICATIONS

A revised application will be returned without review if it does not comply with all of these requirements.

Note: NIH policy limits the number of amended (revised) versions of an application to two and these must be submitted within two years of the original version of the application.

Before a revised application can be submitted, the principal investigator must have received the summary statement from the previous review. There must be substantial changes in the content of the application. The application must include an Introduction of not more than three pages that summarizes the substantial additions, deletions, and changes. The Introduction must also include responses to the criticisms and issues raised in the summary statement. **The changes in the Research Plan must be clearly marked by appropriate bracketing, indenting, or changing of typography, unless the changes are so extensive as to include most of the text.** This exception should be explained in the Introduction. Do not underline or shade changes. The Preliminary Studies/Progress Report section should incorporate any work done since the prior version was submitted. Acceptance of a revised application automatically withdraws the prior version, since two versions of the same application cannot be simultaneously pending.

COMPETING SUPPLEMENTS

A competing supplemental application may be submitted to request support for a significant expansion of a project's scope or research protocol. Applications for competitive supplements are **not appropriate** when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. A supplemental application **will not be accepted** until after the original application has been awarded, and **may not extend beyond the term of the current grant.** The introduction to the supplemental application should provide an overall description of the nature of the supplement and how it will influence the specific aims, research design, and methods of the current grant. Any budgetary changes for the remainder of the project period of the current grant should be discussed under the budget justification. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed supplement in relation to the goals of the original application.

If the supplemental application relates to a specific line of investigation presented in the original application that was not recommended for approval by the SRG, then the applicant must respond to the criticisms in the prior summary statement, and substantial revisions must be clearly evident and summarized in the introduction.

PAGE LIMITATIONS

Do not exceed 25 pages for *Items a-d*. All tables, graphs, figures, diagrams, and charts must be included within the 25-page limit. **Applicants are encouraged to be succinct and are reminded that there is no necessity to use all 25-pages allotted to *Items a-d* of the Research Plan.**

Full-sized glossy photographs of material such as electron micrographs or gels may be included in the Appendix; however, a photocopy of each must also be included within the page limitations of the Research Plan (see Section I-9. Appendix; p. 28.)

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet Web site addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an internet site as it could compromise their anonymity.

The 25-page limit will be strictly enforced. Applications that exceed this limit or do not conform to the type size limitations (see Section I-B; p.3) will constitute grounds for the PHS to return the application without review.

NOTICE OF PROPRIETARY INFORMATION AND TRADE SECRETS

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets or information that is commercial or financial; or information that is confidential or privileged, identify the pages in the application which contain this information by marking those paragraphs or lines containing this information with an asterisk (*) in the left-hand margin and providing the page numbers before "a. Specific Aims."

When information in the application constitutes trade secrets or information that is commercial or financial, and confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

Note: Proprietary Information and Trade Secrets should NOT be included in the project description located on Form Page 2. If the application is funded, the project description will be entered into an NIH database (CRISP) and will become public information.

RESEARCH PLAN FORMAT AND PAGE DISTRIBUTION

The PHS recommends the following format and page distribution.

a. Specific Aims.

List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, or develop new technology. **One page is recommended.**

b. Background and Significance.

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. **Two to three pages are recommended.**

c. Preliminary Studies/Progress Report.

Preliminary Studies. For new applications, use this section to provide an account of the principal investigator/program director's preliminary studies pertinent to the application information that will also help to establish the experience and competence of the investigator to pursue the proposed project.

Peer review committees generally view preliminary data as an essential part of a research grant application. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

Progress Report for Competing Continuation and Supplemental Applications. A progress report must be provided for Competing Continuation and Supplemental Applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Discuss any changes in the specific aims as a result of budget reductions. Include the complete references to appropriate publications and manuscripts accepted for publication (not part of the page limitations). Five collated sets of no more than 10 such items of background material, may be submitted in the appendix, in addition to the original set of appendix material (see Section I-9; p. 28.)

If the competing continuation or supplemental application involves human subjects, then you must also report on the enrollment of women and men and on the race and ethnicity of research subjects. Use the "Targeted/Planned Enrollment Format Page" to provide this information for each relevant funded study and for each relevant study that will be continued. Also report on any subpopulations. These tables will not be included in the research plan page limitation.

Provide a succinct account of published and unpublished results, indicating progress toward their achievement.

List the titles and complete references to all publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. Up to 10 such publications may be included in the five collated sets of appendices.

Do not complete or submit the Personnel Report with the application. When the Personnel Report is requested by the awarding component, use the Personnel Report Form Page.

The publications portion of the Competing Continuation and Supplemental Applications progress report is not included in the 25-page limit.

Six to eight pages are recommended for the narrative portion of the Preliminary Studies/Progress Report.

d. Research Design and Methods.

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as the data sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Although no specific number of pages is recommended for the Research Design and Methods section, the total for *Items a-d* may not exceed 25 pages, including all tables and figures. Applicants are encouraged to be as succinct as possible and reminded that there is no requirement that all 25 pages allotted for this section be used.

e. Human Subjects Research.

Applicants are encouraged to use the decision charts on OHRP's website

(http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm) for guidance in determining whether the proposed research involves human subjects research as defined in part A of the human subjects regulations (45 CFR 46) (See Section III A., "Definitions" p. 35).

If you have marked "Yes" for Item 4 on the Face Page of the application, create a section heading entitled Human Subjects Research immediately following the last entry in the Research Design and Methods section. When you have completed this section, you will need to address the instructions in the sections entitled "Women and Minority Inclusion in Clinical Research" (p. 22.) and the "Inclusion of Children" (p. 25) and Data and Safety Monitoring if the research involves a clinical trial. Although no specific page limitation applies to this section of the application, be succinct.

Special Populations.

Investigators who conduct research involving fetuses, pregnant women, human *in vitro* fertilization, prisoners, or children must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR 46, respectively, which describe the additional protections required for these populations. Relevant information may be obtained at the OHRP website **http://ohrp.osophs.dhhs.gov/polasur.htm**). Exemptions 1-6 below do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization (see Subparts B and C.) Also, Exemption 2 below, for research involving survey or interview procedures or observation of public behavior, does not apply to research with children (see Subpart D), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

HUMAN SUBJECTS RESEARCH SECTION

In the Human Subjects Research section, applicants must (1) address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan (see Non Exempt Human Subjects Research for specific requirements), or (2) provide a justification for exemption with sufficient information about the involvement of the human subjects to allow a determination by peer reviewers and NIH staff that a claimed exemption is appropriate (see **Exempt Human Subjects Research** for specific requirements).

Applications that fail to comply with this requirement will be designated as incomplete and will constitute grounds for the PHS to return the application without peer review.

The following table is intended to provide guidance on what must be addressed in the Human Subjects Research section.

Guidance for Preparing the Human Subjects Research Section

SCENARIO	HUMAN SUBJECTS	EXEMPT	CLINICAL RESEARCH	CLINICAL TRIAL	REQUIREMENTS
A	No	N/A	N/A	N/A	- Indicate "No Human Subjects Research"
B	Yes	No	Yes	No	- Address Protection of Human Subjects - Address Inclusion of Women and Minorities in clinical research - Address Inclusion of Children - Ethnic/racial "Targeted/Planned Enrollment Table Format Page" (New applications; Competing Continuation applications and Competing Supplements if new protocols) - Ethnic/racial "Inclusion Enrollment Report Table Format Page" (Competing Continuations, Competing Supplements, and Annual Grant Progress Reports)
C	Yes	No	Yes	Yes	- All requirements in Scenario B - Data and Safety Monitoring Plan Note: Phase III Trials require a Data and Safety Monitoring Board
D	Yes	Yes	No	N/A	- Indicate Exemption Number - Justification that the designated exemption is appropriate - Address Inclusion of Women and Minorities - Address Inclusion of Children
E	Yes	No	No	N/A	- Address Protection of Human Subjects - Address Inclusion of Women and Minorities - Address Inclusion of Children

Non Exempt Human Subjects Research

Protection of Human Subjects

If you marked "Yes" for Item 4 on the Face Page of the application and did not claim any exemptions from the regulations, create a section entitled **"Protection of Human Subjects."** In this section, you must provide information to **address all four evaluation criteria below** as they apply to the research you are proposing.

Failure to address the following human subjects protection issues will result in the application being designated as incomplete and will be grounds for the PHS to return the application without peer review.

Under each criterion, indicate whether the information relates to the primary research site, or to a collaborating performance site(s), or to all sites.

1. **RISKS TO THE SUBJECTS**

   Human Subjects Involvement and Characteristics: Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects,

such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.

Sources of Materials: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks: Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

2. **ADEQUACY OF PROTECTION AGAINST RISKS**

Recruitment and Informed Consent: Describe plans for the recruitment of subjects and the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document should be submitted to the PHS only if requested.

Protection Against Risk: Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. In studies that involve interventions, describe the plan for data and safety monitoring of the research to ensure the safety of subjects.

3. **POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS**

Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

4. **IMPORTANCE OF THE KNOWLEDGE TO BE GAINED**

Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the principal investigator must provide in this section of the application a list of the collaborating sites and their OHRP assurance numbers. Further, the principal investigator must obtain in writing, and keep on file, an assurance from each site that the four previous points have been addressed adequately at a level of attention that is at least as high as that documented at the applicant organization. Site(s) added after an award is made also must adhere to the above requirements.

Exempt Human Subjects Research

If you marked “Yes” for Item 4 on the Face Page and claimed an exemption from the human subjects regulations, then identify which one or more of the exemptions identified below is claimed. Provide a justification with sufficient information about the involvement of human subjects in the proposed research to allow a determination by peer reviewers and NIH staff that the designated exemption is appropriate.

Population Sample: Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, institutionalized individuals, or others who may be considered vulnerable populations.

Sources: Applicants should identify the sources of research material obtained from living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Note: Even if the research you propose is exempt from these regulations, you must address the inclusion of women and members of minority groups and their subpopulations, and the inclusion of children in developing the research design (specific instructions follow.)

Exemption Categories

The six categories of research that qualify for exemption from coverage by the regulations include activities in which the only involvement of human subjects will be in one or more of the following categories:

Exemption 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Exemption 5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption 6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If the research you propose does not meet the requirements for exempt research, then it is not exempt from human subjects regulations and you must follow the instructions in the Non Exempt Human Subjects Research section.

Note: Some exemptions do not apply when research involves special populations as indicated above.

Women and Minority Inclusion in Clinical Research

If you are conducting clinical research (See definition in Section III. A., DEFINITIONS), create a section heading entitled **"Inclusion of Women"** and a separate section heading entitled, **"Inclusion of Minorities**." Place these sections immediately after the Human Subjects Research section in your application. Address each of the items identified below with respect to your plans for the "Inclusion of Women" and the "Inclusion of Minorities" as they relate to the proposed research. Although no specific page limitation applies to these sections of the application, be succinct.

Applications that fail to address the Inclusion of Women and Minorities in clinical research as subjects in clinical research will be designated as incomplete and will constitute grounds for the PHS to return the application without peer review.

NIH policy requires that women and members of minority groups and their subpopulations be included in all NIH-supported biomedical and behavioral clinical research projects involving human subjects (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html and also see definition in Section III A., "DEFINITIONS"; p. 35)

The inclusion must be addressed in developing a research design appropriate to the scientific objectives of the study. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research. This policy applies to research subjects of all ages.

INFORMATION TO BE PROVIDED FOR ALL CLINICAL RESEARCH STUDIES

See definition of clinical research in Section III., A., DEFINITIONS, (p. 35.)

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic group and provide a rationale for selection of such subjects in terms of the scientific objectives and proposed study design. The description may include (but is not limited to) information on the population characteristics of the disease or condition under study, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned study.

This section of the research plan must include the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design.
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.
- The proposed dates of enrollment (beginning and end).
- A description of proposed outreach programs for recruiting women and minorities in clinical research as subjects.
- The proposed sample composition using the "Targeted/Planned Enrollment Format Page" and/or the "Enrollment Report Format Page."

FOR ALL STUDIES, USE THE FOLLOWING ETHNIC AND RACIAL CATEGORIES AND COMPLETE THE TABLES ON THE "TARGETED/PLANNED ENROLLMENT FORMAT PAGE" OR THE "INCLUSION ENROLLMENT REPORT FORMAT PAGE," AS APPLICABLE. SPECIFIC INSTRUCTIONS FOLLOW.

New Applications. Complete the table on the "Targeted/Planned Enrollment Format Page."

Competing Continuation applications, Supplements and Annual Grant Progress Reports. Complete the table on the "Inclusion Enrollment Report Format Page." Note: If there are changes from the "targeted/planned" enrollment originally approved, you must *also* complete the "Targeted/Planned Enrollment Format Page."

The Office of Management and Budget (OMB) Directive No. 15 (www.whitehouse.gov/OMB/fedreg/ombdir15.html) defines minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting (including NIH). The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. The standards were revised in 1997 and now include two ethnic categories, "Hispanic or Latino" and "Not Hispanic or Latino." There are five racial categories: American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; and White. Reports of data on race and ethnicity shall use these categories. NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases. The following definitions apply for the ethnic and racial categories (OMB Directive 15).

Ethnic Categories:

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino".

Not Hispanic or Latino

Racial Categories:

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Standards for Collecting Data. When an investigator is planning data collection items on ethnicity and race, categories identified above should be used. The collection of greater detail is encouraged. However, more detailed items should be designed in a way that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on ethnicity and race. When ethnicity and race are collected separately, ethnicity shall be collected first. Respondents shall be offered the option of selecting one or more racial designations. When data on ethnicity and race are collected separately, provision shall be made to report the number of respondents in each racial category who are Hispanic or Latino. When aggregate data are presented, the investigator shall provide the number of respondents who selected only one category, for each of the five racial categories.

If data on multiple responses are collapsed, at a minimum the total number of respondents reporting "more than one race" shall be made available. Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

ADDITIONAL INFORMATION TO BE PROVIDED FOR NIH-DEFINED PHASE III CLINICAL TRIALS

Applies when Item 4 (Human Subjects Research) and Item 4c (NIH-defined Phase III Clinical Trial) on the Face Page are marked "Yes."

If an **NIH-defined Phase III clinical trial** (see "Definitions" in Section III-A) is proposed, the application must address whether the investigator expects to find clinically important sex/gender and/or race/ethnicity differences in the intervention effect. The discussion may include supporting evidence and/or data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies.

The research plan also must include one of the following plans:

- plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, **OR**
- plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, **OR**
- plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

NEW APPLICATIONS

Use the "**Targeted/Planned Enrollment Table Format Page.**" Provide the study title and plans for the total number of subjects proposed for the study. Also provide the distribution by ethnic categories and by sex/gender according to the format in the Targeted/Planned Enrollment Table. If there is more than one study, provide a separate table for each study. List any proposed racial/ethnic subpopulations below the table. If the proposed research uses existing data, then applicants must use the formats for Competing Continuations, Competing Supplements and Annual Grant Progress Reports.

COMPETING CONTINUATIONS, COMPETING SUPPLEMENTS AND ANNUAL GRANT PROGRESS REPORTS

Use the "Inclusion Enrollment Report Table Format Page." The table on the Enrollment Report for inclusion of human subjects contains two parts; part A is for all subjects and part B is for Hispanics or Latinos.

Provide the study title and plans for the total (cumulative) number of subjects proposed for the study (total planned enrollment), and the Protocol number, if available. For Part A provide the distribution of subjects by ethnic and racial categories and by sex/gender according to the format in the Inclusion Enrollment Report table. Part B should include information on the race of all Hispanics (or Latinos) enrolled in Part A. If there is more than one study, provide a separate table for each study. List any proposed racial/ethnic subpopulations below the table.

Complete the "Targeted/Planned Enrollment Table Format Page" and the "Inclusion Enrollment Report Table Format Page" if there are changes from the targeted/planned enrollment originally approved.

Note: In filling out the Inclusion Enrollment Report table, the investigator should not assume or guess a subject's racial or ethnic affiliation. The investigator should collect the data using instruments that allow respondents to select their racial or ethnic affiliation separately. **The Targeted/Planned Enrollment Format Page and Inclusion Enrollment Report Table Format Page are not to be**

used for data collection from study participants. Subjects who selected only one of the five racial categories should be put in that category. Subjects that fit two or more racial categories should be put in the "More than one race" category. For previously funded studies that used an earlier NIH reporting format, the investigator should review the instructions and frequently ask questions about using the new format. Information is not directly transferable from the previous format to this new format. See http://www4.od.nih.gov/orwh/inclusion.html.

In conducting peer review for NIH-defined Phase III clinical trials, Scientific Review Groups (SRGs) will evaluate proposed plans for inclusion of women and minorities in clinical research and plans for sex/gender and racial/ethnic subgroup analyses, plans for recruitment/ outreach and retention in the design of clinical trials, and any justifications for exclusion of a sex/gender or racial/ethnic subgroup. This evaluation will be a part of the Approach criterion (see description of review criteria in Section II-B). The evaluation of the inclusion plans will be factored into the overall score that the SRGs assign for scientific and technical merit of the application. In addition, awards will not be made if the research project does not comply with this policy.

Inclusion of Children

If you have marked "Yes" for Item 4 on the Face Page of the application, create a section heading entitled "**Inclusion of Children.**" Place it immediately following the "Women and Minority Inclusion in Clinical Research" section of the application.

NIH policy requires that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

Applications that fail to address the Inclusion of Children will be designated as incomplete and will constitute grounds for the PHS to return the application without peer review.

In the section entitled "Inclusion of Children", the applicant should provide either a description of the plans to include children or if children will be excluded from the research, the application or proposal must present an acceptable justification (see below) for the exclusion.

If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children.

When children are included, the plan also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Scientific Review Groups will assess each application as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of children in the research project.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is not relevant to children.
2. There are laws or regulations barring the inclusion of children in the research.
3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. Documentation of other studies justifying the exclusions should be provided. NIH program staff can be contacted for guidance on this issue if the information is not readily available.
4. A separate, age-specific study in children is warranted and preferable. Examples include:
    a. The relative rarity of the condition in children, as compared to adults (in that

extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or

b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or

c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions, to allow children to be included rather than excluding them; or

5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or

6. Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children); or

7. Other special cases justified by the investigator and found acceptable to the review group and the Institute Director.

Definition of a Child

For the purpose of implementing these guidelines, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to these guidelines (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

Data and Safety Monitoring Plan

If you have marked **"Yes"** for Item 4 on the Face Page of the application, **and** your proposed research includes a **clinical trial** create a section heading entitled "**Data and Safety Monitoring Plan**." Place it immediately following the "Inclusion of Children" section.

NIH policy requires that investigators submit a general description of the Data and Safety Monitoring Plan for clinical trials (biomedical and behavioral intervention studies) as part of the research application. In developing your Data and Safety Monitoring Plan, you should refer to the *NIH Policy For Data and Safety Monitoring* (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html. See also (http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Applications that fail to include a Data and Safety Monitoring Plan will be designated as incomplete and will constitute grounds for the PHS to return the application without peer review.

A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity

that will be responsible for monitoring, and how Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with IND or IDE regulations. Although no specific page limitation applies to this section of the application, be succinct.

The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual/Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for Phase III clinical trials involving interventions that entail potential risk to the participants. Although Phase I and Phase II clinical trials may also use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.

A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects (**http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html**).

f. Vertebrate Animals.

If you have marked Item 5 on the Face Page of the application "Yes," create a section heading entitled **"Vertebrate Animals."** Place it immediately following the "Research Design and Methods" section of the application (or after *Item e*, if applicable.)

Failure to address the following elements will result in the application being designated as incomplete and it and will be grounds for the PHS to return the application without peer review.

Under the Vertebrate Animals heading address the following five points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

g. Literature Cited.

List all references. The list may include, but may not replace, the list of publications required in the Progress Report for competing continuation applications.

Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

h. Consortium/Contractual Arrangements.

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

The signature of the authorized organizational official on the face page signifies that the applicant and all proposed consortium participants understand and agree to the following statement: The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy and are prepared to establish the necessary inter-organizational aggreement(s) consistent with that policy.

i. Consultants.

Attach appropriate letters here from all individuals confirming their roles in the project. **Do not place these letters in the Appendix**.

9. APPENDIX

Include five collated sets of all appendix material, in the same package with the application, following all copies of the application. Identify each item with the name of the principal investigator. **Do not intermingle appendix materials with the application.**

New, Revised, Competing Continuation and Supplemental applications may include the following materials in the appendix:

- Up to 10 publications, manuscripts (*accepted* for publication), abstracts, patents, or other printed materials directly relevant to this project. These may be stapled as sets. *Manuscripts* ***submitted*** *for publication should* <u>*not*</u> *be included.*
- Surveys, questionnaires, data collection instruments, and clinical protocols. These may be stapled as sets.
- Original glossy photographs or color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the 25-page limit of *Items a-d* of the research plan. No photographs or color images may be included in the appendix that are not also represented within the Research Plan.

Note: Do not use the appendix to circumvent the page limitations of the research plan. Graphs, diagrams, tables, and charts that do not need to be in a glossy format to show detail must not be included in the appendix. An application that does not observe these limitations will be returned. These appendix limitations may not apply to specialized grant applications. Request and follow the additional instructions for those applications.

The appendix will not be duplicated with the application and will be sent only to certain members of the SRG who will serve as the primary reviewers of the application.

10. CHECKLIST

(CHECKLIST FORM PAGE, PDF FORMAT)

TYPE OF APPLICATION

Check all that apply:

INVENTIONS AND PATENTS (COMPETING CONTINUATION APPLICATIONS ONLY)

If no inventions were conceived or reduced to practice during the course of work under this project, check “No.” The remaining parts of the item are then not applicable.

If any inventions were conceived or reduced to practice during the previous period of support, check "Yes." Also indicate whether this information has been previously reported to the PHS or to the applicant organization official responsible for patent matters.

NIH has developed an optional on-line Extramural Invention Information Management System, known as "Edison," to facilitate grantee compliance with the disclosure and reporting requirements of 37 CFR 401.14(h). The Internet address for this system is HTTP://iedison.gov. Information from these reports is not made publicly available.

PROGRAM INCOME

If no program income is anticipated during the period(s) for which grant support is requested, no other action is necessary.

If program income is anticipated, use the format provided. If the application is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income.

ASSURANCES/CERTIFICATIONS

Each application to the PHS requires that the assurances and certifications listed on the Checklist be verified by the signature of the official signing for the applicant organization on the Face Page of the application.

FACILITIES AND ADMINISTRATIVE (F&A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS agency cost advisory office. If the applicant organization is in the process of initially developing or renegotiating a rate, or has established a rate with another Federal agency, it should, immediately upon notification that an award will be made, develop a tentative F&A cost rate proposal. This is to be based on its most recently completed fiscal year in accordance with the principles set forth in the pertinent DHHS Guide for Establishing Indirect Cost Rates, and submitted to the appropriate DHHS Regional Office or PHS agency cost advisory office. F&A costs will NOT be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

Special Instructions for Modular Applications

Applicant institutions should calculate the F&A costs using the current negotiated F&A rate, less exclusions, for the initial budget period and all future budget periods. It is not necessary to list the exclusions on the Checklist or anywhere in the application.

Smoke-Free Workplace

Follow instructions on the Checklist. Response to the question has no impact on the review or funding of this application.

11. PERSONAL DATA

(FORM PAGE, PDF FORMAT)

Self Explanatory.

II. SUBMITTING YOUR APPLICATION

A. INSTRUCTIONS

This section provides instructions for assembling your grant application, the application mailing address, and a schedule of the PHS grant application receipt, review and award cycles.

NUMBER OF COPIES, BINDINGS, AND MAILING ADDRESS

Submit the following materials in one package:

COVER LETTER.

If the principal investigator is making a request for assignment to a particular awarding component or initial review group include a cover letter. These suggestions will be taken into consideration at the time of assignment, although the final determination will be made by the PHS.

THE ORIGINAL APPLICATION.

Original plus 5

The original application must be single-sided, with both required signatures on the Face Page. Do not staple or otherwise bind the original application. The pages must be assembled in the order specified in the table of contents. The Personal Data page should be placed at the end of the application; it is not to be duplicated. If appropriate, attach the RFA label provided in the application kit or a facsimile to the Face Page.

Five exact, single-sided copies of the original application.

Do not staple or otherwise bind the five copies of the original application. The copies must be made **after** both individuals have signed the Face Page so that their signatures are present on the copies.

Five collated sets of Appendix material.

The Appendix material, and only the Appendix material, may be stapled or bound. Items should be stapled or bound where appropriate, and each marked with the name of the principal investigator. A summary sheet, listing all of the items included in the Appendix, is helpful.

APPLICATION MAILING ADDRESS

Mailing labels are provided at the end of the forms. Send the application to the following address:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC 7710
Bethesda MD 20892-7710*

***For express mail or courier service, change the zip code to 20817. The telephone number is (301) 435-0715.**

There may be additional instructions for submission of responses to Requests for Applications.

Applicants submitting Investigator-Initiated Interactive Research Project Grant (IRPG) applications should include all of the applications and appendix material in one package with a cover letter identifying the applications as such.

An unsolicited application will be considered on time if it is received by or mailed on or before the published receipt date and a proof of mailing is provided. Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service postmark or a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks are not acceptable.

If a receipt date falls on a weekend, it will be extended to the following Monday; if the date falls on a holiday, it will be extended to the following workday.

SOLICITED APPLICATIONS MUST BE RECEIVED BY THE SPECIFIED DATES. HOWEVER, AN APPLICATION RECEIVED AFTER THE DEADLINE MAY BE ACCEPTABLE IF IT CARRIES A LEGIBLE PROOF-OF-MAILING DATE, ASSIGNED BY THE CARRIER, AND THE PROOF-OF-MAILING DATE IS NOT LATER THAN 1 WEEK PRIOR TO THE DEADLINE DATE. THESE INCLUDE REQUEST FOR APPLICATIONS (RFAS) AND PROGRAM ANNOUNCEMENTS (PAS) WITH SPECIFIED RECEIPT DATES.

The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter with the signed, completed application. No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted.

RECEIPT, REVIEW AND AWARD CYCLES

The PHS receipt, review, and award schedule is provided in Table 2.

Table 2. Receipt, Review, and Award Cycles

Receipt, Review, and Award Cycles			
Types of Applications	**Cycle I**	**Cycle II**	**Cycle III**
Application Receipt Dates			
Institutional National Research Service (NRSA) Awards* (**All** new, competing continuations, supplements and revised applications)	January 10	May 10	September 10
Academic Research Enhancement Award (AREA) (**All** new, competing continuations, and revised applications)	January 25	May 25	September 25
New Research Grants, Conference Grants and Research Career Awards	February 1	June 1	October 1
Program Project Grants and Center Grants (**All** new, competing continuations, supplements and revised applications)	February 1	June 1	October 1
Interactive Research Project Grants (IRPGs)	February 15	June 15	October 15
Competing Continuation and Supplemental Grants **Revised** Research Grants, Conference Grants, and Research Career Awards	March 1	July 1	November 1
Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants (**All** new, supplements, and revised applications)	April 1	August 1	December 1
AIDS-Related Grants (**All** new, competing continuations, supplements and revised applications)	May 1	September 1	January 2
Review and Award Schedule			
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Review	September - October	January - February	May - June
Earliest Project Start Date	December	April	July

Note: Several Institutes/Centers use only one or two of the receipt dates for institutional NRSA awards. Please check the program announcement, which is available at http://grants.nih.gov/training/nrsa.htm.

For specialized grant applications, consult with the appropriate PHS awarding component prior to the preparation of an application.

Submit a complete application. Incomplete applications will be grounds for the PHS to return the application without peer review. An application will be returned if it is illegible, if the instructions were not followed, or if the material presented is insufficient to permit an adequate review.

Unless specifically required by these instructions (e.g., vertebrate animals certification), do not send supplementary or corrective material after the receipt date unless the Scientific Review Administrator of the SRG solicits or agrees to accept this information. The application must be complete and accurate at the time of submission as there is no guarantee that the peer reviewers will consider late material.

Submissions of identical applications to different agencies within the PHS or to different Institutes within an agency are not allowed. Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for an individual research project; and 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application.

APPLICATION ASSIGNMENT INFORMATION.

As soon as possible after the receipt date, usually within 6 weeks, the PHS will send the principal investigator/program director and the applicant organization the application's assignment number; the name, address, and telephone number of the Scientific Review Administrator of the Scientific Review Group (SRG) to which the application has been assigned; and the assigned Institute contact and phone number. If this information is not received within that time, contact the Division of Receipt and Referral, Center for Scientific Review (CSR), National Institutes of Health, Bethesda, MD 20892-7720, (301) 435-0715. If there is a change in assignment, another notification will be sent.

All inquiries regarding the assignment, review, or recommendation on funding of applications are to be made only to PHS officials. It is inappropriate to contact consultants serving on advisory or review committees regarding these issues.

B. THE PEER REVIEW PROCESS

OVERVIEW

Competing grant applications submitted to the PHS agencies must be submitted through the Division of Receipt and Referral, CSR, NIH unless otherwise stated. Administrative information about the application is entered into a computer system. The application is then assigned to the appropriate SRG and Institute(s). Assignment is based on the scientific content of the application using established referral guidelines.

Most applications submitted to the PHS will be reviewed through a two-tier system. The first level of review will be performed by a Scientific Review Group (SRG), often called a study section or review committee. The purpose of the SRG is to evaluate the scientific and technical merit of applications. The SRG does not make funding decisions.

SRG members will be instructed to evaluate research applications by addressing five review criteria (see below) and assigning a single, global score for each scored application. The score will reflect the overall impact that the proposed research could have on the field based on consideration of the following NIH research evaluation criteria. *RFAs and other types of grants may have different and/or additional review criteria.*

Note: Applicants must not ever contact reviewers regarding their applications since discussion of the scientific content of an application or an attempt to influence review outcome will constitute a conflict of interest in the review. Reviewers are required to notify the Scientific Review Administrator if they are contacted by an applicant. Communication by the applicant to a reviewer will result in the return of the application without peer review.

RESEARCH PROJECT EVALUATION CRITERIA

Significance: Does this study address an important problem? If the aims of the

application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

While these review criteria are intended for use primarily with unsolicited research project applications (e.g., R01, R29, P01), to the extent reasonable, they will also form the basis of the review of solicited applications and non-research activities. However, for some activities (e.g., construction grants), use of these criteria as stated may not be feasible.

Human Subjects/Vertebrate Animals: In conducting peer review for scientific and technical merit, SRGs will also evaluate the involvement of human/animal subjects and proposed protections from research risk relating to their participation in the proposed research plan according to the following four review criteria: (1) Risk to Subjects, (2) Adequacy of protection against risks (3) Potential benefits of the proposed research to the subjects and others and (4) Importance of the knowledge to be gained.

When human subjects are involved in the proposed clinical research, the SRG will also evaluate the proposed plans for inclusion of minorities and members of both sexes/genders, as part of the scientific assessment of Approach criterion. The evaluation will be factored into the overall score for scientific and technical merit of the application.

Dual-Level Peer Review: As part of the initial merit review, all applicants will receive a written critique based on the comments and recommendations of the SRG. The review of most research applications will also include a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review.

The second level of review will usually be performed by the Advisory Council or Board of the potential awarding component (Institute, Center, or other unit). Council or Board recommendations are based not only on considerations of scientific merit, as judged by the SRGs, but also on the relevance of the proposed study to an Institute's programs and priorities. The review criteria can be found on the NIH Web site, http://grants.nih.gov/grants/peer/peer.htm or obtained from GrantsInfo, (301) 435-0714, Email: GrantsInfo@nih.gov.

C. INTERACTIONS BEFORE SUBMISSION

Additional information about the PHS peer review process and grant programs can be obtained from GrantsInfo, e-mail: GrantsInfo@nih.gov, (301) 435-0714. Information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate agency.

Applicants are encouraged to contact relevant Institute or Center staff for advice in preparing an application and for information regarding programmatic areas of interest. Phone numbers for contacting Institute or Center staff are listed below.

D. INTERACTIONS AFTER SUBMISSION

If the initial assignment seems inappropriate, the principal investigator/program director may request reassignment. Such requests should be made in writing to the Division of Receipt and Referral, Center for Scientific Review, National Institutes of Health, Suite 2030, 6701 Rockledge Drive, MSC 7720, Bethesda, MD 20892-7720. Fax requests (301-480-1987) are also acceptable. Although these requests will be carefully considered, the final determination will be made by the PHS agency.

E. INTERACTIONS AFTER REVIEW

Feedback to applicants is very important. Once the principal investigator receives the summary statement, s/he may contact the appropriate Institute program official (noted on the summary statement) for an interpretation of the reviews and the disposition of the application.

NATIONAL INSTITUTES OF HEALTH	
Fogarty International Center	301-496-1653
National Cancer Institute	301-496-3428
National Center for Complementary and Alternative Medicine	301-496-4792
National Center on Minority Health and Health Disparities	301-402-1366
National Center for Research Resources	301-496-6023
National Eye Institute	301-496-5301
National Heart, Lung, and Blood Institute	301-435-0260
National Human Genome Research Institute	301-496-7531
National Institute on Aging	301-496-9322
National Institute on Alcohol Abuse and Alcoholism	301-443-4375
National Institute of Allergy and Infectious Diseases	301-496-7291
National Institute of Arthritis and Musculoskeletal and Skin Diseases	301-594-2463
National Institute of Biomedical Imaging and Bioengineering	301-435-6138
National Institute of Child Health and Human Development	301-496-0104
National Institute on Deafness and Other Communication Disorders	301-496-1804
National Institute of Dental and Craniofacial Research	301-594-7710
National Institute of Diabetes and Digestive and Kidney Diseases	301-594-8834

NATIONAL INSTITUTES OF HEALTH	
National Institute on Drug Abuse	301-443-2755
National Institute of Environmental Health Sciences	919-541-7723
National Institute of General Medical Sciences	301-594-4499
National Institute of Mental Health	301-443-3367
National Institute of Neurological Disorders and Stroke	301-496-9248
National Institute of Nursing Research	301-594-6906
National Library of Medicine	301-496-4621
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY	301-594-1447
CENTERS FOR DISEASE CONTROL AND PREVENTION	
National Institute for Occupational Safety and Health	404-639-3343
Procurement and Grants Office	404-842-6630
FOOD AND DRUG ADMINISTRATION	301-827-7185
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH	
Office of Adolescent Pregnancy Programs	301-594-4004
Office of Family Planning	301-594-4008
Agency for Toxic Substances and Disease Registry	404-842-6630
Indian Health Service	301-443-0578

III. OTHER INFORMATION

This section contains information on policy and additional guidance relating to submission of traditional, solicited and unsolicited, investigator-initiated, research project grant and cooperative agreement applications to PHS. Refer to the Foreword and the Grants Information (GrantsInfo) sections for additional sources of information.

A. DEFINITIONS

AIDS Related. Includes: (1) projects relating to the etiology, epidemiology, natural history, diagnosis, treatment, or prevention of AIDS; (2) various sequelae specifically associated with the syndrome; and (3) preparation and screening of anti-AIDS agents as well as vaccine development, including both preclinical and clinical studies. Not all applications examining various influences on T-lymphocytes or retroviruses will be appropriate for the expedited AIDS review process. Applications

only indirectly related to AIDS will be evaluated by established SRGs (study sections) appropriate to the scientific discipline during regular NIH review cycles and should not be submitted in response to the expedited AIDS receipt dates. Applicants are urged to take note of the yearly NIH Plan for HIV-Related Research, and indicate how their application addresses the NIH priorities set forth in that Plan. The Plan can be found on the NIH Office of AIDS Research Home Page.

Applicant Organization Types.

Federal: A cabinet-level department or independent agency of the Executive Branch of the Federal Government or any component part of such a department or agency that may be assigned the responsibility for carrying out a grant-supported program.

State: Any agency or instrumentality of a State government of any of the United States or its territories.

Local: Any agency or instrumentality of a political subdivision of government below the State level.

Nonprofit: An institution, corporation, or other legal entity no part of whose net earnings may lawfully inure to the benefit of any private shareholder or individual.

For profit: An institution, corporation, or other legal entity, which is organized for the profit or benefit of its shareholders or other owners. A "for profit" organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons. Also see definition for Small Business Concern.

Small Business Concern: A small business concern is one that, at the time of award of Phase I and Phase II, meets **ALL** of the following criteria:

1. Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, and is organized for profit.
2. Is at least 51% owned, or in the case of a publicly owned business, at least 51% of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.
3. Has, including its affiliates, a number of employees not exceeding 500, and meets the other regulatory requirements found in 13 CFR Part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

   Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.3-2(a). The term "number of employees" is defined in 13 CFR 121.3-2(t).

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small Business Administration Size District Office at http://www.sba.gov/size/.

Socially and Economically Disadvantaged Small Business Concern: A socially and economically disadvantaged small business concern is one that is at least 51% owned by (a) an Indian tribe or a native Hawaiian organization, or (b) one or more socially and economically disadvantaged individuals; AND whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

Women-Owned Small Business Concern: A small business concern that is at least 51% owned by a woman or women who also control and operate it. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

Child. NIH defines a child as an individual under the age of 21 years. It should be noted that the definition of child described above will pertain notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states. Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address the age at which a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

Clinical Research. NIH defines human clinical research as: **(1)** Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. **(2)** Epidemiologic and behavioral studies. **(3)** Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

Clinical Trial. For purposes of reviewing applications submitted to the NIH, a clinical trial is operationally defined as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious and effective. Clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

> **Phase I** clinical trials are done to test a new biomedical or behavioral intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g. determine a safe dosage range, and identify side effects).
>
> **Phase II** clinical trials are done to study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.
>
> **Phase III** studies are done to study the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.
>
> **Phase IV** studies are done after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

NIH-Defined Phase III Clinical Trial: For the purpose of the Guidelines an NIH-defined Phase III "clinical trial" is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-

pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

Co-Investigator. A co-investigator (collaborator) is an individual involved with the principal investigator in the scientific development or execution of the project. These individuals would typically devote a specific percent of effort to the project and would be identified as key personnel. The individual(s) may be employed by, or affiliated with, either the grantee organization or an organization participating in the project under a consortium or contractual agreement.

Commercialization. The process of developing markets and producing and delivering products for sale (whether by the originating party or by others). As used here, commercialization includes both government and private sector markets.

Consortium or Contractual Agreement. An agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. In this arrangement, the grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium organization's principal investigator and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including Facilities and Administrative costs.

Consultant. An individual hired to give professional advice or services for a fee, normally not as an employee of the hiring party. In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. In order to prevent apparent or actual conflicts of interest, grantees and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants may also include firms that provide paid professional advice or services.

Consulting fees. The fee paid by an institution to a salaried member of its faculty is allowable only in unusual cases and only if both of the following conditions exist: (1) the consultation crosses departmental lines or involves a separate operation; or (2) the work performed by the consultant is in addition to his or her regular workload.

In all other cases, consulting fees paid to employees of recipient or cost-type contractor organizations in addition to salary may be charged to PHS grant-supported projects only in unusual situations and when all of the following conditions exist: (1) the policies of the recipient or contractor permit such consulting fee payments to its own employees regardless of whether Federal grant funds are received; (2) the consulting services are clearly outside the scope of the individual's salaried employment; and (3) it would be inappropriate or not feasible to compensate the individual for these services through payment of additional salary.

For additional clarification on the allowance and appropriateness of consulting fees, refer to NIH Grants Policy Statement.

Cooperative Agreement. A support mechanism that will have substantial Federal scientific and/or programmatic involvement. Substantial programmatic involvement means that after award, scientific or program staff will assist, guide, coordinate, or participate in programmatic activities beyond the normal stewardship responsibility in the administration of grants. Proposed cooperative agreements will be published as policy announcements, program announcements, or requests for applications.

Essentially Equivalent Work. This term is meant to identify "scientific overlap," which occurs when (1) substantially the same research is proposed for funding in more than one proposal (contract proposal or grant application) submitted to the same Federal agency; OR (2) substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; OR (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two

or more proposals or awards, regardless of the funding source.

Feasibility. The extent to which a study or project may be done practically and successfully.

Foreign Component. (1) The use of grant funds to support any element or segment of the project which is to be performed outside the U.S., either by the grantee or by a researcher employed by a foreign institution; or (2) the use of grant funds for extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sample collection, etc. Foreign travel for consultation is not considered a foreign component.

Full-Time Appointment. May be different in terms of actual months per year or days per week at the applicant organization. The definition of a full-time appointment must be in accordance with the institutional pnolicy and used consistently by the institution regardless of the source of support.

Gender. Refers to the classification of research subjects into either or both of two categories: women and men. In some cases, representation is unknown, because gender composition cannot be accurately determined (e.g., pooled blood samples or stored specimens without gender designation).

Grant. A financial assistance mechanism whereby money and/or direct assistance is provided to carry out approved activities.

Human Subjects. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations governing the inclusion of human subjects in research extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46.

Innovation. Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of "innovation" would be new medical or biological products, for improved value, efficiency, or costs.

Institutional Base Salary. The annual compensation that the applicant organization pays for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization. Base salary may not be increased as a result of replacing institutional salary funds with grant funds.

Some PHS grant recipients are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at time of award. Applicants are encouraged to contact their offices of sponsored programs or see the *NIH Guide for*

Grants and Contracts for current guidance on salary requirements.

Key Personnel. Key personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive way, whether or not salaries are requested. (For a more detailed discussion, click here to view.)

Principal Investigator, Program Director, or Project Director. The one individual designated by the applicant organization to direct the project or program to be supported by the grant. The principal investigator is responsible and accountable to applicant organization officials for the proper conduct of the project or program.

Program Income. Gross income earned by the applicant organization that is directly generated by a supported activity or earned as a result of the award. The PHS Grants Policy Statement or NIH Grants Policy Statement contains a detailed explanation of program income, the ways in which it may be generated and accounted for, and the various options for its use and disposition.

Examples of program income include:

- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing;
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds;
- Third party patient reimbursement for hospital or other medical services, such as insurance payments for patients when such reimbursement occurs because of the grant-supported activity;
- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals; and
- Patent or copyright royalties.

Prototype. A model of something to be further developed and includes designs, protocols, questionnaires, software and devices.

Research or Research and Development (R/R&D). Any activity that is:

- A systematic, intensive study directed toward greater knowledge or understanding of the subject studied.
- A systematic study directed specifically toward applying new knowledge to meet a recognized need.
- A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Research Institution. A United States research organization that is:

- A nonprofit college or university **OR**
- A nonprofit research institution, including nonprofit medical and surgical hospitals. (A "nonprofit institution" is defined as an organization that is owned and operated exclusively for scientific or educational purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.) **OR**
- A contractor-operated, federally funded research and development center, as identified by the National Science Foundation in accordance with the Government-wide Federal Acquisition Regulation issued in accordance with section 35(c)(1) of the Office of Federal Procurement Policy Act (or any successor legislation thereto).

  (*Laboratories staffed by Federal employees do not meet the definition of "research institution" for purposes of the STTR program.*)

Significant Difference. For purposes of NIH policy, a "significant difference" is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one

could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

Socially and Economically Disadvantaged Individual. A member of any of the following groups: Black Americans; Hispanic Americans; Native Americans; Asian-Pacific Americans; Subcontinent Asian Americans; other groups designated from time to time by SBA to be socially disadvantaged; or any other individual found to be socially and economically disadvantaged by SBA pursuant to Section 8(a) of the Small Business Act, 15 U.S.C. 637(a).

Subcontract. Any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government prime contractor calling for supplies or services required solely for the performance of the prime contract or another subcontract.

United States. The 50 states, territories and possessions of the U.S., Commonwealth of Puerto Rico, Trust Territory of the Pacific Islands, and District of Columbia.

Valid Analysis. The term "valid analysis" means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are:

Allocation of study participants of both sexes/genders (males and females) and from different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization; unbiased evaluation of the outcome(s) of study participants; and use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the gender and racial/ethnic groups.

B. OTHER SUPPORT

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included.

Information on Other Support should NOT be submitted with the application. If other support information is included in the application, the application will be returned to the applicant organization without peer review.

This information is required for all applications that are to receive grant awards; however, NIH will request complete and up to date "Other Support" information from applicants at an appropriate time after peer review. The Institute's scientific program and grants management staff will review this information prior to award.

OTHER SUPPORT POLICY

Information on other support assists awarding agency staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and only funds necessary to the conduct of the approved project are not included in the award.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.

Commitment overlap occurs when a person's time commitment exceeds 100 percent, whether or not salary support is requested in the application. While information on other support is only requested for key personnel

(excluding consultants), no individuals on the project may have commitments in excess of 100 percent.

Scientific Overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source. Potential scientific overlap is to be addressed by the SRG *only* by its identification in an Administrative Note in the summary statement.

Resolution of Overlap. Resolution of overlap occurs at the time of award in conjunction with applicant institution officials, the principal investigator, and awarding agency staff.

SUBMISSION OF OTHER SUPPORT INFORMATION

(SEE OTHER SUPPORT FORMAT PAGE)

Information on other support should ONLY be submitted when requested by the NIH Institute/Center (I/C).

There is no "form page" for other support. Follow the sample format on the "Other Support Format Page." The sample is intended to provide guidance regarding the type and extent of information requested.

The following instructions should be followed in completing the information:

- Information on active and pending other support is required for key personnel, excluding consultants. For individuals with no active or pending support, indicate "None." Neither the application under consideration nor the current PHS award for this project should be listed as other support.
- If the support is provided under a consortium/subcontract arrangement or is part of a multiproject award, indicate the project number, principal investigator, and source for the overall project and provide all other information for the subproject only.

INSTRUCTIONS FOR SELECTED ITEMS

Project Number: If applicable, include a code or identifier for the project.

Source: Identify the agency, institute, foundation, or other organization that is providing the support.

Major Goals: Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

Dates of Approved/Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

Annual Direct Costs: In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

Percent Effort: For an active project, provide the level of effort (even if unsalaried) as approved for the current budget period. For a pending project, indicate the level of effort as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

Overlap: After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual's committed effort. (See Section III B. Other Support to view definitions of the three types of overlap.)

C. PERSONNEL REPORT

(PERSONNEL FORM PAGE, PDF FORMAT; for Competing Continuation Applications Only)

Use only when requested by the awarding component.

List all key personnel, salaried and unsalaried, at the applicant organization or elsewhere, who participated in the project during the current budget period. Include all degrees, role on project, date of birth, annual percent of effort, and Social Security number. When requesting Social Security numbers from personnel, explain that provision of the Social Security number is voluntary, and the information will be used only for program management purposes.

D. GRANT SOLICITATIONS

Specific Program Announcements (PAs) and Requests for Applications (RFAs) are published in the *Federal Register* and in the *NIH Guide for Grants and Contracts* The *Guide* also contains vital information about policies and procedures. For information on obtaining the *Guide* go to http://grants.nih.gov/grants/guide. Definitions regarding the use of PAs and RFAs are as follows:

Program Announcement: A formal statement about a new or ongoing extramural activity or mechanism. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or mechanism, and/or invite applications for grant support. Most applications in response to PAs may be submitted for any appropriate receipt date and are reviewed with all other applications received at that time.

Request for Applications: A formal statement that invites grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. The RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, and the application receipt date(s). Applications submitted in response to an RFA usually are reviewed by an SRG convened by the awarding component that issued the RFA.

E. START DATES

Awarding components may not always be able to honor the requested start date of an application. Therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding component.

F. INVENTIONS AND PATENTS

NIH recipient organizations must promptly report inventions to the Extramural Inventions and Technology Resources Branch of the Office of Policy for Extramural Research Administration, OER, NIH, Bethesda, MD 20892-2750, (301) 435-1986. This should be done prior to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202 and may result in loss of the rights of the applicant institution, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

G. ASSURANCES AND CERTIFICATIONS

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application.

The assurances listed and explained below may or may not be applicable to your project, program, or type of applicant organization. There are a number of additional public policy requirements with which applicants and grantees must comply. Refer to your institution's research grant administrative office or the *NIH Grants Policy Statement* for additional information. A copy of the *NIH Grants Policy Statement* may be obtained from the NIH Web site (http://grants.nih.gov/grants/policy/policy.htm). In signing the application Face Page, the duly authorized representative of the applicant organization certifies that the applicant

organization will comply with the following policies, assurances and/or certifications:

HUMAN SUBJECTS

(**SEE SECTION III. A – DEFINITIONS**)

The DHHS regulations, for the protection of human subjects (see definition in Section III. A), provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. The regulations stipulate that an applicant organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations require that applicant organizations proposing to involve human subjects in nonexempt research, file a written Assurance of Compliance with the Office for Human Research Protections (OHRP), establishing appropriate policies and procedures for the protection of human subjects. These regulations, 45 CFR 46, Protection of Human Subjects, are available from the OHRP, National Institutes of Health, Rockville, MD 20892, (301) 496-7041.

Investigators, who conduct research involving fetuses, pregnant women, children, human in vitro fertilization, or prisoners, must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR 46, which describe the additional protections required for these subjects.

No DHHS award for nonexempt research involving human subjects will be made to an applicant organization unless that organization is operating in accord with an approved Assurance of Compliance and provides certification that an appropriate Institutional Review Board (IRB) has reviewed and approved the proposed activity in accordance with the DHHS regulations. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the DHHS regulations. Foreign applicant organizations must also comply with the provisions of the regulations.

The Center of Biologics Evaluation and Research (CBER), FDA, regulates the use of biological products in humans, at the investigational and marketing phases, including somatic cell therapies and gene therapies. If your work involves these areas or preclinical research that will support later work in these areas, please see the Office of Recombinant DNA Activities Web site at http://www4.od.nih.gov/oba/.

RESEARCH ON TRANSPLANTATION OF HUMAN FETAL TISSUE

In signing the application Face Page, the duly authorized representative of the applicant organization certifies that if research on the transplantation of human fetal tissue is conducted, the applicant organization will make available, for audit by the Secretary, DHHS, the physician statements and informed consents required by section 498A (b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure DHHS access to those records, if maintained by an entity other than the applicant organization.

WOMEN AND MINORITY INCLUSION IN CLINICAL RESEARCH POLICY

Research involving human subjects must comply with the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." The following excerpts provide the key policy statements. Investigators should obtain full copies of the Guidelines from NIH staff, the *NIH Guide for Grants and Contracts* (August 2, 2000) or the *Federal Register* (59FR 11146-11151). The NIH Guide can be found at http://grants.nih.gov/grants/guide.

The policy of NIH is that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects in clinical research, unless a clear and compelling rationale and justification establishes inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and

justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Include a description of the proposed outreach programs for recruiting women and minorities as participants.

Funding: Awards will not be made if the research project does not comply with this policy. In addition, awardees must report annually on enrollment of women and men, and on the race and ethnicity of research participants in the "Targeted Planned Enrollment Format Page" or the "Inclusion Enrollment Report Format Page."

Note: Under DHHS regulations to protect human subjects (see Section III.A. D) from research risks, certain research areas are exempt. (See Exemption Categories). Nonetheless, studies that are exempt from the human subjects regulations must still address the inclusion of women and minorities in clinical research in the study design. Therefore, applications will be evaluated for compliance with this policy. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable are also to be included within the term "research involving human subjects."

INCLUSION OF CHILDREN POLICY

(See Section III-A, "DEFINITIONS;" p. 35)

Research involving children must comply with the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects," issued March 6, 1998. The following excerpts provide the key policy statements. Investigators should obtain full copies of the Policy and Guidelines from NIH staff, or from the NIH grants Web site under the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/notice-files/not98-024.html).

NIH policy requires that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them. This policy applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accord with Section 401 (b) of 45 CFR 46 Subpart A - Federal Policy for the Protection of Human Subjects. The inclusion of children as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

Additionally, IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the State or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

RESEARCH USING HUMAN PLURIPOTENT STEM CELLS

In signing the application Face Page, the duly authorized representative of the applicant organization certifies that if research using human pluripotent stem cells is proposed, the applicant organization will be in compliance with the National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells published in the Federal Register http://www.nih.gov/news/stemcell/stemcellguidelines.htm.

VERTEBRATE ANIMALS

The PHS *Policy on Humane Care and Use of Laboratory Animals* requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office for Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163.

The PHS policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes."

No PHS award for research involving vertebrate animals will be made to an applicant organization unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides certification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the IACUC for further review in the case of apparent or potential violations of the PHS policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

DEBARMENT AND SUSPENSION

Executive Order 12549, "Debarment and Suspension," mandated development of a Government-wide debarment and suspension system for nonprocurement transactions with Federal agencies. Executive Order 12689 and Section 2455 of the Federal Acquisition Streamlining Act of 1994 further required Federal agencies to establish regulations for reciprocal Government-wide effect across procurement and nonprocurement debarment and suspension actions. This reciprocity rule is effective for any debarment, suspension or other Government-wide exclusion initiated on or after August 25, 1995. DHHS regulations implementing Executive Orders 12549 and 12689, and Section 2455 of the Federal Acquisition Regulation, are Provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." Accordingly, before a grant award can be made, the applicant organization must make the following certification (Appendix A of the DHHS regulations):

"1. The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals (including research personnel):

   "a. Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal department or agency;

   "b. Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a

public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

"c. Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

"d. Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

"2. Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal."

Grantees are required to obtain a similar certification from most subawardees, called "lower tier participants." (See 45 CFR 76, Appendices A and B.)

DRUG-FREE WORKPLACE

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D) requires that all grantees receiving grants from any Federal agency certify to that agency that they will maintain a drug-free workplace. DHHS regulations implementing the Act are provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." Accordingly, before a grant award can be made, the applicant organization must make the certification set forth below (Appendix C of the DHHS regulations). The certification is a material representation of fact upon which reliance will be placed by the PHS awarding component. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or Government-wide suspension or debarment.

The applicant organization certifies, "that it will continue to provide a drug-free workplace by:

"(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

"(b) Establishing an ongoing drug-free awareness program to inform employees about:

The dangers of drug abuse in the workplace;

The grantee's policy of maintaining a drug-free workplace;

Any available drug counseling, rehabilitation, and employee assistance programs, and

The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

"(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

"(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will:

Abide by the terms of the statement; and notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than 5 calendar days after such conviction;

"(e) Notifying the agency in writing within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity

the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

"(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted:

Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

"(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f)"

For purposes of paragraph (e), regarding agency notification of criminal drug convictions, the DHHS has designated the following central point for receipt of such notices:

Division of Grants Management and Oversight
Office of Management and Acquisition
Department of Health and Human Services
Room 517-D
200 Independence Avenue, S.W.
Washington, DC 20201

LOBBYING

Title 31, United States Code, Section 1352, entitled "Limitation on Use of Appropriated Funds to Influence Certain Federal Contracting and Financial Transactions," generally prohibits recipients of Federal grants and cooperative agreements from using Federal (appropriated) funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific grant or cooperative agreement. Section 1352 also requires that each person who requests or receives a Federal grant or cooperative agreement must disclose lobbying undertaken with non-Federal (nonappropriated) funds. These requirements apply to grants and cooperative agreements exceeding $100,000 in total costs. DHHS regulations implementing Section 1352 are provided in 45 CFR Part 93, "New Restrictions on Lobbying."

The complete Certification Regarding Lobbying is provided below.

"The undersigned (authorized official signing for the applicant organization) certifies, to the best of his or her knowledge and belief that:

"(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

"(2) If any funds other than Federally appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

"(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

"This certification is a material representation of fact upon which reliance was placed when this

transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure."

Standard Form LLL, "Disclosure of Lobbying Activities," its instructions, and continuation sheet are available from GrantsInfo, National Institutes of Health, e-mail: GrantsInfo@nih.gov, (301) 435-0714.

NONDELINQUENCY ON FEDERAL DEBT

The Federal Debt Collection Procedure Act, 28 U.S.C. 3201 (e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the authorized organizational official of the applicant organization (or individual in the case of an individual National Research Service Award) certifies, by means of his/her signature on the application, that the organization is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal Government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed.

RESEARCH MISCONDUCT

Each institution that receives or applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by (1) 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science" and (2) 42 CFR 94, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers" (effective on the date set forth in the final rule.)

The signature of the official signing for the applicant organization on the Face Page of the application serves as certification that:

1. The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 94;
2. The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;
3. The institution will provide its policies and procedures to the Office of Research Integrity upon request; and
4. The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January.

"Misconduct in Science" and "Research Misconduct" are defined by the Public Health Service as "fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretation or judgments of data."

For further information, please contact:

Office of Research Integrity
Division of Education and Integrity
Rockwall II, Suite 700
5515 Security Lane
Rockville, MD 20852,
Phone: (301) 443-5300
Fax: (301) 594-0042 or (301) 445-5351.

ASSURANCE OF COMPLIANCE (CIVIL RIGHTS, HANDICAPPED INDIVIDUALS, SEX DISCRIMINATION, AGE DISCRIMINATION)

Before a grant award can be made, a domestic applicant organization must certify that it has

filed with the DHHS Office for Civil Rights: an Assurance of Compliance (Form HHS 690) with Title VI of the Civil Rights Act of 1964 (P.L. 88352, as amended), which prohibits discrimination on the basis of race, color, or national origin; Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended), which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (P.L. 92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (P.L. 94-135), which prohibits discrimination on the basis of age.

The Assurance of Compliance Form HHS 690 is available from GrantsInfo, e-mail: GrantsInfo@nih.gov, (301) 435-0714.

Note: Assurance of Compliance Form HHS 690 is now used in lieu of individual assurances: Form HHS 441, Civil Rights; Form HHS 641, Handicapped Individuals; Form HHS 639-A, Sex Discrimination; and Form HHS 680, Age Discrimination.

FINANCIAL CONFLICT OF INTEREST

NIH requires grantees and investigators (except Phase I SBIR/STTR applicants) to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." These requirements promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator.

The signature of the authorized organizational official on the face page of the application serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F, including that:

1. There is in effect, at the organization, a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought.
2. Prior to the expenditure of any NIH funds awarded under a new award, the organization will inform NIH of the existence of any conflicting financial interests of the type covered by 42 CFR 50.605 and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations;
3. The Institution will continue to make similar reports on subsequently identified conflicts; and it will make information available to NIH, upon request, as to how identified conflicting interests have been handled.

H. PHS METRIC PROGRAM

Consistent with Government-wide implementing regulations, 15 CFR Part 19, Subpart B and/or any other Government-wide requirements, PHS policy is to support Federal transition to the metric system and to use the metric system of measurement in all grants, cooperative agreements, and all other financial assistance awards. Likewise, measurement values in reports, publications, and other communications regarding grants will be in metric.

I. SMOKE-FREE WORKPLACE

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

J. PROHIBITION ON AWARDS TO 501(C)4 ORGANIZATIONS THAT LOBBY

Organizations described in section 501(c)4 of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive grant/cooperative agreement awards. This is not to be confused with 45 CFR Part 93,

Section 1352, “New Restrictions on Lobbying”
See Section IIIG, Item 9, "Lobbying."

K. GOVERNMENT USE OF INFORMATION UNDER PRIVACY ACT

The Privacy Act of 1974 (5 U.S.C. 552a) is a records management statute and regulates the collection, maintenance, use, and dissemination of personal information by Federal agencies. In accordance with the Act, the PHS is required to provide the following notification to each individual whom it asks to supply information.

The PHS maintains applications and grant records pursuant to its statutory authority for awarding grants. The purpose of the information collection is to aid in the review, award, and administration of PHS programs. Provision of information is voluntary; however, a lack of sufficient information may hinder PHS' ability to review applications, monitor grantee performance, or perform overall management of grant programs.

The Privacy Act authorizes discretionary disclosure of this information within the Department of Health and Human Services and outside the agency to the public, as required by the Freedom of Information Act and the associated DHHS regulations (45 CFR 5), including the Congress acting within its legislative authority, the National Archives, the General Accounting Office, the Bureau of Census, law enforcement agencies, and pursuant to a court order. Information may also be disclosed outside the Department, if necessary, for the following purposes:

1. To a Congressional office at the request of the record subject;
2. To the Department of Justice as required for litigation;
3. To the cognizant audit agency for auditing;
4. To qualified experts not within the definition of Department employees as prescribed in Department Regulations (45 CFR 5b.2) for opinions as part of the application review/award process;
5. For an authorized research purpose under specified conditions;
6. To contractors for the purpose of processing, maintaining, and refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records;
7. To a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the records are relevant and necessary to the requesting agency's decision on the matter; and
8. To the applicant organization in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.

L. INFORMATION AVAILABLE TO THE PRINCIPAL INVESTIGATOR

Under the provisions of the Privacy Act, principal investigators may request copies of records pertaining to their grant applications from the PHS component responsible for funding decisions. Principal Investigators are given the opportunity under established procedures to request that the records be amended if they believe they are inaccurate, untimely, incomplete, or irrelevant. If the PHS concurs, the records will be amended.

M. INFORMATION AVAILABLE TO THE GENERAL PUBLIC

The PHS makes information about awarded grants available to the public, including the title of the project, the grantee institution, the principal investigator, and the amount of the award. The description, on Form Page 2 of a funded research grant application is sent to the National Technical Information Service (NTIS), U.S. Department of Commerce, where the information is used for the dissemination of scientific information and for scientific

classification and program analysis purposes. These descriptions are available to the public from the NTIS.

The Freedom of Information Act and implementing DHHS regulations (45 CFR Part 5) require the release of certain information about grants, upon request, irrespective of the intended use of the information. Trade secrets and commercial, financial, or otherwise intrinsically valuable information that is obtained from a person or organization and that is privileged or confidential information may be withheld from disclosure. Information, which, if disclosed, would be a clearly unwarranted invasion of personal privacy, may also be withheld from disclosure. Although the grantee institution and the principal investigator will be consulted about any such release, the PHS will make the final determination. Generally available for release, upon request, except as noted above, are: all funded grant applications including their derivative funded noncompeting supplemental grant applications; pending and funded noncompeting continuation applications; progress reports of grantees; and final reports of any review or evaluation of grantee performance conducted or caused to be conducted by the DHHS. Generally, not available for release to the public are: competing grant applications (initial, competing continuation, and supplemental) for which awards have not been made; evaluative portions of site visit reports; and summary statements of findings and recommendations of review groups.

ACCESS TO RESEARCH DATA

By regulation (45 CFR 74.36), grantees that are institutions of higher education, hospitals, or non-profit organizations are required to release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (e.g., regulations and administrative orders). "Research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential to a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g. intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy or information that could be used to identify a particular person in a research study.

These requirements do not apply to commercial organizations or to research data produced by State or local governments. However, if a state or local governmental grantee contracts with an educational institution, hospital or non-profit organization, and the contract results in covered research data, those data are subject to these disclosure requirements.

N. RECOMBINANT DNA AND HUMAN GENE TRANSFER RESEARCH

The *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* apply to NIH-funded and non-NIH-funded gene transfer projects that are conducted at or sponsored by an institution that receives NIH support for recombinant DNA research. As defined by the *NIH Guidelines*, recombinant DNA molecules are either: (1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules that result from the replication of those described in (1). The *NIH Guidelines* set forth principles and standards for safe and ethical conduct of recombinant DNA research and apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in the appendix of the document (Appendix M.) The *NIH Guidelines* should be carefully reviewed to ensure compliance with all other requirements for the conduct of projects involving recombinant DNA research and human gene transfer. Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of NIH funds for recombinant DNA research at the organization or a

requirement for NIH prior approval of any or all recombinant DNA projects at the organization. A copy of *the NIH Guidelines* is posted at the following URL: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and may be obtained from the NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301-496-9838.

O. INFORMATION RESOURCES

A list of the NIH program guidelines and other publications is available on the NIH Web site http://www.nih.gov/index.html and from http://grants.nih.gov/grants/index.cfm. A partial list of the most frequently requested program guidelines is provided below. Applicants may contact GrantsInfo, by e-mail: GrantsInfo@nih.gov, or by telephone (301) 435-0714.

EXTRAMURAL PROGRAM GUIDELINES

NIH National Research Service Award Individual Postdoctoral Fellowship (F32) Guidelines

These fellowships are awarded to qualified individuals holding the doctoral or equivalent degree to support full-time research training in designated biomedical science areas. (Applicants should use the F32 guidelines and PHS 416-1 to apply for support.) See http://grants.nih.gov/training/nrsa.htm.

NIH National Research Service Award Senior Fellowship (F33) Guidelines

Investigators who hold a doctorate or equivalent degree and have had at least 7 subsequent years of relevant research or professional experience may apply for senior fellowships. The award is designed to provide opportunities for experienced scientists to make major changes in the direction of their research careers, to acquire new research capabilities, to broaden their scientific background, to enlarge their command of an allied research field, or to take time from regular professional responsibilities to increase their capabilities for engaging in health-related research. (Applicants should use the F33 guidelines and Form PHS 416-1 to apply for support.) See http://grants.nih.gov/training/nrsa.htm.

NIH National Research Service Award Institutional Grant (T32) Guidelines

These awards are made to domestic institutions that have the facilities and faculty to provide for research training programs in scientific specialties. Grant funds may be used for personnel, equipment, supplies, trainee stipends (both pre and postdoctoral), and related costs. (Applicants should use the T32 guidelines with the PHS 398 application to apply for support.) See http://grants.nih.gov/training/nrsa.htm.

NIH National Research Service Award Short-Term Training for Students in Health Professional Schools (T35) Guidelines

The goal of these institutional training awards is to provide predoctoral students in health professional schools with research experience during off-quarters or summer periods, so as to encourage them into a research career. (Applicants should use the T35 guidelines and the PHS 398 application.) See http://grants.nih.gov/training/nrsa.htm.

Research Grants to Foreign Institutions and International Organizations

See http://grants.nih.gov/grants/policy/nihgps/part_iii_5.htm#wardsforeign.

The K Awards-Research Career Program Awards

Among NIH components, several types of career awards are available to research and academic institutions on behalf of scientists with clear research potential, but requiring additional experience in a productive scientific environment in preparation for careers in independent biomedical research. (Applicants should use the PHS 398.) See http://grants.nih.gov/training/careerdevelopmentawards.htm.

ACADEMIC RESEARCH ENHANCEMENT AWARD (AREA, R15) GUIDELINES

Support is provided to scientists at eligible domestic institutions for small-scale health-related research projects, such as pilot research projects and feasibility studies; development, testing, and refinement of research techniques; and similar discrete research projects that demonstrate research capability. This award is directed toward those smaller public and private colleges and universities that provide undergraduate training for a significant number of the U.S. research scientists. (Applicants should use the PHS 398 with the AREA guidelines.) See http://grants.nih.gov/grants/funding/area.htm.

APPLICATIONS AVAILABLE FROM OTHER OFFICES

International Research Fellowship Award Application (NIH 1541-1)
Available from:
Fogarty International Center
(301) 496-1653

Nonresearch Training Grant Application (PHS 6025)
Available from:
Health Resources and Services Administration
(301) 443-6960

Health Services Project Application (5161-1)
Available from:
Substance Abuse and Mental Health Services Administration (SAMHSA)
(301) 436-8451

If You Want to Obtain.....

- Publications about NIH extramural research and research training programs, visit the Grants pages of the NIH Web site system: http://grants.nih.gov/grants/oer.htm.

If You Want to Know More About....

- The telephone number for an NIH staff person, visit the NIH Web site: http://directory.nih.gov.
  Telephone: (301) 496-4000 (the NIH locator).

- NIH Extramural Research and Research Training Programs (general information,) visit the Grants pages of the NIH Web site: http://grants.nih.gov/grants/oer.htm.
  E-mail: GrantsInfo@nih.gov.
  Telephone: (301) 435-0714.

- A specific application, before review, telephone or e-mail the Scientific Review Administrator named on the "notification of assignment."

- Receipt and referral of an application, contact: Division of Receipt and Referral Center for Scientific Review
  Telephone: (301) 435-0715;
  Fax: (301) 480-1987.

- Human Subject Protections, Institutional Review Boards, or related assurances (Office for Human Research Protections, visit the OHRP Web site: http://ohrp.osophs.dhhs.gov/index.htm.
  Telephone: (301) 496-7041.

- Animal Welfare and related regulations and assurances (Office of Laboratory Animal Welfare (OLAW). Visit the Web site for OLAW at http://grants.nih.gov/grants/olaw/olaw.htm
  Telephone: (301) 496-7163.

Form Approved Through 05/2004
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Services

ADDITIONAL INSTRUCTIONS FOR PREPARING INDIVIDUAL RESEARCH CAREER AWARD (RCA) APPLICATIONS – "K" SERIES

IV. RESEARCH CAREER AWARD

A. INTRODUCTION

This section includes additional instructions to be used when applying for an individual Research Career Award (RCA), and includes a summary of current RCA award mechanisms, a **substitute** Table of Contents (RCA Substitute Form Page 3), and guidelines for reference reports. The instructions in this section of the PHS 398 application should be used along with the instructions in the preceding sections.

These instructions do not cover applications for program awards (K12 and K30), which provide support for institutional career development programs. Institutions planning such applications should contact the potential awarding component concerning eligibility, award criteria, and application procedures.

Before applying for an RCA, applicants should carefully review general guidelines for the specific career award(s) of interest, noting especially the eligibility requirements, award provisions, requirements for a sponsor, and review criteria. The guidelines are issued periodically in the *NIH Guide for Grants and Contracts* and should be available from the sponsored programs office of the applicant institution. General NIH program announcements are available on the NIH Web site http://grants.nih.gov/training/careerdevelopmentawards.htm and may be requested from GrantsInfo, National Institutes of Health (NIH), e-mail: GrantsInfo@nih.gov, (301) 435-0714.

In addition, the eligibility criteria, support levels, and other important aspects of specific career awards, including availability, may vary depending on which NIH Institute or Center supports the award. For this reason, **it is strongly recommended that applicants contact the program director of the appropriate NIH awarding component prior to the preparation of an application**. A list of program contacts is available in the general NIH program announcements for these programs (see http://grants.nih.gov/training/careerdevelopmentawards.htm).

B. SUMMARY OF INDIVIDUAL CAREER AWARDS AWARD TYPE	Sponsor/ (Mentor)	Reference Letters
K01 Mentored Research Scientist Development Award	Yes	Yes
K02 Independent Scientist Award	No	No
K05 Senior Scientist Award	No	No
K07 Academic Career Award	*	*

B. SUMMARY OF INDIVIDUAL CAREER AWARDS AWARD TYPE	Sponsor/ (Mentor)	Reference Letters
K08 Mentored Clinical Scientist Development Award	Yes	Yes
K22 Career Transition Award	*	Yes
K23 Mentored Patient-Oriented Research Career Development Award	Yes	Yes
K24 Mid-Career Investigator Award in Patient Oriented Research	No	No
K25 Mentored Quantitative Research Career Development Award	Yes	Yes
K26 Midcareer Investigator Award in Mouse Pathobiology Research	No	No

*Varies with career status and source of award. Check the announcement.

C. BASIC ADMINISTRATIVE DATA

1. FACE PAGE

(FORM PAGE 1, PDF FORMAT)

ITEM 2. RESPONSE TO SPECIFIC PROGRAM ANNOUNCEMENT

Check "Yes." Provide appropriate K Award Program Announcement or Request for Applications number (see previous section) and title for the specific type of RCA requested.

ITEM 3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR.

Provide the name of the candidate. Indicate the doctoral degree(s) in 3b. If the candidate is not located at the applicant organization at the time the application is submitted, the mailing address (Item 3e) and telephone (Item 3h) should indicate where the applicant can be reached prior to the requested award date; items 3d, 3f, and 3g should reflect the candidate's projected position at the applicant organization.

ITEM 6. DATES OF PROPOSED PERIOD OF SUPPORT

The period of support must be within specified limits for the type of RCA requested. If the application involves a change of applicant organization for an active RCA awardee, indicate the time remaining in the original award.

2. DESCRIPTION AND PERSONNEL

(FORM PAGE 2, PDF FORMAT)

DESCRIPTION

Provide an abstract of the whole application (candidate, environment, and research). Include the candidate's immediate and long-term career goals, research career development plan, and a description of the research project.

PERSONNEL.

Name the candidate and, if applicable, the sponsor(s) (mentor). For RCAs with no sponsor, name the candidate's department head and senior staff member, if other than the department head, who will assume responsibility for the candidate's research career development at the applicant organization.

3. TABLE OF CONTENTS

(RCA SUBSTITUTE FORM PAGE 3, PDF FORMAT)

Use the **substitute** Table of Contents at the back of this section. Follow the instructions below for verifying citizenship.

Citizenship.

All applicants must provide information regarding citizenship on the bottom of the substitute Table of Contents. Candidates for an award must be citizens or noncitizen nationals of the United States or its possessions and territories, or must have been lawfully admitted to the United States for permanent residence by the time of the award.

4. DETAILED BUDGET FOR INITIAL BUDGET PERIOD

(FORM PAGE 4, PDF FORMAT)

Do not complete the Form Page 4. It is not required nor will it be accepted at the time of application. In some cases it may be requested prior to award. Should Form Page 4 be requested prior to award, specific instructions will be provided.

5. BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT

(FORM PAGE 5, PDF FORMAT)

Do not complete the categorical budget table on Form Page 5. Only the requested total direct costs for each year and total direct costs for the entire proposed period of support should be shown. Begin the budget justification in the space provided, using continuation pages as needed.

BUDGET JUSTIFICATION

List the name, role on project, and percent effort for all project personnel (salaried or unsalaried) and provide a narrative justification for each person based on his/her role on the project and proposed level of effort.

Identify all consultants by name and organizational affiliation and describe the services to be performed.

Provide a narrative justification for any major budget items, other than personnel, that are requested for the conduct of the project that would be considered unusual for the scope of research. No specific costs for items **or categories should be shown.**

6. BIOGRAPHICAL SKETCH

(FORMAT PAGE, PDF FORMAT)

A biographical sketch (***limited to four pages for each person***) is required for the candidate, sponsor(s), co-sponsor(s), and other key personnel. Biographical sketches should follow in the order as listed on Form Page 2. Sponsor(s), co-sponsor(s), and other key personnel should follow the "Biographical Sketch Format Page."

Candidates should follow the instructions below.

EDUCATION

The candidate should give the month as well as the year for each degree conferred. For nondegree education, indicate the time period covered. List professional certifications received within the last 10 years.

RESEARCH AND/OR PROFESSIONAL EXPERIENCE

The candidate should use the headings given below instead of the instructions on the biographical sketch. Identify each heading.

EMPLOYMENT

Start with the first position held following the baccalaureate and give a consecutive record to date. Indicate the department and organization, department head or supervisor, rank, tenured or nontenured, status (full-or part-time), and inclusive dates. Where applicable, include information on military service, internships, residencies, research assistantships, fellowships, etc.

HONORS

List academic and professional honors.

PROFESSIONAL SOCIETIES

Identify professional societies and related organizations in which membership has been held within the last 10 years, giving dates.

PUBLICATIONS

List all publications (chronologically), divided into the following groups:

- Original research and theoretical treatises;
- Nonexperimental articles, e.g., review of literature in field, etc.;
- Books, pamphlets, etc.
- If the list of publications cannot be accommodated within the four-page limit, select the most pertinent publications. If a copy of a publication is being submitted with the application, indicate with an asterisk and footnote ("copies sent"). For competing continuation applications, also identify with a double asterisk and appropriate footnote all papers published during the concluding period of support.

7. RESOURCES

(RESOURCES FORMAT PAGE, PDF FORMAT)

Carefully complete this section following instructions on the “Resources Format Page.” The information provided is of major importance in establishing the feasibility of the project to further the applicant's research career.

D. SPECIALIZED INFORMATION

1. INTRODUCTION TO REVISED APPLICATION

This applies only to amended/revised applications. **Not to exceed three pages.**

List each area of concern noted in the summary statement for the previous application and provide a detailed response to each concern. Summarize clearly the changes that have been made in the revised application. Do not include an extensive description of each change in this introduction. In the body of the application, highlight paragraphs with significant changes since the previous application by bracketing, indenting, or changing the typography. If the changes are so extensive as to include most of the text, this exception should be explained in the Introduction to the Revised Application. Do not underline, bold type or shade changes.

2. LETTERS OF REFERENCE

Letters are required for all new and revised RCA applications, except for the K02, K05, K24, and they are also required for experienced investigators submitting a K07. See specific program guidelines for more information. **Applications with fewer than three reference letters will be returned without review**. These letters should be from individuals in addition to/other than those directly involved in the application (i.e., sponsors, cosponsors, and collaborators. **The sponsor/mentor of this application cannot be counted as a reference.**

Complete the upper section of the RCA Reference Guidelines Format Page, including the application submission deadline. Then send copies of the RCA Reference Guidelines Format Page to those who have agreed to serve as referees. Referees should be provided with postage-paid return envelopes *addressed to the candidate* with the following words in the front bottom left corner "DO NOT OPEN PHS USE ONLY." **Attach unopened references to the Face Page of the original application and submit the entire package by the**

submission deadline. Applicants reapplying must also include reference letters.

Such letters are critically important and should address the candidate's competence and potential to develop into an independent biomedical or behavioral investigator. Only those individuals who can make the most meaningful comments about the candidate's professional training and qualifications for a research career should be used.

Where possible, select some referees (knowledgeable about your qualifications) who are not from your current department or organization. Request reference letters only from individuals who will be able to return them in time for submission of the application. Consider any factor (e.g., illness or extended vacation) that might cause an inordinate delay.

3. THE CANDIDATE

CANDIDATE'S BACKGROUND

Use this section to provide any additional information not described in the “Biographical Sketch Format Page,” such as research and/or clinical training experience.

CAREER GOALS AND OBJECTIVES: SCIENTIFIC BIOGRAPHY

Describe your past scientific history, indicating how the award will fit into past and future research career development. If there are consistent themes or issues which have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. It is important to justify the award and how it will enable you to develop or expand your research career.

CAREER DEVELOPMENT/TRAINING ACTIVITIES DURING AWARD PERIOD

Stress the new, enhanced research skills and knowledge you will acquire as a result of the proposed award. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career. For mentored awards, describe structured activities, such as course work or technique workshops, which are part of the developmental plan. **All RCA applications must contain a description of a plan to acquire (or provide) training in the responsible conduct of research.**

Briefly discuss each of the activities, except research, in which you expect to participate. Include a percentage of time involvement for each activity by year and explain how the activity is interrelated with the proposed research and the career development plan.

4. STATEMENTS BY SPONSOR(S), COSPONSOR, CONSULTANT(S), AND COLLABORATOR(S)

For mentored awards (see Summary of Awards table, Section B), the sponsor must explain how the award will enhance the development of the candidate's research career. The program, as proposed by the sponsor and candidate, must provide, in detail, the plan for the candidate's training and research career development as well as a clear commitment of staff time, facilities, and resources by the sponsor. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations. It should discuss expectations for publications over the entire period of the proposed project. The sponsor should describe the candidate's teaching load for the period of the award (number and types of courses or seminars), clinical responsibilities (including number of patients currently seen and professional consultations), committee and administrative assignments, and the proportion of time available for research. The sponsor should describe his/her experience as a mentor including information on the course outcome of former trainers. The sponsor should also describe the nature and extent of supervision that will occur during the award period.

The sponsor and the sponsoring institution must provide assurance that the candidate will be released from other duties for the amount of time required by the RCA. The sponsor must

also describe the source or anticipated source of support for the candidate's research project for each year of the award period.

List all cosponsors, consultants, and collaborators involved with this project. A co-sponsor must specifically address the nature of his/her role in the career development plan and how the responsibility for the candidate's development is shared with the sponsor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Describe previous experience as a mentor. Also describe the nature of any resources committed to this experience. **Letters** from each cosponsor, consultant, and collaborator, confirming their participation in the project and describing their specific roles, **must be included in this section of the application. Do not place these letters in the Appendix.**

5. ENVIRONMENT AND INSTITUTIONAL COMMITMENT TO THE CANDIDATE

DESCRIPTION OF INSTITUTIONAL ENVIRONMENT

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the resources description (Resources Format Page), indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

INSTITUTIONAL COMMITMENT TO THE CANDIDATE'S RESEARCH CAREER DEVELOPMENT

Introduction

The institutional commitment should document the agreement of the institution to provide adequate time and support for the candidate to devote nearly full-time to research career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured career development experience. It is essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award.

Because of the diverse types of K awards, applicants should contact the appropriate program director at NIH to determine the level of commitment required for this application.

Agreement

The applicant organization must:

a. Agree to release the candidate from other duties and activities to devote the required percentage of time for development of a research career. For most K awards, commitment of 75-80 percent of time is required. Describe actions that will be taken to ensure this, for example, reduction of the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities for the current academic year. Include the proportion of time currently available for the candidate's research experience and what the candidate's institutional responsibilities will be in the event that an award is made. Also describe the candidate's academic appointment, bearing in mind that it must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status) and the continuation of salary are not contingent upon the receipt of this award.

b. Provide the candidate with appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed research plan; and

c. Provide appropriate time and support for any proposed sponsor(s) and/or other staff consistent with the career development plan.

Signatures

The institutional commitment must be dated and bear the signature of the head of the organizational unit who is authorized to commit the institution to the agreements and assurances listed above. In most cases, this will be the dean or the chairman of the department. "Per" signatures are not acceptable.

The signature must appear over the signer's name and title at the end of the statement. When a candidate will be working away from the home institution, signatures from both the home and the host institution are required.

The sponsoring institution, through its signatures on the application and the institutional commitment, certifies that all items outlined above will be provided and that the institution will abide by the applicable assurances and PHS policies.

6. RESEARCH PLAN

The Research Plan is the major component of the research career development plan. It is important to relate the research to the candidate's goals and aspirations. The candidate should describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to launch and conduct an independent research career.

Applicants for all types of individual K awards should provide a Research Plan to be carried out in the course of this award. For most types of research, the plan should include: a specific hypothesis; a list of the specific aims and objectives that will be used to examine the hypothesis; a description of the methods/approaches/techniques to be used in each aim; a discussion of possible problems and how they will be avoided; and, when appropriate, alternative approaches that might be tried if the initial approaches do not work.

The plan should be appropriate to develop skills needed by a researcher. Projects that lack a clearly stated aim or hypothesis, such as studies involving routine data gathering to see where leads might develop and other types of descriptive projects, usually do not receive favorable recommendations from reviewers. This also applies to projects that are overly ambitious and describe more work than can be done in the requested time, as well as more routine projects that might be done, in large part, by a skilled technician.

Although candidates are expected to write the Research Plan for mentored K awards, the sponsor should review a draft of the plan and discuss it in detail with the candidate. Review by other knowledgeable colleagues is also helpful.

If the research involves collaboration with individuals, other than the sponsor, describe who will provide research materials, data, guidance, or advice. Then include letters from such individuals documenting their willingness to participate in the project (click here to view further instructions).

The headings for the first four sections of the Research Plan are:

1. Statement of Hypothesis and Specific Aims
2. Background, Significance, and Rationale
3. Preliminary Studies and Any Results
4. Research Design and Methods.

For more information about these sections, see the equivalent headings in the main instructions (Section I, Item 8, "Research Plan Format and Page Distribution.")

Note: The total number of pages for Item 3 (The Candidate) and A-D of Item 6 (Research Plan) combined may not exceed 25. In many cases, RCA applications will be shorter than the limit.

Although it is understood that RCA applications do not require the extensive detail usually incorporated in regular research applications, a fundamentally sound research plan and a reasonably detailed methods section should be provided.

In general, less detail will be expected in descriptions of research planned for the future years of the proposed RCA, but there should be sufficient detail to enable the reviewers to

determine that the plans for those years, including the methods to be used, are worthwhile and are likely to enhance development of the candidate.

Include required information on Women and Minority Inclusion, Inclusion of Children, Human Subjects, Data and Safety Monitoring, Vertebrate Animals, Consortium/Contractual Arrangements, and Consultants, when applicable. If your research plans to involve Human Subjects Research or Vertebrate Animals, read the full instructions in Section I. Failure to provide complete information may result in delay of the consideration of your application. Literature cited should be included in this section.

7. APPENDIX

No more than six publications and manuscripts accepted for publication should be submitted with applications. Do not submit abstracts or unpublished theses. Submit five collated sets.

Note: Do not submit the Checklist Page with the application. A completed Checklist will be required prior to award. Facilities and Administrative (F&A) costs will be awarded at 8 percent of modified total direct costs.

Form Approved Through 05/2004
OMB No. 0925-000

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

Institutional National Research Service Award

Instructions for Preparing Institutional National Research Service Award Applications

V. INSTITUTIONAL NATIONAL RESEARCH SERVICE AWARD

Sequential Guide for Preparing an Institutional NRSA Application (Requires use of both the General and NRSA Instructions.)	
Web Document Links	**Page**
Form Page 1	
Item 1. Specific PHS 398 Instructions	PHS 398-4
Item 2. NRSA Instructions and Specific PHS 398 Instructions	NRSA-63 PHS 398-4
Item 3. Specific PHS 398 Instructions	PHS 398-5
Item 4. NRSA Instructions	NRSA-63
Item 5. NRSA Instructions	NRSA-63
Item 6. NRSA Instructions and Specific PHS 398 Instructions	NRSA-65 PHS 398-30
Item 7. Specific PHS 398 Instructions	PHS 398-8
Form Pages 2-3: NRSA Instructions (Form Page 2) and (Form Page 3)	NRSA-65
Form Page 4: NRSA Instructions and Stipends	NRSA-65
Form Page 5: NRSA Instructions	NRSA-66
Biographical Sketch Format Page: NRSA Instructions	NRSA-66
Resources Format Page: NRSA Instructions	NRSA-66
Research Training Program Plan: NRSA Instructions	NRSA-66

A. INTRODUCTION

This section includes instructions to be used when applying for a competing (new, competing continuation, and supplemental) PHS Institutional National Research Service Award (NRSA); substitute form pages for the table of contents and both budget pages; and instructions for the Research Training Program Plan. Begin by reading the General Instructions (Section I-B) and then follow both sets of instructions using the Sequential Guide for Preparing an Institutional NRSA Application below.

Prior to preparing an application, consult with the appropriate PHS awarding component. Also review the current T32, T34 or T35 NRSA Program Announcement available at (http://grants.nih.gov/training/nrsa.htm). Note especially the eligibility requirements, receipt dates, award provisions, payback provisions, and review criteria. Program announcements, are also issued periodically by the individual NIH Institutes or Centers in the *NIH Guide for Grants and Contracts*. This information is available from the appropriate PHS awarding component, from grantee offices of sponsored programs or equivalent offices, or from the NIH grants Web site.

The training grant director must explain the terms of the payback service requirement to all prospective postdoctoral training candidates. A complete description of the service payback obligation is available in the NRSA Program Announcement or the NIH Grants Policy Statement.

B. SPECIFIC INSTRUCTIONS

1. FACE PAGE

(FORM PAGE 1, PDF FORMAT)

ITEM 2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATION (RFA) OR PROGRAM ANNOUNCEMENT (PA)

Indicate "Institutional National Research Service Award" and include the specific PHS awarding component and specialized program area, if applicable.

ITEM 4. HUMAN SUBJECTS

Check “Yes” if training plans include involvement of trainees in projects that include human subjects. If the applicant organization has an approved Federal Wide Assurance (FWA) or Multiple Project Assurance (MPA) on file with the Office for Human Research Protections (OHRP), insert the FWA or MPA in Item 4b. If an award is made, human subjects may **not** be involved until a certification of the date of IRB approval or a designation of exemption has been submitted to the PHS awarding component.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IRB review of human subjects is already complete or an exemption is already designated. This review or exemption designation is sufficient, provided the IRB determines that the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation. If space is insufficient in Item 4, indicate at 4a "Sec. f," and provide the information under the Research Training Program Plan.

ITEM 5. VERTEBRATE ANIMALS

Check “Yes” if training plans include trainee participation in projects involving vertebrate animals. If the applicant organization has an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), insert the assurance number in Item 5a. If at the time of application, plans for the involvement of vertebrate animals are so

indefinite that Institutional Animal Care and Use Committee (IACUC) review and approval are

not feasible, insert "Indefinite" at Item 5a. If an award is made, vertebrate animals may not be involved until a verification of the date of IACUC approval has been submitted to the PHS awarding component.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IACUC review is already complete. This review is sufficient, provided the IACUC determines that the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC review dates. If space is insufficient in Item 5, indicate at 5a "Sec. G," and provide the information under the Research Training Program Plan.

ITEM 6. DATES OF ENTIRE PROPOSED PERIOD OF SUPPORT

The usual starting date for an institutional NRSA is July 1, but there are other possible starting dates. Consult the review and award schedule in Section I of the general instructions (Table 2. Receipt, Review, and Award Cycles.) A few PHS awarding components restrict receipt and review dates to once a year. **Applicants are strongly encouraged to contact appropriate awarding component staff before submitting an application.**

2. DESCRIPTION, PERFORMANCE SITES, AND KEY PERSONNEL

(FORM PAGE 2, PDF FORMAT)

Description. Summarize the essence and major features of the program. Include research areas and disciplines, levels of training, numbers and background experience of trainees, anticipated duration of training, and primary facilities.

3. TABLE OF CONTENTS

(NRSA SUBSTITUTE FORM PAGE 3, PDF FORMAT)

Use the substitute Table of Contents (NRSA Substitute Form Page 3) in this addendum.

4. DETAILED BUDGET FOR INITIAL BUDGET PERIOD

(NRSA SUBSTITUTE FORM PAGE 4, PDF FORMAT)

Use the NRSA Substitute Form Page 4 and NRSA Substitute Form Page 5 in this addendum and follow the instructions below. **Refer to the NRSA Information Statement or consult the PHS awarding component for current allowable costs and stipend levels**. Provide information where possible on the substitute NRSA Substitute Form Page 4, with additional details starting in the budget justification block on the substitute NRSA Substitute Form Page 5.

STIPENDS

Enter the number of trainees and total stipend amount for each trainee category as appropriate use the current NRSA stipend schedule, (http://grants.nih.gov/training/nrsa.htm.) If a category contains different stipend levels, e.g., for varying levels of postdoctoral experience and/ or varying appointment periods, itemize. Enter the total stipends for all categories.

TUITION, FEES, AND HEALTH INSURANCE

Explain in detail the composition of this item. Itemize tuition, individual fees, and medical insurance. If tuition varies, (e.g., in-state, out-of-state, student status) identify these separately. Tuition at the postdoctoral level is limited to that required for specified courses. Tuition and fees (including self-only or family health insurance) may be requested only to the extent that the same resident or nonresident tuition, and health insurance fees are charged to regular non-Federally supported students and postdoctorates.

TRAINEE TRAVEL

State the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested, bearing in mind that PHS policy requires coach class air travel be used. Justify

foreign travel in detail, describing its importance to the training experience.

TRAINING RELATED EXPENSES

Funds to defray other costs of training, such as staff salaries, consultant costs, equipment, research supplies, staff travel, etc., are requested as a lump sum based on the amounts specified in the program announcement for each predoctoral and postdoctoral trainee. Give the number of trainees at the predetermined rate and enter the total dollar figure. No further itemization or explanation is required.

5. BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT

(NRSA FORM PAGE 5, PDF FORMAT)

Use the NRSA Substitute Form Page 5 in this addendum.

6. BIOGRAPHICAL SKETCH

(BIOGRAPHICAL SKETCH FORMAT PAGE 6, PDF FORMAT)

There is no Form Page for biographical sketches. Follow the format on the "Biographical Sketch Format Page." Include biographical sketches, not to exceed four pages each, for all professional personnel contributing to the training program. Assemble sketches with the program director first and others following in alphabetical order.

7. RESOURCES

(RESOURCES FORMAT PAGE, PDF FORMAT)

There is no Form Page for resources. Follow the format on the "Resources Format Page." Describe the facilities and resources that will be used in the proposed training program. Indicate in what ways the applicant organization will support the program (e.g., supplementation of stipends.)

8. RESEARCH TRAINING PROGRAM PLAN

The following instructions are for new and competing applications. If you are preparing a **revised** or **supplemental** application, first see instructions provided earlier in Section I (Revised Applications.) Then follow the outline suggested below in describing the Research Training Program Plan. **Do not exceed 25 pages of narrative for sections A-D.** Much of the information requested may be provided in tabular form, which will not be counted toward the page limitation; however, these table pages should be numbered consecutively to maintain the integrity of the application. If tables are placed in the Appendix, they should be numbered consecutively.

Before completing the training plan, contact the appropriate PHS awarding component, which may have further advice or suggestions for organizing the relevant data into particular formats.

BACKGROUND

Give the rationale for the proposed research training program, relevant background history, and the need for the research training proposed. Indicate how the proposed program relates to current training activities.

Summarize the research training activities of the major participating unit(s) and department(s) represented in the proposed program. Give the current number of faculty members in each unit and department, as well as the total numbers of current predoctoral students and postdoctoral trainees.

In a table, list all current and pending training support available to the participating faculty and department(s). Include funding source, complete identifying number, title of the training program, name of the program director, project period, number of training positions (predoctoral and postdoctoral), and amount of the award. For each grant listed, name only those participating faculty members who are also named in this application and indicate their percent effort in those programs.

PROGRAM PLAN

1. **Program Direction**. Describe the program director's relevant scientific background, research, experience in research training, and qualifications for providing leadership for the program. Indicate the program director's percent effort in the proposed program.

   Describe the administrative structure of the program and the distribution of responsibilities within it, including the means by which the program director will obtain continuing advice with respect to the operation of the program.

2. **Program Faculty**. List each training faculty member, his/her primary departmental affiliation, role, and percent effort in the proposed program. Describe each faculty member's research that is relevant to this program and indicate how trainees will participate in this research. In a table**,** indicate active and pending research support for each participating faculty member that will provide the context for research training experiences. Include all Federal, non-Federal, and institutional research grant and contract support. If none, state "None." Include the source of support, grant number and title, dates of the entire project period, and annual direct costs. If part of a larger project, identify the principal investigator and provide the above data for both the parent grant and the subproject.

   Describe the extent to which participating faculty members cooperated, interacted, and collaborated in the past, including joint publications and joint sponsorship of student research.

   In a table, for each faculty member participating in this application, list all past and current students for whom the faculty member has served, or is serving, as thesis advisor or sponsor (limit to past 10 years). For each student listed, indicate: (1) the training level, either predoctoral or postdoctoral; (2) the training period; (3) the institution and degree received prior to entry into training, including date; (4) title of the research project; and (5) for past students, their current positions, and for current students, their source of support.

   For **new** applications, list representative recent publications of some of the above students or postdoctorates.

   In competing continuation applications, mark those trainees who were or are supported by this training grant with an asterisk. Individuals who were trained by proposed participating faculty members at sites other than the applicant organization may be included but should be specifically identified. Publications of past trainees supported by this grant, provided in the Progress Report of this application, will suffice.

3. **Proposed Training**. Describe the proposed training program. Give the level and number of trainees. For postdoctoral trainees, provide the proposed distribution by degree (e.g., M.D., Ph.D.) Describe course work and research opportunities, the extent to which trainees will participate directly in research, and the duration of training, i.e., usual period of time required to complete the training offered.

   Indicate how the individual disciplinary and/or departmental components in the program are integrated and coordinated for the program and for an individual trainee's experience.

   For training programs emphasizing research training for clinicians, describe the interactions with basic science departments and scientists. In addition, include plans for ensuring that the training of these individuals will provide a substantive foundation for a competitive research career. Generally, a minimum of 2 years of research training is required for all postdoctoral trainees with health professional degrees. Describe fully any trainee’s access to and responsibility for patients including percent of effort.

   Provide representative examples of programs for individual trainees. Include curricula, degree requirements, didactic courses, laboratory experiences, qualifying

examinations, and other training activities, such as seminars, journal clubs, etc. Describe how the preceptor and research problems are chosen, how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated.

4. **Trainee Candidates**. Describe recruitment plans, including the sources and availability of trainees. Give the qualifications of prospective trainees and the criteria and procedures by which trainees will be selected.

   Create **a table** for each participating department/unit for each of the past 5 years. Include the following information:

   a. number of individuals who have formally applied for training;

   b. number offered admission;

   c. number who entered training;

   d. number who completed or are currently in training; and

   e. number who left the program. Indicate whether these individuals were applying for predoctoral or postdoctoral training, and for postdoctoral fellows, give their degrees (e.g., M.D., Ph.D.)

   Prospective predoctoral trainees. In a **table**, anonymously indicate the credentials and application outcomes of the predoctoral applicant pool for the most recent year for each participating department and unit. For each applicant (identified with a number in sequence, rather than by name, to safeguard privacy), indicate the previous institution attended, Graduate Record Examination scores, and grade point average. Indicate whether applicants were or were not offered admission, which applicants matriculated, and whether applicants were U.S. citizens or had permanent resident status.

   Prospective postdoctoral trainees. In a **table**, present the qualifications of prospective postdoctoral trainees in the most recent applicant pool. Provide the name, degree(s) and year awarded, previous institution, thesis research topic, preceptor, citizenship or permanent resident status, and residency training (when appropriate.) for each prospective applicant to the program. Indicate whether applicants were or were not offered admission and which applicants entered the program.

RECRUITMENT OF INDIVIDUALS FROM UNDERREPRESENTED RACIAL/ETHNIC GROUPS

The policy of the NIH is to promote broad and systematic efforts to recruit individuals from minority groups currently underrepresented in biomedical and behavioral research. NRSA programs are intended to attract and train individuals to pursue independent careers as investigators. Accomplishments of NRSA programs in these areas, with respect to recruiting and retaining individuals from underrepresented groups, will ensure that minority scientists are progressively better represented in the National research effort.

The application must contain information related to the program's plan and experiences in recruiting and training graduate students and/or postdoctoral trainees from underrepresented ethnic or racial groups. **Applications without a description of minority recruitment efforts will be considered incomplete and may be returned to the applicant without peer review.** The description of such plans and efforts should be arranged as follows:

History

In new applications, describe efforts to recruit minority students into the existing training program. In competing continuation applications, also describe past efforts to recruit and retain underrepresented minority students into NRSA training positions.

Achievements

Provide recruitment statistics indicating the number of minority individuals who applied to the program and/or participating units in each of the past 3 years. Give the number of minority candidates offered admission and the number who entered the program. For those who

entered the program, indicate their current status, e.g., training, graduated or completed training, and how they were supported. For those who have left the program or completed training, include information about their subsequent career development or employment. In competing continuation applications, indicate which of the minority individuals were supported by the NRSA grant.

Proposed Plans

Describe steps to be taken during the proposed award period regarding the identification, recruitment, and retention of graduate students and postdoctorates from underrepresented groups. Consider the success and/or failures of recruitment strategies used in the past. In particular, describe the specific efforts to be undertaken by the training program and how these might relate to the recruitment efforts of the medical school, graduate school, and/or the university at large. In most cases, institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups.

PLAN FOR INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH

Every NRSA trainee **must** receive instruction in the responsible conduct of research, and each training grant application must include a description of the plan to provide trainees with formal and informal instruction on scientific integrity and ethical principles in research. Institutions are encouraged to incorporate this instruction into the training of other non-NRSA supported pre- and postdoctoral trainees. **Review of applications lacking a plan for instruction in the responsible conduct of research may be delayed until a plan is provided.**

There are no specific curriculum or format requirements for this instruction; however, conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, and data management are areas that are strongly suggested for consideration. The plan must address the format and subject matter of the instruction and the frequency and degree of participation of the trainees and faculty that are expected to attend. A rationale for the proposed plan of instruction must be provided. For **competing** continuation applications, progress reports on the type of instruction provided, the degree of student participation, and other relevant information will be required.

PROGRESS REPORT (COMPETING CONTINUATION APPLICATIONS ONLY)

Briefly describe the accomplishments of the training program. State the period covered. Provide **a table** documenting for each year of the current project period, the program's actual assignment of awarded trainee positions. Provide: (1) the total number of positions awarded in each year; (2) the number of predoctoral trainees appointed and months of support committed; and (3) the number of postdoctoral trainees appointed, with what degrees, at what levels, and for how many months. Indicate and explain any trainee positions that were not filled.

Provide **a table** listing all trainees who were, or are, supported by this training grant. (Where applicable, provide the data for the past 10 years.) For each student give: (1) the name; (2) the year of entry into the training program; (3) prior institution, and degree at entry; (4) the source of support during each year of training, e.g., this training grant, another (specify) training grant, research grant, university fellowship, individual (specify) fellowship, etc.; (5) the research mentor; (6) the research topic; and (7) for trainees who have completed the program, their current positions and institutional affiliations. Give a brief summary of the research conducted by each trainee supported during the period covered, and list all publications that resulted from the work done during training. Where possible for past trainees, describe the extent of their current involvement in research, including research grant support and representative recent publications. This information will be used to track the pattern of support of trainees and the subsequent research career development of former trainees.

If any postdoctoral trainee with a health professional degree who was appointed to the grant during the most recent award period received less than 2 years of research training, explain why. This explanation should appear in the narrative section of the Progress Report. Describe any specific effects of this training program on curriculum and/or research directions. Describe how the funds provided under Training Related Expenses were utilized to benefit the program.

HUMAN SUBJECTS

As indicated earlier in these instructions for Item 4 on the Face Page, where appropriate include a list of already reviewed research project grants and their IRB review dates or exemption designations.

VERTEBRATE ANIMALS

As indicated earlier in these instructions for Item 5 on the Face Page, where appropriate include a list of already reviewed research project grants and their IACUC review dates.

9. APPENDIX

Appendix material is generally not needed with training grant applications. Oversized documents, brochures, and catalogues may be exceptions. If tables or other materials are included, the pages should be numbered consecutively. Five collated sets should be submitted.

10. CHECKLIST

(CHECKLIST FORM PAGE, PDF FORMAT)

INVENTIONS AND PATENTS

Not applicable.

FACILITIES AND ADMINISTRATIVE COSTS

Facilities and Administrative (F&A) costs under institutional NRSAs, other than those issued to State or local government agencies, will be awarded at 8 percent of total allowable direct costs (exclusive of tuition and related fees). Equipment is also excluded from the F&A costs on those training grants, where Training Related Expenses are not calculated on a lump-sum basis, such as the MARC or COR Honors Undergraduate Research Training Program. State and local government agencies will receive the full F&A cost rate.

11. PERSONNEL REPORT

(PERSONNEL REPORT FORM PAGE, PDF FORMAT)

Not applicable.

Forms Approved Through 05/2004
OMB No. 0925-0001

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

SMALL BUSINESS GRANT PROGRAMS

INSTRUCTIONS FOR PREPARING SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PHASE I AND PHASE II GRANT APPLICATIONS

VI. SMALL BUSINESS RESEARCH GRANT PROGRAMS

A. INTRODUCTION

This section includes instructions to be used when applying for a competing (new Phase I or Phase II) PHS Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) grant.

Begin by reading Section I, "Preparing Your Application"), and then follow *both* sets of instructions (**Section I** and **"Specific SBIR/STTR Grant Application Instructions and Requirements"** in this section), using the Sequential Guide for Preparing Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grant Applications below.

The applicant organization and the Principal Investigator are jointly responsible for the accuracy and validity of all the administrative, fiscal and scientific information in the application. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions such as withdrawal of an application or the suspension and/or termination of an award, as well as possible criminal penalties.

Sequential Guide for Preparing Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grant Applications (Requires use of both the 398 and SBIR/STTR Instructions.)	
Web Version **Dynamic Links**	**Printed Version** **Page References**
Form Page 1: Face Page	
Item 1: Specific PHS 398 Instructions	PHS 398-4
Item 2: SBIR/STTR Instructions	SBIR-75
Item 3a: SBIR/STTR Instructions Items 3b- 3g Specific PHS 398 Instructions	SBIR-76 PHS 398-5
Item 4: Specific PHS 398 Instructions	PHS 398-5
Item 5: Specific PHS 398 Instructions	PHS 398-7

Sequential Guide for Preparing Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grant Applications (Requires use of both the 398 and SBIR/STTR Instructions.)	
Web Version **Dynamic Links**	**Printed Version** **Page References**
Form Page 1: Face Page	
Item 6: SBIR/STTR Instructions	SBIR-77
Item 7: SBIR Instructions	SBIR-77
Items 8-10: SBIR Instructions	SBIR-77
Items 11-15: Specific PHS 398 Instructions	PHS 398-8
Form Page 2: Description/Performance Sites/Key Personnel SBIR Instructions	SBIR-78
Form Page 3: Table of Contents SBIR Instructions	SBIR-79
Modular Budget Format Page: Budget Justification for Modular Grant Applications: Use for budget requests of $100,000 total costs or less. SBIR Instructions	SBIR-79
Form Page 4: Detailed Budget for Initial Budget Period: Use for budget requests greater than $100,000 total costs. SBIR Instructions	SBIR-81
Form Page 5: Budget for Entire Proposed Project Period: Use for budget requests greater than $100,000 total costs. SBIR Instructions	SBIR-84
Biographical Sketch Format Page Specific PHS 398 Instructions	PHS 398-14
Resources Format Page SBIR Instructions	SBIR-86
Research Plan: No Form Page SBIR Instructions	SBIR-86
Checklist Form Page SBIR Instructions	SBIR-90
Personal Data Form Page SBIR Instructions	SBIR-93

B. GENERAL INSTRUCTIONS

Note: In addition to reading and following the instructions in this section (Section VI), also refer to Section I-C, "Specific Instructions" and Section III, "Other Information" for important policy information and guidance in preparing an application to NIH.

GRANT APPLICATION FORMS

Read and follow the instructions carefully to avoid delays and misunderstandings.

- The Public Health Service Grant Application (PHS 398) will be used for all SBIR and STTR (Phase I and Phase II) applications submitted after August 1, 2001. This change is in concert with steps that NIH is taking toward streamlining the NIH grant application procedures. These forms, as well as instructions for completion and submission, are available electronically at http://grants.nih.gov/grants/funding/funding.htm#forms.
- Use English only and avoid jargon and unusual abbreviations.
- Prepare the application, single-sided and single-spaced, staying within the ½" margin limitations indicated on the forms.
- Use ½ inch margins for all continuation pages.
- Use standard size, black type that can be photocopied; do not use photo reduction.
- Draw all graphs, diagrams, tables, and charts in black ink.
- Submit the **original and five** exact, clear, single-sided photocopies of each application.
- *Do not include glossy or colored photographs* or materials that cannot be photocopied in the body of the application. NIH uses black ink photocopiers to reproduce applications. Applicants must contact the Scientific Review Administrator to request permission to submit pertinent glossy photographs or color images (5 sets) that are pertinent to the review of an application. In these circumstances, the original application must include black ink copies of the photographs or images so as not to give the impression that page limitations are being circumvented.

PAGE LIMITATIONS

Failure to comply with SBIR/STTR page limitations will be grounds for the PHS to return the application without peer review.

PHASE I SBIR/STTR

NOTE: *Items a-d* of the RESEARCH PLAN are limited to a total of 15 pages for Phase I applications.

SBIR/STTR Phase I applications *may not exceed 25 single-spaced standard size (8 ½" x 11") pages,* ***excluding***:

- Cover letters.
- One-page "Introduction" required when submitting a revised (amended) application.
- Biographical Sketch Format Page(s) (*maximum* of 4 pages, for each key person)
- Letters of commitment from collaborators and consultants
- Checklist Form Page
- Personal Data on Principal Investigator Form Page
- Page(s) furnishing information required under "Prior SBIR/STTR Phase II Awards" (Item k; p. 89), if applicable.
- "Research Institution Certification Format Page" (STTR only)

Unless specifically solicited by NIH, Phase I appendices are not permitted and will not be considered in the review of the application.

PHASE II SBIR/STTR

Items a-d of the Phase II RESEARCH PLAN are limited to 25 pages. There is no further limitation on the total number of pages for the entire Phase II application.

TYPE SIZE

Adherence to type size and line spacing requirements is necessary for several reasons. No applicant should have the advantage, by using small type characteristics, of providing more text in his/her application than other applicants. Small type may also make it difficult for reviewers to read the application. The application must be clear, readily legible, and conform to the following requirements:

1. The height of the letters must not be smaller than 10 point.
2. Type density, including characters and spacing, must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi.
3. There must be no more than 6 lines of type within a vertical inch.
4. All margins must be ½ inch wide.
5. Figures, charts, tables, figure legends, and footnotes may be smaller in size but MUST be readily legible.

Type size and format specifications must be observed throughout the application. Failure to comply with formatting specifications will be grounds for the PHS to return the application without peer review.

Type requirements should be checked on the printed document using a standard device for measuring type size, rather than relying on the font selected for a particular word processing/ printer combination.

The Division of Receipt and Referral, Center for Scientific Review (CSR), NIH has the responsibility and authority to make the final determination of legibility, which is final and not appealable. Further inquiries should be directed to the:

Division of Receipt and Referral
CSR
Phone: (301) 435-0715; Fax: (301) 480-1987.

REMINDER SHEET

Applicants are encouraged to refer to the appropriate Phase I SBIR Reminder Sheet or Phase I STTR Reminder Sheet and, if necessary, Fast Track Reminder Sheet, to ensure that the requirements for submission have been met.

INFORMATION REQUIRED PRIOR TO AWARD

If the application has the likelihood for funding, the following items will be routinely requested by the awarding component prior to making the grant award:

- Documentation to establish the "primary employment" of the Principal Investigator with the applicant small business concern. (SBIR only)
- Documentation regarding the performance site(s) of the applicant small business concern as shown on the Face Page of the application, if that site(s) is not owned by the applicant organization.
- "Other support" for the Principal Investigator and the other "Key Personnel Engaged on Project" named on Form Page 2, excluding consultants.

PHASE I/PHASE II FAST-TRACK APPLICATIONS (APPLICABLE TO NIH ONLY)

The SBIR/STTR "Fast-Track" option is designed to expedite the decision of Phase II funding through *concurrent submission* and peer review of both Phase I and Phase II projects. An advantage of the Fast-Track application process is the reduction or elimination of a funding gap between the Phase I and Phase II.

Fast-Track is an option available to those small business concerns whose Phase I and Phase II applications are scientifically meritorious and whose applications satisfy additional criteria (described below) that will enhance the potential for the project's commercial success. Applications that do not meet these criteria may be redirected for review through the standard review procedures described above.

SBIR/STTR FAST-TRACK APPLICATION INSTRUCTIONS

- Submit a complete Phase I *and* Phase II application, including the Face page, Abstract, Budget, Biographical Sketch and Bibliography, and Research Plan for each, in accordance with **SPECIFIC SBIR/STTR GRANT APPLICATION INSTRUCTIONS AND REQUIREMENTS (Section VI-C).** Incomplete Fast-Track Applications and will be grounds for the PHS to return the application without peer review.

- Identify the application as Fast-Track, by typing the words "Fast-Track" in Item 2 on the Face Page of the Phase I and Phase II application.

- Prepare and submit both a Phase I and Phase II SBIR/STTR application together for concurrent initial peer review and evaluation.

- Mail a complete Phase I and Phase II application package in a ***single*** envelope or box.

- Review the **Fast-Track Reminder Sheet** before submitting the application.

- Specify in the Phase I application clear, appropriate measurable goals (milestones) that should be achieved prior to initiating Phase II. **Failure to provide clear, measurable goals may be sufficient reason for the scientific peer review group to exclude the Phase II application from Fast-Track review.** The scientific peer review group will evaluate the goals and may suggest other milestones that should be achieved prior to Phase II funding.

- Submit a concise Product Development Plan (limited to ten pages). Label this section clearly and ***include it in Section J of the Research Plan***. See specific grant application instructions and requirements. **Note:** The Phase I Final Report must be submitted to the awarding component upon completion of Phase I and prior to the award of the Phase II.

Applicants are ENCOURAGED to seek commitment(s) of funds and/or resources or letters of interest from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant.

Before submitting applications under "Fast-Track," applicant small business concerns and investigators are strongly encouraged to consult with the NIH program staff named in the table "Awarding Component/Agency Contact Information." Contacts are provided in the SBIR/STTR Grant Solicitation.

C. SPECIFIC SBIR/STTR GRANT APPLICATION INSTRUCTIONS AND REQUIREMENTS

See also PHS 398 Specific Instructions (Section I; p. 4) for instructions on items not described in this section. Use the Sequential Guide for Preparing Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grant Applications to aid in completing the application.

1. FACE PAGE

(FACE PAGE, PDF FORMAT)

ITEM 1. TITLE OF PROJECT

See Specific 398 Instructions (p. 4)

Ordinarily, the SBIR/STTR Phase II application should carry the same title as the Phase I grant.

ITEM 2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATION (RFA) OR PROGRAM ANNOUNCEMENT (PA) OR SOLICITATION

Check "Yes.

For Phase I SBIR/STTR applications, insert the solicitation number (e.g., PHS 2001-2) listed on the cover page of the Omnibus Solicitation of the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration for SBIR and STTR Grant Applications. **Type "Fast-Track," if appropriate: Do not type PHS 398 in this line.**

For Phase II SBIR/STTR applications, type "Phase II SBIR" or "Phase II STTR," as appropriate.

Attach to the bottom of the face page the appropriate SBIR or STTR label. The SBIR and STTR labels are under the general mailing label, following the checklist and personal data pages.

If the application is submitted in response to an RFA or a PA, check "Yes" and identify the appropriate announcement number and title of the PA or RFA.

ITEM 3. PRINCIPAL LNVESTIGATOR/PROGRAM DIRECTOR

Item 3a. Name of Principal Investigator

Name the ONE person responsible to the applicant small business concern for the scientific and technical direction of the project.

NOTE: Under the SBIR Program, the primary employment (more than 50 percent time) of the Principal Investigator must be with the small business concern *at the time of award* and during the conduct of the proposed project. Under the STTR Program, primary employment with the small business concern is not stipulated.

Primary employment means that more than one half of the Principal Investigator's time is spent in the employ of the small business concern. Primary employment precludes full-time employment with another organization.

Item 3b. Degree(s)

See Specific 398 Instructions (p. 5)

Item 3c. Position Title

See Specific 398 Instructions (p. 5)

Item 3d. Mailing Address

See Specific 398 Instructions (p. 5)

Item 3e. Department, Service, Laboratory, or Equivalent

See Specific 398 Instructions (p. 5)

Item 3f. Major Subdivision

See Specific 398 Instructions (p. 5)

Item 3g. Telephone and Fax Numbers

See Specific 398 Instructions (p. 5)

ITEM 4. HUMAN SUBJECTS

See Specific 398 Instructions (p. 5)

Item 4a. Exemptions from Human Subjects Regulations

See Specific 398 Instructions (p. 6)

Item 4b. Human Subjects Assurance Number

Item 4b. Human Subjects Assurance Number (p. 6)

Item 4c. Phase III Clinical Trial

See Specific 398 Instructions (p. 8)

ITEM 5. VERTEBRATE ANIMALS

See Specific 398 Instructions (p. 6)

Item 5a. IACUC Certification.

See Specific 398 Instructions (p. 7)

Item 5b. Animal Welfare Assurance

See Specific 398 Instructions (p. 7)

ITEM 6. DATES OF PROPOSED PERIOD OF SUPPORT

Phase I: Routinely, SBIR Phase I awards do not exceed six (6) months and STTR Phase I awards do not exceed one year.

Phase II: Routinely, SBIR and STTR Phase II awards do not exceed two years.

Under special circumstances, applicants to NIH may propose longer periods of time for completion of the research project (e.g., feasibility demonstration.) Such requests that deviate from the guidelines must be thoroughly justified.

To select an appropriate beginning date for a **new** application, consult the review and award schedule. (See "Submitting Your SBIR/STTR Grant Application.)

PHS awarding components may not always be able to honor the requested start date. No commitments or obligations should be made until confirmation of the actual start date by the awarding component.

ITEM 7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD

Routinely, SBIR and STTR Phase I awards do not exceed $100,000 total costs (direct costs, indirect costs, and negotiated fixed fee.) Routinely, total costs for the entire proposed Phase II period do not exceed $750,000 for SBIR and $500,000 for STTR projects. However, under special circumstances, applicants may propose greater amounts of funds for completion of the project. All amounts requested in Items 7 and 8 and on the budget pages must be in U.S. dollars.

Item 7a. Direct Costs Requested for Initial Budget Period

Enter the direct costs from Form Page 4. (Do not include amount requested for fixed fee.)

Item 7b. Total Costs Requested for Initial Budget Period

Enter the **sum** of (a) the total direct costs from Form Page 4; (b) the amount requested for fixed fee on Form Page 4, and (c) the indirect costs derived from the Checklist Form Page.

For Phase I SBIR/STTR applications that do not exceed one year, the direct and total costs for the entire "proposed period of support" (Item 8) will be the same as the direct and total costs for the "initial budget period" (Item 7).

ITEM 8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT

Item 8a. Direct Costs Requested for Proposed Period of Support

Enter the "total **direct** costs for entire project period" from Form Page 5 or the "Modular Budget Format Page."

Item 8b. Total Costs Requested for Proposed Period of Support.

Enter the **sum** of (a) the total direct costs from Form Page 5; (b) the amount requested for "Total fixed fee requested for entire proposed period" on Form Page 5 or the "Modular Budget Format Page;" and (c) the indirect costs derived from the Checklist Form Page.

NOTE: The above applies to NIH ONLY, as CDC and FDA do not make awards greater than the stated guidelines.

ITEM 9. APPLICANT ORGANIZATION

Name the one organization (small business concern) that will be legally and financially responsible for the conduct of activities supported by the award. The small business concern is ALWAYS the applicant organization for an SBIR or STTR.

ITEM 10. TYPE OF ORGANIZATION

Check the appropriate box.

Small Business Certification.

The applicant organization must certify that it will qualify as a small business concern at the time of award. Check the appropriate box under "For-Profit." Check the boxes designating the small business as "woman-owned" or "socially and economically disadvantaged," if appropriate. (See Section III-A, for definition of a small business concern.) Please note that the

capture of information on socially and economically disadvantaged small business concerns and women-owned small business concerns is strictly for statistical purposes (as requested by the Small Business Administration).

ITEM 11. ENTITY IDENTIFICATION NUMBER, DUNS NUMBER, CONGRESSIONAL DISTRICT.

See Specific PHS 398 Instructions. (p. 8)

ITEM 12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE

See Specific PHS 398 Instructions. (p. 8)

ITEM 13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION

See Specific PHS 398 Instructions. (p. 8)

ITEM 14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE

See Specific PHS 398 Instructions. (p. 9)

ITEM 15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE.

See Specific PHS 398 Instructions. (p. 9)

Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. When the application contains information that constitutes trade secrets; or is commercial or financial information; or confidential or privileged information, identify the information by asterisks (*) and page numbers in the Research Plan. The information is furnished to the Government in confidence with the understanding that it shall be used or disclosed only for evaluation of this application. If a grant is awarded as a result of, or in connection with, the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

2. DESCRIPTION, PERFORMANCE SITES, AND KEY PERSONNEL

(FORM PAGE 2, PDF FORMAT)

DESCRIPTION (ABSTRACT OF RESEARCH PLAN)

Note the instructions on Form Page 2 for the information requested. In addition, discuss the potential of the research for technological innovation. The Abstract of Research Plan is limited to 200 words. If the application is funded, this description will become public information. Therefore, **do not include proprietary or confidential information in the abstract**.

PERFORMANCE SITES

Indicate where the work described in the "Research Plan" will be conducted. **One of the sites indicated must be that of the applicant small business concern.** If there is more than one performance site, list all the sites and provide an explanation on the Resources Format Page of the application. **The research or R&D project activity must be performed in its entirety in the United States**. However, based on a rare and unique circumstance, for example, a supply or material or other project requirement that is not available in the United States, agencies may allow that portion of the research or R&D work to be performed or obtained in a country outside of the United States. Approval by the funding officer for such specific condition(s) must be in writing.

KEY PERSONNEL

Key personnel are defined as all individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. Consultants should also be included if they meet the definition of "key personnel."

Start with the principal investigator. All other key personnel should be listed in alphabetical order, last name first. For each individual provide: name, organization (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project. Use additional pages as necessary.

Disclosure Permission Statement. Check "YES" or "NO." If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and email address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaboration, investment)?

3. RESEARCH GRANT TABLE OF CONTENTS

(FORM PAGE 3, PDF FORMAT)

Provide the page number for each category listed on the Table of Contents. Number pages consecutively, at the bottom of each page, throughout the application. Do not include unnumbered pages and do not use suffixes, such as 5a, 5b.

4. MODULAR APPLICATIONS: SPECIAL INSTRUCTIONS FOR BUDGETS OF $100,000 TOTAL COSTS OR LESS

The following unique features of the modular grant application apply ONLY to SBIR/STTR applications requesting up to $100,000 total costs (direct costs, indirect costs, and fixed fee).

For all other applications, refer to the specific "Instructions for Preparing Budget Requests that Exceed $100,000 Total Costs (p. 81). (See detailed budget information following this section.)

MODULAR GRANT APPLICATION AND AWARD

NIH is employing only certain features of the Modular Grant application and award procedures under its SBIR/STTR programs. Application budgets are simplified; detailed categorical budget information is not submitted with Phase I applications that request $100,000 total costs or less; budget form pages are used for internal worksheets only. Instead, information, in narrative form, is provided only for Personnel (all), Consortium/Contractual Costs, Consultant Costs, and Fixed Fee. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have agreed also to join the NIH in engaging the Modular Grant Application and Award procedures for use in their SBIR/STTR programs.

Scientific Review Groups (SRG) will evaluate the budget on the basis of a general, expert estimate of the total costs and resources required to carry out the proposed research in the requested period, rather than on the basis of detailed categorical costs.

Under certain circumstances, additional budget information will be requested by the awarding component.

NOTE: Budget requests are NOT made in increments of $25,000 (as they are for other grant mechanisms such as R01, R03, R15, and R21).

INSTRUCTIONS FOR PREPARING BUDGET REQUESTS UP TO $100,000 TOTAL COSTS

On the **Face Page** of the application, enter the **sum** of (a) the total direct costs from Item 7a; (b) the amount requested for fixed fee; and (c) the indirect costs derived from the Checklist Form Page.

OMIT Form Page 4 and Form Page 5 in the application submission. They are to be used as *internal* "worksheets" only, in the development of the total direct costs.

STTR Modular Applications: Also, include the STTR Research Institution Certification (see "STTR Research Institution Certification Format Page.")

BUDGET INSTRUCTIONS FOR SBIR/STTR MODULAR GRANT APPLICATIONS

Use the **"Modular Budget Format Page"**, and provide*, **in narrative format,*** the following information on Personnel, Consultant Costs, Contractual Costs and Fixed Fee. **Use continuation page(s), if necessary**. See specific STTR instructions, if applicable, for describing the work to be performed by the partnering research institution.

1. **Personnel.** Starting with the Principal Investigator, list **all** personnel, including **names**, percent of **effort** and their specific **roles** on the Phase I project. No individual salary information should be provided.

2. **Consortium/contractual costs.** Provide the name of each contractor organization and an estimate of the total costs (direct plus facilities and administrative (F&A) costs **[formerly called "indirect costs"]** for each year, rounded to the nearest $1,000. Describe their specific functions and state the percentage of effort that individuals will devote to the subcontract. No individual salary information should be provided. Collaborating institutions must be domestic. The total cost for a consortium/contractual arrangement is included in the overall requested "modular" direct cost amount. Include a total cost estimate for any Consortium/contractual costs.

   SBIR. The total amount of contractual costs and consultant fees normally may not exceed 33% of the total costs requested on a Phase I SBIR project and 50% of the total costs requested on a Phase II SBIR project. Contractual arrangements for scientific or technical services (e.g., laboratory testing of biological materials, clinical services) may involve costs such as personnel, supplies, and any other allowable expenses, including indirect costs.

   STTR. STTR projects are required to be conducted through "cooperative research and development," as defined in Section III, Definitions. **The small business concern must perform at least 40% of the work on the STTR project and the single partnering research institution must perform at least 30% of the work.** The principal investigator must spend a minimum of **ten percent effort** on an STTR grant.

   Provide information for Personnel, and Consultant Costs and Contractual Costs (Consortium) associated with the Research Institution's portion of the budget, in the same manner as described above in items 1 and 2.

   Indicate the total costs (sum of direct and F&A costs) of the portion of the project to be performed by the Research Institution" on the "Modular Budget Format Page." **Note: The "Total Cost" (direct and F&A costs) for the Research Institution is *included* in the Direct Costs of the Small Business Concern's budget.**

Note: A letter from the partnering research institution must be included with the application certifying that at least 30% of the work of the project will be performed by the research institution. Use the STTR Research Institution Certification Format Page. (This 30% requirement applies to the single collaborating organization identified as the "research institution.")

The "duly authorized representative" of the research institution must be an individual other than someone identified under "Key Personnel Engaged on Project" on Form Page 2 of the application who is authorized to act for and bind the research institution to similar arrangements on a routine basis. This may be the same individual who was authorized by the research institution to sign the agreement allocating between the small business concern and the research institution intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization applicable to the proposed project (see Model Agreement for Allocation of Rights; included in the Omnibus Solicitation for SBIR/STTR Grant Applications.)

Costs pertaining to arrangements for a portion of the project to be conducted by *other than* the

"research institution" should also be identified in narrative format on the "Modular Budget Format Page." Indicate total costs.

3. **Consultant Costs.** Provide the names and organizational affiliations of any consultants, other than those involved in contractual arrangements, who have agreed to serve in that capacity. Include consultant physicians in connection with patient care. Briefly describe the services to be performed, including the number of days of anticipated consultation, and the total costs requested for each individual. Letters of commitment from consultants and collaborators must be submitted with the application, but are *excluded* from the 25-page limitation.

   The total amount of all consultant costs and contractual costs normally may not exceed 33% of the total costs requested on a Phase I SBIR project and 50% of the total costs requested on a Phase II SBIR project.

4. **Fixed Fee.** Explain the basis for the amount of fixed fee requested. A reasonable fixed fee is available to small business concerns receiving awards under the SBIR/STTR program. *The amount of the fee approved by the agencies participating in this solicitation normally will not exceed **7% of total costs** (direct and indirect) for each Phase (I and II) of the project*. The fee is not a "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work. The fixed fee applies solely to the small business concern receiving the SBIR/STTR award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

BUDGET INSTRUCTIONS FOR SBIR/STTR NON-MODULAR GRANT APPLICATIONS

5. DETAILED BUDGET FOR INITIAL BUDGET PERIOD

(FORM PAGE 4, PDF FORMAT)

Routinely, SBIR/STTR Phase I total costs do not exceed $100,000. Routinely, SBIR Phase II awards may not exceed $750,000 in total costs (direct costs, indirect costs, and negotiated fixed fee) for a period normally not to exceed 2 years, and STTR Phase II awards normally may not exceed $500,000 total costs (direct costs, indirect costs, and negotiated fixed fee) for a period normally not to exceed 2 years.

However, applicants may propose a greater amount of funds necessary and appropriate for completion of the research project. (The above applies to NIH ONLY—applications to CDC and FDA are limited to $100,000 and therefore should use the Modular Budget Format Page.)

INSTRUCTIONS FOR PREPARING BUDGET REQUESTS THAT EXCEED $100,000 TOTAL COSTS.

- **Submit Form Page 4** (Detailed Budget for Initial Budget Period, – Direct Costs Only*)* and submit Form Page 5 (Budget for Entire Proposed Period of Support.)

- Detailed categorical budget information is to be included with the application. Budget information on Form Page 4 should reflect the total direct costs requested, which includes the total costs (direct and indirect) of any "contractual costs," for the initial 12-month period (e.g., the entire Phase I project period or, in the case of a Phase II, the first year of the two-year project.) All amounts must be in U.S. dollars.

- Enter Direct Costs in Item 7a of the Face Page. *The amount requested by the small business concern for "fixed fee" is not a "cost."* Therefore, it should be included *as a separate line* item on Form Page 4.
- Enter Total Costs (sum of direct, F&A, and fixed fee) in Item 7b of the Face Page.
- Enter Direct Costs for ENTIRE Proposed Period of Support in Item 8a of the Face Page.
- Enter Total Costs (sum of direct, F&A and fixed fee) for ENTIRE Proposed Period of Support in Item 8b of the Face Page.
- STTR applications: Include the STTR Research Institution Budget Form Page and Justification on Form Page 5.
- Renumber pages as necessary.
- Refer to the SBIR or STTR Reminder Sheet before submitting the grant application.

Do not include any items that are treated by the applicant organization as indirect costs according to a Federal rate negotiation agreement, except for those indirect costs included in consortium/contractual costs.

The following items pertain individually to the completion of Detailed Budget for Initial Budget Period – Direct Costs Only (Form Page 4) for budget requests greater than $100,000 total costs.

Information for some items, marked as *"Do not complete at the time of application" will be requested by the awarding component if the application has the likelihood for funding*.

PERSONNEL

Name. Starting with the principal investigator, list the names of all applicant organization employees who are to be involved on the project during the initial budget period, regardless of whether a salary is requested.

Role on Project. Indicate how the individual will function with regard to the proposed project (for example, principal investigator, statistician.) Describe their specific functions under Budget Justification on Form Page 5.

Type of Employment. List the number of months per year reflected in an individual's employment agreement with the organization. If employment is less than full time (e.g., 1/2 time or 3/4 time), enter an asterisk (*) after the number of months and provide a full explanation under Budget Justification on Form Page 5.

Percent Effort on Project. For each individual at the applicant organization, list the percent of each appointment to be spent on this project. If an individual engages in other corporate responsibilities, such as management, the total percentage devoted to all research activities by the individual must be less than 100%. *For STTR projects, the Principal Investigator must devote a minimum of 10% effort to the project*.

Institutional Base Salary

(Do not complete at the time of application)

This information will be requested by the awarding component if the application has the likelihood for funding. The institutional base salary is defined as the annual compensation that the organization pays for the individual's employment, whether that individual's time is spent on research, administration, or other activities. Base salary excludes any income the individual may be permitted to earn outside of duties to the organization. Base salary may not be increased as a result of replacing corporate salary funds with grant funds.

Dollar Amount Requested

Salary Requested. Enter the dollar amounts for each position for which funds are requested. The maximum salary that may be requested is calculated by multiplying the individual's institutional base salary, defined above, by the percent of effort on this project. Congress has imposed and may continue to impose salary caps. *Organizations should request appropriate salary support without regard to Congressional salary caps. Any amount*

requested for salary that may be in excess of a salary cap will be adjusted at the time an award is issued. Calculate the totals for each position and enter the subtotals in each column where indicated.

Fringe Benefits. *Commercial (for-profit) organizations usually treat "fringe benefits" as indirect costs*. These fringe benefits are applied to direct salaries charged to projects either through a fringe benefit rate or as part of an overhead/indirect cost rate. Therefore, fringe benefits treated as indirect costs should not be included as a direct cost in the Personnel category of the budget on Form Page 3 of the grant application. In certain cases, fringe benefits may be requested as a direct cost to the extent that they are treated consistently by the organization as a direct cost to all sponsors.

Totals. Calculate the totals for each position and enter the subtotals in each column where indicated. While totals for personnel do not need to be itemized, enter a total amount for all organizational personnel for whom a salary is requested.

CONSULTANT COSTS

Whether or not costs are involved, provide the names and organizational affiliations of any consultants, other than those involved in consortium/contractual arrangements, who have agreed to serve in that capacity. Include consultant physicians in connection with patient care.

REMINDER: Letters of commitment from collaborators and consultants must be submitted with the application, but are excluded from the Phase I 25-page limitation.

If this category exceeds $10,000 and/or a consultant(s) is identified as "Key Personnel Engaged on Project" on Form Page 2, state the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs. See Section III-A. DEFINITIONS for definition of "Key Personnel Engaged on Project."

EQUIPMENT

Provide the total dollar amount requested. Itemize and justify according to the following instructions only if this category exceeds $15,000. List separately each item of equipment with a unit acquisition cost of $5,000 or more, and justify the request on Form Page 5. Explain the need for any item that appears to be duplicated or equivalent to those listed in the "Resources" portion on these forms.

SUPPLIES

Provide the total dollar amount requested. Itemize and justify the request on Form Page 5 according to the following instructions *only if this category exceeds $15,000*. Itemize supplies in separate categories, i.e., glassware, chemicals, radioisotopes. Categories in amounts less than $1,000 do not have to be itemized. If animals are involved, state how many are to be used, their unit purchase cost, and their unit care cost.

TRAVEL

Provide the total dollar amount requested. Itemize and justify the request on Form Page 5 according to the following instructions *only if this category exceeds $5,000*. Describe the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested, bearing in mind that agency policy requires that less than first-class air travel be used. Travel of a reasonable amount ($1,500-$2,000) may be proposed to attend conferences and similar meetings in the scientific field(s) of endeavor, to learn of new or emerging scientific interests of the PHS awarding components (for example, bioengineering), and to improve post award management. Travel to a scientific meeting in a foreign country is allowable, but this request should be thoroughly justified regardless of the dollar amount requested.

PATIENT CARE COSTS

The applicant organization may be reimbursed for inpatient and outpatient charges incurred incident to the proposed research. Provide the names of the hospitals and/or clinics to be used

and the amounts requested for each. Indicate in detail the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. Patient care costs do not include travel, lodging, and subsistence; request these costs in the "Other Expenses" category. Request consultant physician fees in the "Consultant Costs" category.

CONTRACTUAL COSTS

Each participating consortium/contractual organization must submit a separate detailed budget for both the "Initial (Phase I) Budget Period" (Form Page 4) and, if the project period exceeds one year, the "Entire Proposed Project Period" (Form Page 5).

Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including Facilities and Administrative (indirect) costs. Contractual arrangements for scientific or technical support services (e.g., laboratory testing of biological materials, clinical services, or data processing) may involve costs such as personnel, supplies, and any other allowable expenses, including indirect costs. Such contracts may be of sufficient scope to warrant a similar categorical breakdown of costs.

SBIR: For SBIR projects, the total amount of all contractual costs and consultant fees normally may not exceed 33% of the total costs requested on a Phase I project and 50% of the total costs requested on a Phase II project.

STTR: STTR projects are required to be conducted through "cooperative research and development," as that term is defined in Section III, Definitions. At least 40% of the work on the project must be performed by the small business concern and at least 30% of the work on the project must be performed by the single, partnering research institution. See instructions for preparing the "Budget of Research Institution" at the end of this section.

OTHER EXPENSES

These might include animal maintenance (unit care costs and number of care days), patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission in lieu of salary. Provide the total dollar amount requested. Itemize and justify the request on Form Page 5 *only if this category exceeds $5,000*.

FIXED FEE

Explain the basis for the amount of fixed fee under Budget Justification on Form Page 5. A reasonable fixed fee is available to small business concerns receiving awards under the SBIR/STTR program. The fee is not a "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work. However, the amount of the fee approved by the agencies participating in this solicitation normally will not exceed seven **7% of total costs** (direct and indirect) for each phase (I and II) of the project. The fixed fee applies solely to the small business concern receiving the SBIR/STTR award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

6. BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT

(FORM PAGE 5, PDF FORMAT)

Enter the totals under each budget category for all additional years of support requested. Identify with an asterisk (*), and justify any significant increases or decreases from the initial year budget, if applicable. Also, justify budgets with more than a standard escalation from the initial to the future year(s) of support.

SBIR Applicants may proceed directly to the next section, "Biographical Sketch."

STTR applicants must refer to the following instructions on preparing the budget of the research institution.

BUDGET OF RESEARCH INSTITUTION (STTR ONLY)

Phase I. Use **STTR Research Institution Budget Form Page** (STTR Additional Page) to identify costs pertaining to the portion (minimum 30%; maximum 60%) of the STTR project to be conducted by the "research institution." Provide information for Personnel, Consultant Costs, Equipment, Supplies, Travel, Patient Care Costs, Other Expenses, Total Direct Costs, Facilities and Administrative (F&A) Costs, and Total Costs associated with the research institution's portion of the budget in the same manner as described above.

Note: The partnering research institution must certify at the time of application that at least 30% of the work of the project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the "research institution." Space has been provided on the form for the requisite signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution upon signing the budget page.

On the Small Business Concern's Budget Page (Form Page 4) enter the "Direct Costs" and "Facilities and Administrative Costs" for the research institution in the field labeled "Consortium/Contractual Costs." Provide the F&A cost base and rate. **That is, when the research institution requests F&A costs, these costs must be included on the Small Business Concern's budget page as a direct cost.** *If the STTR project period exceeds one year, use Form Page 4 and Form Page 5 to enter the information.*

Justify costs under "Budget Justification" on Form Page 5 and identify them as pertaining to the research institution. Total costs of the portion of the project to be performed by the research institution are also to be shown in the Justification section of Form Page 5.

Phase II. For the "Initial Budget Period," use the **STTR Research Institution Form Page** (STTR Additional Page) to identify costs pertaining to the portion (minimum 30%; maximum 60%) of the STTR project to be conducted by the "research institution."

For the "Entire Proposed Project Period", use a ***separate*** Form Page 5 to identify costs pertaining to the portion of the STTR project to be conducted by the "research institution." Identify the research institution's budget page by typing "Budget of Research Institution" at the top of Form Page 5. Insert these additional pages *after* the budget pages of the small business concern (Form Page 4 and Form Page 5), numbering them sequentially. (Do not use 5a, 5b, 5c, etc.)

Provide information for Personnel, Consultant Costs, Equipment, Supplies, Travel, Patient Care Costs, Other Expenses, Subtotal Direct Costs, Total Direct Costs, and Consortium/Contractual Costs associated with the research institution's portion of the budget in the same manner as described above.

On the small business concern's budget pages for Initial Budget Period (Form Page 4) and Entire Proposed Project Period (Form Page 5), enter the "Direct Costs" and "Facilities and Administrative Costs" for the research institution in the field labeled "Consortium/Contractual Costs." Provide the F&A cost base and rate. That is, when the research institution requests F&A costs, these costs must be included on the Small Business Concern's budget page as a direct cost.

On Form Page 5, justify costs under "Justification" and identify them as pertaining to the research institution. Total costs of the portion of the project to be performed by the research institution are also to be shown in the Justification section of Form Page 5. If space is not available on the form, attach a continuation page(s) for this purpose.

Costs pertaining to arrangements for a portion of the project to be conducted by *other than* the

"research institution" should be identified by way of photocopying budget Form Page 4 and completing it in the same manner as described above. Contractual arrangements for scientific or technical services, such as the laboratory testing of biological materials, clinical services, etc., may involve costs such as personnel, supplies, and any other allowable expenses, including indirect costs. Costs of all contracts that are of sufficient scope to warrant a categorical breakdown of costs must be identified on a photocopied budget Form Page 4.

7. BIOGRAPHICAL SKETCH

(BIOGRAPHICAL SKETCH FORMAT PAGE, PDF FORMAT)

There is no form page for the Biographical Sketch. Follow the format on the "Biographical Sketch Format Page." See specific PHS 398 instructions in Section I, Item 6, "Biographical Sketch."

OTHER SUPPORT INFORMATION.

NOTE: Information on "other support" should NOT be submitted with the application. If "other support" information is included in the application, the application will be returned to the applicant organization without peer review. "Other support" information is required for all applications that are to receive grant awards; however, NIH will request complete and up to date "other support" information from applicants at an appropriate time after peer review. The Institute's or Center's scientific program and grants management staff will review this information prior to award.

8. RESOURCES

(RESOURCES FORMAT PAGE, PDF FORMAT)

There is no form page for resources. Follow the format on the "Resources Format Page." **One of the sites indicated must be that of the applicant small business concern.** If there are multiple performance sites, then resources available at each site should be described.

All performance sites identified in Item 8 on the Face Page of the application should be described under "Facilities." Use continuation pages, if necessary.

NOTE: The research to be performed by the applicant small business concern and its collaborators must be in U.S. facilities that are **available to and under the control of each party** for the conduct of each party's portion of the proposed project.

9. RESEARCH PLAN

(NO SPECIFIC FORM PAGE. USE CONTINUATION PAGES)

***Items a-d* of the Research Plan are limited to a total of 15 pages, including all tables and figures, for a Phase I application. *Items a-d* of the Research Plan are limited to a total of 25 pages for a Phase II application.**

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application.) Be specific and informative and avoid redundancies. Unless specifically solicited by the agency, no appendices may be submitted with Phase I SBIR/STTR applications.

INTRODUCTION. (REVISED OR SUPPLEMENTAL APPLICATIONS ONLY).

All revised and supplemental applications must include an Introduction. Do not exceed **one page** for a revised Phase I application or supplemental application. Do not exceed **three** pages for a revised Phase II application. The "Introduction" is excluded from the page limitations of the Phase I or Phase II application.

Insert the Introduction at the very beginning of the Research Plan. In the "Introduction," summarize any substantial additions, deletions, and changes that have been made. Include responses to criticisms in the previous summary statement. Identify these changes within the text of the Research Plan by appropriate bracketing, indenting, or changing of typography. Do not underline or shade

changes. Incorporate any work done since the prior version was submitted. A revised application will be returned if substantial revisions are not clearly apparent. Acceptance of a REVISED application automatically withdraws the prior version.

Competing Supplements

In certain well-justified circumstances, SBIR/STTR projects may warrant consideration of a supplemental award. A competing supplemental SBIR/STTR application may be submitted to request support for a significant expansion of a project's scope or research protocol.

Applications for competitive supplements must be discussed with NIH program staff prior to submission.

A supplemental application may not extend beyond the term of the current grant. The introduction to the supplemental application should provide an overall description of the nature of the supplement and how it will influence the specific aims, research design, and methods of the current grant. Any budgetary changes for the remainder of the project period of the current grant should be discussed under the budget justification. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed supplement in relation to the goals of the original application.

Phase I SBIR/STTR. *Items a-d* of the Phase I research plan are limited to a total of 15 pages.

Phase II SBIR/STTR. *Items a-d* of the Phase II "research plan" are limited to 25 pages, including all tables and figures. There is no further limitation on the total number of pages for the entire application. **NOTE:** A Phase I Progress Report is required for all Phase II SBIR/STTR applications.

CONTENT OF RESEARCH PLAN

Organize *Items a-d* to answer these questions: (1) What do you intend to do? (2) What are the anticipated commercial products, processes, services and societal benefits? Why is the work important? (3) What has already been done? (4) How are you going to do the work?

The suggested format for the Research Plan (see page limitations above) is as follows:

a. Specific Aims

State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product to ultimately be developed. Applicants are encouraged to include milestones for each of the aims. **One page is recommended.**

b. Significance

Briefly sketch the background to the present grant application, critically evaluate existing knowledge, and specifically identify the commercial opportunities that the project is intended to address. State concisely the importance of the proposed research by relating its specific aims to the longer-term objectives of Phase II. **Two to three pages are recommended.**

c. Preliminary Studies/Phase I Final Report

Phase I
Preliminary data are not required for Phase I applications; however, such results may assist reviewers in assessing the likelihood of success of the proposed project and should be included in this section. Otherwise, note "Not applicable" in *Item c*, and proceed to *Item d.*

Phase II
Phase I Final Report
(Applicable to Phase II applications only)

A Phase I Final Report is required for all Phase II applications. The report should be a presentation of the accomplishments of the Phase I effort. Abbreviations and language that may not be generally known to the broader scientific community should be avoided unless clearly defined.

1. State the beginning and ending dates for the period covered by the SBIR Phase I grant.

2. List all key personnel who have worked on the project during that period, their titles, dates of service, and number of hours devoted to the project.
3. Summarize the specific aims of the Phase I grant and provide a succinct account of published and unpublished results, indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims of Phase I since the project was initiated.
4. List the titles and complete references to publications, manuscripts *accepted* for publication, patents, invention reports, and other printed materials, if any, that have resulted from the Phase I effort.
5. Submit five copies of such items, except patent and invention reports, as an APPENDIX. **Ten pages are recommended** for the narrative portion of the Phase I Final Report.

d. Experimental/Research Design and Methods

Preliminary data are not required for Phase I applications. Discuss in detail the experimental design, procedures and protocols to be used, and the means by which the data will be analyzed and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. *Discuss the criteria that will be used to determine that feasibility has been demonstrated*. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

e. Human Subjects

Please give thorough consideration for the need of any human subject involvement in the Phase I feasibility work.

If **Item 4 on the Face Page** of the application has been marked **"Yes", refer to** Section I-E. "Human Subjects Research"of the PHS 398 Specific Instructions. It is very important that you follow the detailed instructions in that section. Be sure to also consult information under "Section III-G, " Assurances and Certifications."

Note: Information regarding the "Inclusion of Women and Minorities in Clinical Research" and the "Inclusion of Children in Research Involving Human Subjects" MUST be included in this portion of the Research Plan or the application will be designated as incomplete and will be grounds for the PHS to return the application without peer review.

Although no specific page limitation applies to this section of the application, be succinct.

In conducting peer review, Scientific Review Groups (SRGs) will evaluate proposed plans for inclusion of minorities and members of both sexes/genders, plans for sex/gender and racial/ethnic subgroup analyses of NIH defined Phase III clinical trials, plans for recruitment/outreach and retention in the design of clinical trials, and any justifications for exclusion of a sex/gender or racial/ethnic subgroup. This evaluation will be a part of the Approach criterion (see SBIR/STTR Review Criteria; p. 96). The evaluation of the inclusion plans will be factored into the overall score that the SRGs award for scientific and technical merit of the application. In addition, awards will not be made if the research project does not comply with this policy.

f. Vertebrate Animals

If Item 5 on the FACE PAGE of the application has been marked "YES", address the following five points. Be sure to consult information under Section III. G. Assurances and Certifications (p. 43).

1. Provide a detailed description of the proposed use of the animals in the work previously outlined in the Experimental Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers used.

3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices where appropriate to minimize discomfort, distress, pain and injury.
5. Describe any euthanasia method to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present justification for not following the recommendations.

NOTE: If the applicant small business concern does not have its own animal facilities and plans to utilize the facilities of a collaborating institution, such arrangements must be detailed in the application. Both the applicant small business concern and the collaborating institution, as well as any other performer at a different performance site, must have OLAW-approved Animal Welfare Assurances on file before an award can be made.

g. Literature Cited

List literature citations at the end of the Research Plan. Each citation must include the names of all authors, the name of the book or journal, volume number, page numbers, and year of publication. Be judicious in compiling a relevant and current bibliography. It need not be exhaustive.

h. Contractual Arrangements

Explain the programmatic and fiscal arrangements made between the applicant small business concern and the contractor(s). The consortium investigator and the authorized official at the consortium institution(s) must provide a signed statement or confirming letters that the appropriate programmatic and administrative personnel of each organization involved in the application are aware of the NIH consortium grant policy and are prepared to establish inter- institutional agreements consistent with that policy. Attach confirming letters or copies of the contract, if available.

i. Consultants

Attach appropriate letters from each individual confirming his or her role in the project. Include biographical sketches for each consultant. The Phase I 25-page limitation of the application excludes letters of commitment from collaborators and consultants.

j. Product Development Plan

(Applicable to all Phase II applications and Phase I/ Phase II Fast-Track Applications)

Note: All Phase II applications and Fast Track applications must include a succinct commercialization plan, hereafter referenced as a "Product Development Plan (PDP)." ***The PDP is limited to ten pages.***

Create a section entitled, "Product Development Plan," and address each of the following areas:

1. Company information: including size; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization (see Section III. A; p. 35 for definition of "commercialization".)
2. Value of SBIR/STTR project, including lay description of key technology objectives, current competition, and advantages compared to competing products or services.
3. Commercialization plans, milestones, target dates, market analyses of market size, and estimated market share after first year sales and after five years.
4. Patent status or other protection of project intellectual property.

k. Prior SBIR Phase II Awards

Excluded from Phase I page limitations. A small business concern that submits an SBIR Phase I application and that has received more than 15 Phase II SBIR awards during the preceding five (5) fiscal years must document the extent to

which it was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards. The following information must be submitted in the Phase I application regarding each such prior Phase II award: (1) name of awarding agency; (2) award number and date; (3) amount of award; (4) title of project; (5) source, date, and amount of Phase III funding agreement; and (6) commercialization status of each Phase II award shown in item 1 above.

I. Research Institution Certification

(Applicable to STTR Phase I and Phase II only)

Use "Research Institution Certification Format Page."

Excluded from the Phase I page limitation. A letter must be included with the application certifying that at least 30% of the work proposed on the Phase I or Phase II project will be performed by the partnering research institution. Include the letter at the end of the application following any letters from consultants. Information to be included in the letter is provided on the "**Research Institution Certification Format Page."**

The certification, with the signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution, must be included with the application or the application will be deemed incomplete and returned without peer review.

10. APPENDIX

(APPLICABLE ONLY TO PHASE II AND FAST-TRACK SBIR/STTR APPLICATIONS UNLESS SPECIFICALLY SOLICITED FOR PHASE I APPLICATIONS)

See Section I, Item 9 (p.28) of the Specific PHS 398 instructions.

11. CHECKLIST

(CHECKLIST FORM PAGE, PDF FORMAT)

Excluded from the Phase I page limitation. This is the next-to-last form page of the application, but is the last page to be numbered.

TYPE OF APPLICATION

Check all that apply.

INVENTIONS AND PATENTS

(Phase II Applications Only).

Check "No" if no inventions were conceived or reduced to practice during the course of work under this project. The remaining parts of the item are then not applicable.

Check "Yes" if any inventions were conceived or reduced to practice during the previous period of support. Also indicate whether this information has been previously reported to the PHS or to the applicant organization official responsible for patent matters.

PROGRAM INCOME

NIH policy requires applicants for research grants to include in their grant applications an estimate of the amount and source of program income (defined below) expected to be generated as a result of the project for which funding is being sought. The specific policies that govern the treatment of program income under research grants are set forth in the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/). See Section III A. DEFINITIONS (p. 35) for a definition of "Program income."

If **no program income** is anticipated during the period(s) for which grant support is requested, no other action is necessary.

If the response to this item is "Yes," follow the prescribed format to reflect, by budget period, the amount and source(s) of anticipated program income. If the application is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income. (See NIH Grants Policy Statement for the policy on the treatment of program income earned under research grants.) **All program income**

earned during the budget period must also be identified on the Financial Status Report.

The distribution of any income derived from royalties or licensing of an invention or patent is subject to specific provisions under 37 CFR Part 401. If any such income is anticipated, the applicant small business concern is encouraged to contact the Extramural Inventions and Technology Resources Branch, NIH, Phone: (301) 435-1986; Fax: (301) 480-0272; Email: gs60a@nih.gov or edison@od.nih.gov.

Applicants with questions concerning any aspect of this topic are encouraged to contact the Grants Management Officer of the appropriate PHS awarding component or the Division of Grants Policy, NIH, Phone: (301) 435-0949; Fax: (301) 435-3059.

ASSURANCES/CERTIFICATIONS

Each application to the PHS requires that the following assurances and certifications listed on the Checklist be verified by the signature of the official signing for the applicant organization on the Face Page of the application. See Section III, "Policy and Additional Guidance."

Human Subjects
Research on Transplantation of Human Fetal Tissue
Women and Minority Inclusion Policy
Inclusion of Children Policy
Research Using Human Pluripotent Stem Cells
Vertebrate Animals
Debarment and Suspension
Drug-Free Workplace
Lobbying
Delinquent Federal Debt
Research Misconduct
Civil Rights
Handicapped Individuals
Sex Discrimination
Age Discrimination
Financial Conflict of Interest (not applicable to Phase I SBIR/STTR)
Recombinant DNA
Certification of Research Institution Participation (STTR Only)

FACILITIES AND ADMINISTRATIVE COSTS

Note: Facilities and Administrative Costs, which are defined as costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program, were previously known as "indirect costs," and, in most instances, will be referred to in this document as "F&A costs."

Policy

Phase I Grants. If the applicant small business concern has a currently effective negotiated F&A costs rate with a Federal agency, it should be used when calculating proposed F&A costs. (However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by the Department of Health and Human Services [HHS]. See "Discussion and Negotiation of Indirect Costs" later in this section.)

Note: If the applicant small business concern does not have a currently effective negotiated indirect costs rate with a Federal agency, the applicant organization should propose estimated indirect costs at a rate not to exceed 40% of the total direct costs.

Only actual F&A costs are to be charged to projects. (If awarded at a rate of 40% or less, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the small business concern negotiates an F&A cost rate[s] with a federal agency.)

Phase II Grants. If the applicant small business concern has a currently effective negotiated F&A cost rate with a Federal agency, it should be used when calculating proposed F&A costs. (However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by the Department of Health and Human Services [HHS]. (See "Discussion and Negotiation of Indirect Costs" later in this section.)

Note: If the applicant small business concern does not have currently effective negotiated F&A costs rates with a Federal agency, the applicant organization should propose estimated F&A costs.

If the requested F&A rate is 25 percent or less, F&A costs will be awarded at the requested rate. However, applicant organizations are reminded that only actual F&A costs are to be charged to projects. (If awarded at a rate of 25% or less of total direct costs, the rate used to charge actual F&A costs to projects cannot exceed the awarded rate unless the small business concern negotiates an F&A cost rate[s] with a federal agency.) **If the requested F&A rate is greater than 25 percent, additional information will be required prior to award.**

Discussion and Negotiation of Facilities and Administrative (F&A) Costs

The Division of Financial Advisory Services (DFAS), Office of Contracts Management, NIH, is the office authorized to negotiate F&A cost rates with small business concerns receiving NIH SBIR/STTR awards. ***Upon request of the NIH,* the applicant small business concern should provide DFAS with an F&A cost proposal and supporting financial data for the most recently completed fiscal year.** If financial data is not available for the most recently completed fiscal year, proposals showing estimated rates and support for same should be submitted.

Applicants are encouraged to visit the home page of the DFAS, Office of Contracts Management, at http://ocm.od.nih.gov/dfas/dfas.htm or contact DFAS staff at 301-496-2444.

To facilitate preparation of an F&A cost proposal, applicants are encouraged to read the following information on the DFAS Indirect Cost Branch (http://ocm.od.nih.gov/dfas/rates.htm.) Information on this site includes (1) definitions of the term "F&A costs," (2) a brief discussion of F&A cost rate structures and a simple example of an F&A cost rate computation, (3) a listing of data that should accompany your proposal submission, and (4) a listing of unallowable/unallocable costs extracted from Federal cost principles for commercial organizations, that is, the Federal Acquisition Regulation (FAR Part 31.2). The Federal Acquisition Regulation is available electronically at **http://www.arnet.gov/far/**.

Generally, F&A cost rate structures for commercial organizations follow a single, two-rate (for example, fringe and overhead rates), or three-rate (for example, fringe, overhead, and General and Administrative expense rates) system. A Single Rate structure is illustrated at http://ocm.od.nih.gov/dfas/examples.htm.

Commercial (for-profit) organizations usually treat **"fringe benefits"** as F&A costs. These fringe benefits are applied to direct salaries charged to projects either through a fringe benefit rate or as part of an overhead/ F&A cost rate. Therefore, fringe benefits treated as F&A costs should not be included as a direct cost in the "Personnel" category of the budget on Form Page 3 of the grant application.

The F&A cost proposal, based on company-wide cost data, should be accompanied by the following supporting information:

1. The profit and loss statement and balance sheet for the applicant organization's most recently completed fiscal year. Certified statements prepared by a CPA engaged to conduct an annual audit should be submitted, if available. The F&A cost proposal should include a reconciliation with the income statement; that is, there should be a cross-referencing from amounts on the income statement to amounts shown in the proposal, and a clear identification of individual elements (labor, materials, other expenses, etc.) of independent (self-sponsored) research and development (IR&D) expenses. IR&D costs are not allowable under NIH awards.
2. A listing of categories of costs normally classified and claimed as direct costs on Federal awards and non-Federally supported projects or activities.
3. An explanation of how the organization accounts for paid absences (vacation, holiday, and sick leave).

4. A Certification of Final Indirect Costs as specified in FAR Part 52.242-4. This Certificate is to be completed by an official at a level no lower than a vice president or chief financial officer of the business segment submitting the proposal.

In determining what costs should be included in the proposed indirect cost pool(s), the applicant organization should refer to the list below of unallowable/unallocable costs.

Smoke-Free Workplace

Does your organization currently provide a smoke-free workplace and/or promote the nonuse of tobacco products or have plans to do so? Check the appropriate box marked "YES" or "NO." Response to the question has no impact on the review or funding of this application.

12. PERSONAL DATA

(PERSONAL DATA FORM PAGE, PDF FORMAT)

Self explanatory.

D. SUBMITTING YOUR SBIR/STTR GRANT APPLICATION

The NIH's Center for Scientific Review (CSR) is the single point of receipt for all NIH, CDC, and FDA SBIR/STTR grant applications.

RECEIPT DATES

Grant applications submitted under this SBIR/STTR Phase I Grant Solicitation must be received by the published receipt dates. *If the receipt date falls on a weekend, it will be extended to the following Monday; if the date falls on a holiday, it will be extended to the following workday*. An application received after the published receipt date may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier and the proof-of-mailing date is not later than one week prior to the deadline date. The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter, addressed to the Division of Receipt and Referral, Center for Scientific Review, with the signed, completed application. No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted.

SBIR RECEIPT, REVIEW AND AWARD DATES

NOTE: SBIR and STTR applications have coincident receipt dates.

SBIR AND STTR RECEIPT DATES PHASE I AND PHASE II	NATIONAL TECHNICAL MERIT REVIEW	ADVISORY COUNCIL BOARD REVIEW	ESTIMATED AWARD DATE
April 1	June/July	Sept/Oct	November
August 1	Oct/Nov	Jan/Feb	March
December 1*	Feb/March	May/June	July

* Applications to the Centers for Disease Control and Prevention may be submitted only on the August 1 and December 1 receipt date. CDC and FDA do not participate in the STTR program.

RECEIPT OF FAST TRACK APPLICATIONS

Fast Track applications may be submitted on any of the three scheduled receipt dates. The face pages for both the Phase I and Phase II portions should be clearly marked "Fast Track", and copies of both portions should be assembled and submitted together.

RECEIPT OF SBIR/STTR PHASE II APPLICATIONS (NON-"FAST-TRACK")

Phase II applications may be *submitted on any of the three scheduled receipt dates, either before or after expiration of the Phase I budget period*. However, *Phase II grant applications should be submitted no later than the first six receipt dates following expiration of the Phase I budget period*.

Applicants are cautioned that applications demonstrating insufficient results in Phase I may not receive a score in the peer review process (see Method of Selection and Evaluation Criteria).

NUMBER OF COPIES

Submit the original and five exact, clear, single-sided photocopies of each application. The *original* must be signed by the Principal Investigator and a corporate official authorized to act for the applicant organization.

BINDINGS AND PACKAGING

Do not bind or staple the six sets together, but secure each with rubber bands or paper clips.

MAILING AND/OR DELIVERY ADDRESSES

Affix the relevant SBIR or STTR label in the forms package to the bottom of the face page of the original, and place the original on top of your entire package.

Mail or deliver the complete, signed, and typewritten **original and five** signed, exact, clear, single-sided photocopies of the application in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive
Room 1040-MSC 7710
Bethesda, MD 20892*-7710
Phone: (301) 435-0715

***Change zip code to 20817 for express mail or courier service.**

ASSIGNMENT OF GRANT APPLICATIONS

The Center for Scientific Review (CSR) will assign appropriately completed applications to the Scientific Review Groups (commonly referred to as "SRGs" or "study sections") that will perform the scientific/ technical merit review. In addition, CSR will assign each application to the agency awarding component that is the potential funding component Applications submitted in response to special SBIR Program Announcements (PA) or Requests for Applications (RFA) issued through the NIH Guide for Grants and Contracts may be reviewed by the Institute. See the relevant RFA or PA for additional information.

Cover Letters. The small business concern applicant organization is encouraged to include a cover letter with the application to suggest an awarding component(s) to which the application could be appropriately assigned for potential funding, to indicate a specific area of expertise that should be represented on the study section, and/or to indicate peer reviewers who may have a direct conflict of interest.

When the scientific areas and the research proposed in a grant application are sufficiently relevant to the program responsibilities of two or more awarding components, CSR may assign the application to all such components. The component that has the most relevant program responsibility is designated as the primary assignee. The other components that have an interest in the application are designated as secondary assignees. If the application is eligible for funding and the primary assignee does not intend to make an award, the secondary assignees will be given the opportunity to do so. Although these suggestions will be taken into consideration, the final determination will be made by the agencies participating in this solicitation.

NOTIFICATION OF RECEIPT

Usually within six weeks after the receipt date, the CSR/NIH will send the Principal Investigator and the applicant organization a notification of receipt of the application. The mailer will indicate a grant application assignment number as well as the name, address, and telephone number of the Scientific Review Administrator (SRA) of the Scientific Review Group (SRG) to which the application has been assigned. If this information is *not received within that time, contact*:

Division of Receipt and Referral
Center for Scientific Review, NIH
(301) 435-0715; Fax: (301) 480-1987

INCOMPLETE APPLICATIONS

Do not submit an incomplete application. An application will be considered incomplete and will be returned if it is illegible, if it does not conform to the instructions, or if the material presented is insufficient to permit an adequate review.

SUPPLEMENTARY OR CORRECTIVE INFORMATION

Supplementary or corrective material pertinent to the review of an application may be submitted after the receipt date, but only if it is specifically solicited by or agreed to through prior discussion with the Scientific Review Administrator of the SRG. Phase I appendix materials, including demonstration materials (e.g., videos, CD-ROMs) are not permitted unless specifically solicited by the agency.

METHOD OF SELECTION AND EVALUATION CRITERIA

All Phase I and Phase II grant applications will be evaluated and judged on a competitive basis. Initially, applications will be screened for completeness and *those found to be incomplete in any way or programmatically unrelated to the agency's mission will be returned* without review to the applicant small business concern. Those passing the initial screening will be reviewed for technical and scientific merit. Each application will be judged on its own merit, according to the review criteria described below. The participating agencies are under no obligation to fund any specific application or make any specific number of awards in a given research topic area. Also, they may elect to fund several or none of the proposed projects within a given topic area.

REVIEW PROCESS

Grant applications are subjected to a peer review process involving two sequential steps that are required by law. The first step is performed by the Scientific Review Groups (SRGs), composed primarily of non-Federal scientists, physicians, and engineers (from academia and industry) selected for their expertise and stature in particular scientific fields. The second step is performed by the National Advisory Council or Board of the potential awarding component (Institute, Center, or other unit) to which the grant application is assigned.

SCIENTIFIC REVIEW GROUPS

The first task of the SRGs is to evaluate each SBIR/STTR application for scientific and technical merit and potential for commercialization, and to make an SRG recommendation for each application on the basis of this evaluation. While NIH uses a numerical range from 1.00 (most meritorious) to 5.00 (least meritorious), a streamlined procedure is used to determine those applications that the SRG considers to be in the “upper” or “lower half”. Applications in the “upper half” are discussed by the SRG and *generally* receive a score between 1.0 and 3.0, and applications in the “lower half” are not discussed and receive an “unscored” designation (i.e., those that would generally have received a score between 3.0 and 5.0). However, any review group member may identify an application that he or she

believes should be discussed at the meeting and receive a numerical score. Under the currently employed streamlining procedures, a rating of 3.00 would be considered the median score for the cohort of applications that a scientific review group might review.

Individual reviewers mark scores to two significant figures, e.g., 1.2, and the individual scores are averaged and then multiplied by 100 to yield a single overall score for each scored application, e.g., 153. Abstaining members and those not present during the discussion do not assign a numerical rating and are not counted in calculating the average of the individual ratings.

The second task of the SRGs is to make budget recommendations concerning time and dollar amounts that are appropriate for the work proposed.

Regardless of the study section recommendation, all applicants receive a summary statement that includes a single rating/designation and the essentially unedited, verbatim critiques of two or more assigned reviewers.

NATIONAL ADVISORY COUNCIL OR BOARD

The second level of review is performed by the National Advisory Council or Board of the potential awarding component (Institute, Center, or other unit) to which the grant application is assigned. These groups, composed of scientists, physicians, and members of the public, are chosen for their expertise, interest, or activity in matters related to the awarding component's mission. In order for an application to be funded, it must be recommended by the Council or Board.

RELEASE OF GRANT APPLICATION REVIEW INFORMATION

Following evaluation of grant applications by the SRGs but prior to National Advisory Council or Board action, summary statements will be sent automatically to Principal Investigators.

Applicants normally receive their summary statements within four to six weeks following the study section meeting in which it was reviewed. A "summary statement" documents the evaluation of an application by the SRG and conveys the SRG's recommendations to the awarding component and its Council or Board. No one other than the Principal Investigator (and appropriate NIH staff) may receive the summary statement and evaluation rating.

After receipt/review of the summary statement, applicants should contact their Program Director, rather than the Scientific Review Administrator, for guidance and advice.

SBIR/STTR REVIEW CRITERIA

"Formulae" do not exist for calculating an individual reviewer's score on an application. In considering the scientific and technical merit of each application, the following criteria will be used:

ALL SBIR/STTR APPLICATIONS

1. Significance
    a. Does the proposed project have commercial potential to lead to a marketable product or process? Does this study address an important problem?
    b. What may be the anticipated commercial and societal benefits of the proposed activity?
    c. If the aims of the application are achieved, how will scientific knowledge be advanced?
    d. Does the proposal lead to enabling technologies (e.g., instrumentation, software) for further discoveries?
    e. Will the technology have a competitive advantage over existing/alternate technologies that can meet the market needs?

2. Approach
   a. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?
   b. Is the proposed plan a sound approach for establishing technical and commercial feasibility?
   c. Does the applicant acknowledge potential problem areas and consider alternative strategies?
   d. Are the milestones and evaluation procedures appropriate?
3. Innovation
   a. Does the project challenge existing paradigms or employ novel technologies, approaches or methodologies?
   b. Are the aims original and innovative?
4. Investigators
   a. Is the Principal Investigator capable of coordinating and managing the proposed SBIR/STTR?
   b. Is the work proposed appropriate to the experience level of the Principal Investigator and other researchers, including consultants and subcontractors (if any)?
   c. Are the relationships of the key personnel to the small business and to other institutions appropriate for the work proposed?"
5. Environment
   a. Is there sufficient access to resources (e.g., equipment, facilities)?
   b. Does the scientific and technological environment in which the work will be done contribute to the probability of success?
   c. Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

In accordance with NIH policy, the following criteria will be applied to ALL applications:

<u>Biohazards</u>

- Is the use of materials or procedures that are potentially hazardous to research personnel and/or the environment proposed?
- Is the proposed protection adequate?

<u>Animal Welfare</u>

- If vertebrate animals are involved, are adequate plans proposed for their care and use?
- Are the applicant's responses to the five required points appropriate?
- Will the procedures be limited to those that are unavoidable in the conduct of scientifically sound research?

<u>Budget</u>

- For all applications, is the percent effort listed for the PI appropriate for the work proposed?
- On applications requesting up to $100,000 total costs, is the overall budget realistic and justified in terms of the aims and methods proposed?
- On applications requesting over $100,000 in total costs, is each budget category realistic and justified in terms of the aims and methods?

In accordance with NIH policy, all applications will also be reviewed with respect to the following:

1. Protection of Human Subjects from Research Risks - for all studies involving

human subjects. See instructions and "Guidance for Preparing the Human Subjects Research Section".

a. If an exemption is claimed, is it appropriate for the work proposed? If no exemption is claimed, are the applicant's responses to the six required points appropriate?

b. Are human subjects placed at risk by the proposed study? If so, are the risks reasonable in relation to the anticipated benefits to the subjects and others? Are the risks reasonable in relation to the importance of the knowledge that reasonably may be expected to be gained?

c. Are the plans proposed for the protection of human subjects adequate?

2. Inclusion of Women Plan - *for clinical research only.* See instructions.

a. Does the applicant propose a plan for the inclusion of both genders that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent?

b. Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?

3. Inclusion of Minorities Plan - *for clinical research only*

a. Does the applicant propose a plan for the inclusion of minorities that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent?

b. Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?

4. Inclusion of Children Plan- for all studies involving human subjects

a. Does the applicant describe an acceptable plan in which the representation of children of all ages (under the age of 21) is scientifically appropriate and recruitment/retention is addressed realistically?

b. If not, does the applicant provide an appropriate justification for their exclusion?

5. Data and Safety Monitoring Plan - *for clinical trials only*

a. Does the applicant describe a Data and Safety Monitoring Plan that defines the general structure of the monitoring entity and mechanisms for reporting Adverse Events to the NIH and the IRB?

PHASE II APPLICATION REVIEW CRITERIA

In addition to the above criteria:

1. How well did the applicant demonstrate progress toward meeting the Phase I objectives, demonstrating feasibility, and providing a solid foundation for the proposed Phase II activity?

2. Did the applicant submit a concise Product Development Plan that adequately addresses the four areas described in Section I, item 9, J?

3. Does the project carry a high degree of commercial potential, as described in the Product Development Plan?

AMENDED APPLICATIONS

In addition to the above criteria, the following criteria will be applied to revised applications.

1. Are the responses to comments from the previous SRG review adequate?

2. Are the improvements in the revised application appropriate?

PHASE I/PHASE II FAST-TRACK APPLICATION REVIEW CRITERIA

For Phase I/Phase II Fast Track applications, the following criteria also will be applied:

1. Does the Phase I application specify clear, appropriate, measurable goals (milestones) that should be achieved prior to initiating Phase II?
2. Did the applicant submit a concise Product Development Plan that adequately addresses the four areas described in Section I, item 9, J?
3. To what extent was the applicant able to obtain letters of interest, additional funding commitments, and/or resources from the private sector or non-SBIR/STTR funding sources that would enhance the likelihood for commercialization?
4. Does the project carry a high degree of commercial potential, as described in the Product Development Plan?

Phase I and Phase II Fast-Track applications that satisfy all of the review criteria will receive a single rating. Failure to provide clear, measurable goals may be sufficient reason for the scientific review group to exclude the Phase II application from Fast-Track review.

FUNDING DECISIONS

When making funding decisions, the awarding components take into consideration the following: (1) ratings resulting from the scientific and technical evaluation process; (2) areas of high program relevance; (3) program balance (that is, balance among areas of research); (4) available funds; and (5) the commercialization status where the small business concern has received more than 15 Phase II awards in the prior five (5) fiscal years (see this application requirement under "Prior SBIR Phase II Awards (p. 89).

The awarding component will notify the applicant small business concern of the final disposition of the application.

PHASE II FUNDING DECISIONS FOR FAST-TRACK APPLICATIONS

Fast-Track Phase II applications that are recommended for approval may be funded following submission of the Phase I progress report and other documents necessary for continuation. Phase II awards will be recommended based on the project's scientific and technical merit, the awarding component's assessment of the Phase I progress report and determination that the Phase I goals were achieved, an update and verification of the Product Development Plan and any commitment(s) for funds and/or resources from an investor or partner organization, as described above, the project's potential for meeting the mission of the awarding component, the project's potential for commercial success, and the availability of funds.

REVISION AND RESUBMISSION OF GRANT APPLICATIONS

Grant applications that are not funded may be revised for resubmission at a future receipt date. However, applicant organizations may submit no more than two revised (amended) applications within a time period of two years from the receipt date of the initial, original application. The limit of two revisions allows applicant small business concerns and Principal Investigators sufficient time to consider new findings in the area of research and to take a fresh start at their research plans.

Resubmitted applications without substantive changes will not be accepted. The revised application MUST address the issues identified in the previous summary statement for the previous submission that was not fund. *Revised sections must be clearly marked (as described in the "Introduction and Application Instructions" portion of this solicitation).* Upon acceptance of a revised application by the CSR, the

prior version will be withdrawn from further consideration by the awarding components. Acceptance of the revised application will generally mean that it will fall into a later review and award cycle. *Resubmission of an application that merely duplicates a previous application is not acceptable and the duplicate application will be returned without review*.

SUBMISSION OF SIMILAR GRANT APPLICATIONS BY THE APPLICANT ORGANIZATION

The submission of similar grant applications to the NIH by the same applicant small business concern is strongly discouraged. Applicants are cautioned not to prepare multiple grant applications with essentially the same research focus, that is, a product or technology that, with non-substantive modifications, can be applied to a variety of purposes. In evaluating groupings of applications with a common scientific focus or objective (for example, implantation sensors/sensor materials, medical applications of lasers, immunology/immunoassays), SRGs are in a position to easily identify multiple grant applications from the same small business concern for essentially the same project. In these cases, the HHS will give funding consideration to only one application.

E. SBIR/STTR POLICY AND ADDITIONAL GUIDANCE

Refer to Section III (p. 35) for important information (e.g., Definitions, Other Support, Inventions and Patents, and Assurances and Certifications) on policy and guidance relating to submission of traditional, solicited and unsolicited, investigator-initiated research project grant and cooperative agreement applications to PHS. The following section includes *additional* policy information and guidance specific to SBIR/STTR applications.

AUDIT REQUIREMENTS OF FOR-PROFIT ORGANIZATIONS

The Department of Health and Human Services (HHS) has specified requirements for non-Federal audits of for-profit (commercial) organizations in HHS' Title 45, Code of Federal Regulations (CFR), Part 74.26, "Non-Federal Audits." Per the regulations, a for-profit (commercial) organization is subject to audit requirements for a non-Federal audit if, during its fiscal year, it expended $300,000 or more under HHS awards and at least one award is an HHS grant.

Title 45 CFR Part 74.26 essentially incorporates the thresholds and deadlines of Office of Management and Budget (OMB) Circular No. A-133, "Audits of States, Local Governments and Non-Profit Organizations," but provides for-profit organizations with two options regarding the type of audit that will satisfy the audit requirements either: (1) a financial related audit (as defined in the Government Auditing Standards, GPO Stock #020-000-00-265-4, **http://www.gao.gov/govaud/ybk01.htm**) of all the HHS awards in accordance with Government Auditing Standards, or (2) an audit that meets the requirements contained in OMB Circular No. A-133, **http://www.whitehouse.gov/OMB/circulars/a133/a133.htm**.

Audits shall be completed and submitted to the office shown below within a period that is either (1) the earlier of 30 days after receipt of the auditor's report(s), or (2) nine months after the end of the audit period (i.e., the organization's fiscal year).

National External Audit Resources
HHS Office of Audit Services
Lucas Place
323 West 8th Street, Room 514
Kansas City, MO 64105

The HHS will be identifying organizations not meeting audit requirements. Failure to comply may jeopardize eligibility for receiving future HHS awards.

TIME AND EFFORT REPORTING FOR COMMERCIAL ORGANIZATIONS

POLICY

Commercial (for-profit) organizations must document salaries and wages charged to contracts and grants by maintaining a labor distribution system for all employees regardless of function. The labor distribution system *must account for total hours and charge direct and indirect labor to the appropriate cost objectives* to accurately identify labor costs:

- Charged to direct projects.
- Charged to indirect activities.
- Included in the base to which indirect costs are allocated.

Internal Controls

Timekeeping procedures and controls on labor charges are of utmost concern. Unlike other costs, labor is not supported by external documentation or physical evidence, which provides independent checks and balances. It is critical that managers indoctrinate individual employees on their independent responsibility for accurately recording their time. Internal controls over labor charging should meet the following criteria:

- Responsibility for timekeeping and payroll accounting should be separated.
- Procedures must be clear and reasonable so there is no confusion regarding the rationale for the controls or misunderstanding as to what is and is not permissible.
- Maintenance of controls must be verified continually, and violations must be acted upon promptly and effectively to serve as a deterrent to prospective violations.
- Individual employees must be constantly made aware of controls that act as an effective deterrent against violations. This awareness can be accomplished by emphasizing the importance of accurate time and effort reporting in orientation
- sessions, periodic meetings, and the posting of messages as reminders.
- Changes on timesheets to the number of hours recorded or the cost center identified should be made by the employee and *must be initialed by the employee*.
- Company policy must state that the nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant, or other factors.
- Company policy should emphasize that complete and accurate time and effort reporting is an important part of an employee's job. Careless or improper reporting may lead to disciplinary actions under company policies as well as applicable Federal statutes.

Time and Effort Documentation Requirements and Responsibilities

Detailed instructions for time documentation should be established in written company procedures. A manual system would require handwritten pen and ink entries on a paper timesheet reflecting all the days in the pay period. An automated timekeeping system typically would use remote data entry for recording labor charging data and sending it directly to a central computer for processing. Supporting documentation for an automated system would normally consist of computer printouts showing data that appear on source documents, i.e., timesheets in a manual system.

Employee Responsibilities

Whether a manual or automated time and effort reporting system is in place, the employee is personally responsible for:

- After the fact recording of hours (or fractions thereof) on a daily basis.
- Recording all hours worked and all hours absent. All hours should be recorded whether or not they are paid.
- Recording of hours on the timesheet in ink (manual system only).
- Recording the correct distribution of hours by project or indirect category. The nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant, or other factors.
- To ensure accuracy, a listing of project numbers/indirect categories and their descriptions should be provided in writing to each employee.
- Any changes/corrections to timesheets should be made by the employee and must show what was initially recorded, i.e., *no erasures or "white out" of entries*. The employee also *must initial any change(s)*.
- At the end of each pay period, the employee must sign the timesheet or electronically certify the labor distribution in an automated system.

Supervisor Responsibilities

- An authorized company official (e.g., supervisor) must cosign timesheets or electronically certify individual time and effort reporting at the end of each pay period.
- The supervisor is prohibited from completing an employee's timesheet or entering hours in an automated system unless the employee is absent for an extended period of time on some form of authorized leave.