Fellowship Panel Reviewer Training

Special Emphasis Panel

Fellowship:

Council Round:

Scientific Review Officer:

Date:



Review Integrity is the Foundation for a Fair, Independent Review, Free from Inappropriate Influences

- Maintain absolute Confidentiality of all review materials and discussions.
 - Do not share with anyone.
 - Delete/discard all materials 30 days after the review meeting.
- Report any Conflict of Interest (COI) that may directly affect or appear to affect the integrity of the peer review process.
 - Report a COI as soon as you identify it -- at any point in the process.
- Contact the SRO <u>in private</u> (to avoid tainting the review) if you suspect Research Misconduct: Data fabrication, data falsification, plagiarism
- All comments must be independently generated by the reviewer.
 - Not copied from the application, prior summary statements, or other reviewers' critiques
 - Not generated using generative AI technologies

Ruth L. Kirschstein National Research Service Award (NRSA)

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. NRSA fellowships support the training of pre-and postdoctoral scientists, dual-degree investigators, and senior researchers.



Types of NRSA Individual Fellowship Applications

NRSA Activity	Program & Percent Effort for Research	NOFO	Duration of Support (including T32)
F30 Predoctoral (Institutions with/without dual degree T32 grant)	Dual-Degree e.g. MD/PhD (>50% effort to PhD work during the project period)	PA-25-425 PA-25-426	Up to 6 Years
F31 Predoctoral	Doctoral-Degree (100%)	PA-25-422	Up to 5 Years
F32 Postdoctoral	Research and Career	PA-25-423	Up to 3 Years
F33 Senior Fellow	Development Training (100%)	PA-25-424	Up to 2 Years

Difference between Fellowship Awards and Research Awards

A fellowship application has a research project that is integrated with the training plan. The review will emphasize the candidate's potential for a productive career, the candidate's need for the proposed training, and the degree to which the research project and training plan, the sponsor(s), and the environment will satisfy those needs.



Evaluating a Fellowship Application

Overall Impact

(Includes overall impact score and an evaluative paragraph)

 Addressing the likelihood that the fellowship will enhance the candidate's potential for, and commitment to, a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria.

Scored Review Criteria

(Include individual scores and bulleted strengths/weaknesses)

- Candidate's Preparedness and Potential (1)
- Research Training Plan (2)
- Commitment to Candidate (3)

Additional Review Criteria

(Not individually scored, but can affect overall impact)

 Protections for Human Subjects; Inclusion of Women, Minorities, and Individuals Across the Lifespan; Vertebrate Animals; Biohazards; Resubmissions



Scored Review Criteria: What to Consider?

Candidate's Preparedness and Potential

- Career stage and training readiness
- Candidate's key qualities
- Potential training benefit



Research Training Plan

- Rigor and feasibility
- Training goals
- Needed development
- Adequate guidance and resources

Commitment to Candidate

- Sponsor mentoring plan
- Sponsor and organizational commitment
- Level of commitment

Scored Review Criteria: Where to Look?

Candidate's Preparedness and Potential

- Biosketch
- Candidate's Goals,
 Preparedness, and Potential
- Sponsor(s) Commitment
- Reference Letters



Research Training Plan

- Training Activities and Timeline
- Research Training Project
 Specific Aims
- Research Training Project Strategy
- Facilities and Other Resources

Commitment to Candidate

- Sponsor(s) Commitment
- Facilities and Other Resources

Scored Review Criterion 1: Candidate's Preparedness and Potential

What to consider?

- Candidate's stage of training and the opportunities available.
- Candidate's qualities, such as scientific understanding, creativity, curiosity, resourcefulness, and drive, that will improve the likelihood of a successful research training outcome.
- Candidate's potential to benefit from the fellowship research training plan.

What to expect in Reference Letters?

- Examples of personal characteristics (such as skills, abilities, traits, attitudes) that are likely
 to contribute significantly to further advancement in the candidate's defined career path in
 the biomedical research workforce.
- Areas for development to improve the candidate's prospects of a productive career in the biomedical research workforce.
- An overall assessment of the candidate's preparedness and likelihood for success in the proposed research training plan.
- <u>Absence</u> of a reference letter from a previous advisor should not affect score for F32 post-doctoral fellowship candidates.

Scored Review Criterion 1: Candidate's Preparedness and Potential

Points to Note:

- Training needs and plans vary significantly depending on a candidate's career stage and training environment. Therefore, it is essential to first assess the candidate's current stage of training and the opportunities available to them.
- Candidate's qualities are more relevant to their research potential than their grades from years ago. Therefore, grades are no longer required or allowed.
- Candidates can propose to become researchers in an industrial or academic research setting.

F30 – Predoctoral Dual-Degree Fellowships

• Candidate's research and clinical training plan should be individually tailored and well integrated with the research project.

Scored Review Criterion 2: Research Training Plan

What to consider?

- Rigor and feasibility of the research training project.
- Research training goals and the extent to which the plan will facilitate the attainment of the goals.
- Whether the research training plan identifies areas of needed development and contains appropriate, realistic activities and milestones to address those needs.
- Whether there are sufficient and appropriate guidance and resources for the proposed research training plan.

Scored Review Criterion 2: Research Training Plan

Points to Note:

- Preliminary data are not required (Reviewers should evaluate quality if provided).
- Do not undervalue certain types of research training. NIH supports training in basic and mechanistic research, non-hypothesis driven research, method and technology development, all model systems, etc.
- The proposed research topic can be similar to candidate's previous research, but the research project should provide opportunities to test new concepts and learn new methods and approaches.
- Innovation is not a review criterion.
- Reviewers will NOT assess if there are adequate research funds to support the candidate's proposed research training—Program staff at funding institutes will make the assessment.

Scored Review Criterion 2: Research Training Plan

Points to Note:

F30 – Predoctoral Dual-Degree Fellowships

- Dual degree candidates can propose basic science research projects.
- The clinical program (MD) and dissertation research activities should be structured for the candidate to complete the Ph.D. training successfully.
- Timeline and percentage of effort between research and clinical training expected.

F32 – Postdoctoral Fellowships

A fellowship research project is not a source for an independent research path – i.e., do not need
to specify that the project can be taken to start an independent lab.

If Training in Clinical Trials is Proposed:

- Evaluate whether there is evidence of the appropriate expertise, experience, resources, and ability on the part of the sponsor(s) to guide the applicant during the clinical trial research experience.
- The sponsor must include a statement to document leadership of the clinical trial including the source of funding and the ClincalTrials.gov identifier (NCT#).

Scored Review Criterion 3: Commitment to Candidate

What to consider?

- Whether the sponsor(s) presents a strong mentoring plan appropriate to the needs and goals of the candidate.
- The extent to which the sponsor(s) and organizational commitment is appropriate, sufficient, and in alignment with the candidate's research training plan.
- Whether the level of commitment provided will contribute to the successful completion of the proposed plan and allow the candidate to advance to a productive career in the biomedical research workforce.

Scored Review Criterion 3: Commitment to Candidate

Points to Note:

- Focus on the mentoring plan NOT the professional rank of the sponsor(s) in evaluating whether the sponsor(s) are appropriate for that candidate's needs and goals. Assistant Professors or early career investigators can serve as sponsors.
- A co-sponsor is not mandatory. If a co-sponsor is included, their role should be clearly defined.
- Assess both the physical and intellectual environment and commitment from the institution.

F30 – Predoctoral Dual-Degree Fellowships

A sponsor with a clinical degree is not required unless necessary for the research project.

F32 – Postdoctoral Fellowships

• The institutional and/or lab environment should provide appropriate and sufficient opportunities for the candidate to gain the professional skills needed for a successful research career.

Additional Review Criteria: Protections for Human Subjects

Evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five points:

- 1. Risk to subjects.
- 2. Adequacy of protections against risk.
- 3. Potential benefits of the research to subjects & others.
- 4. Importance of the knowledge to be gained.
- 5. Data and safety monitoring for clinical trials.

Additional Review Criteria: Inclusion

Sex: Unless scientifically justified, both sexes should be included. The distribution should be justified by the scientific question being asked.

Race/ethnicity: All minority populations should be included and if excluded, it should be justified based on the study question. Also, the distribution should be appropriate to answer the study question.

Inclusion Across the Lifespan: NIH expects that all ages be included unless the study question requires limitations (for example research in neonates or Alzheimer's).

Additional Review Criteria: Vertebrate Animals

For any proposed use of live vertebrate animals, comment on the following points:

- 1. Description of procedures, including species, strains, ages, sex, and total number of animals.
- 2. Justification for the choice of species.
- 3. Minimization of pain and distress.
- 4. Methods of euthanasia and justification for selected methods (if NOT consistent with the AVMA).

Additional Review Criteria: Biohazards

Biohazards are research components known in the professional community to pose a risk to research personnel and/or the environment (biological organisms, toxins, radioactivity, dangerous chemicals, or recombinant DNA).

- <u>Applications do not contain a separate section on Biohazards.</u> They can be addressed throughout the application, including the Facilities section.
- Determine whether proper handling procedures and adequate protections are addressed (personnel training, safety protocols, containment facilities, waste disposal).

Additional Review Criteria: Resubmissions

- For Resubmissions, the committee will <u>evaluate the application as now presented</u>, taking into consideration the responses to comments from the previous scientific review group and changes made to the application.
- Resubmissions (A1 applications) should have a one-page introduction.
- Prior summary statement is available in the grant folder.
- During discussion, do not indicate if you were a prior reviewer for the grant application.

Scoring

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

NIH uses a 9-point scale 5= Average

Start with a score of 5
assuming that every
application is of average
training value as you begin
evaluation. Move the scores
up or down based on the
strengths and
weaknesses identified.

Major strengths leading to high training value

Major weaknesses reducing training value

Non-Score-Driving: Additional Review Considerations

Training in the Responsible Conduct of Research: Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee. See NOT-OD-10-019 and NOT-OD-22-055.

• Format of instruction, Subject Matter, Faculty Participation, Duration of Instruction, Frequency of Instruction must all be addressed and assessed by reviewers.

Applications from Foreign Organizations: Evaluate if other countries present special opportunities not available in the US.

Select Agents: Hazardous materials that pose a **severe** threat to public as listed by DHHS (not general Biohazards). Assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Non-Score-Driving: Additional Review Considerations

Resource Sharing Plans: Comment on whether the Resource Sharing Plan(s) for Model Organisms or Research Tools, or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources: For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support: including support received through individual or institutional training awards

- Are the budget and requested period of support fully justified and reasonable in relation to proposed training?
- The scope of the research training activities should justify the requested budget duration.
 - F31: dissertation research training only up to 5 years
 - F30: both dissertation and clinical training up to 6 years
 - F32: research training up to 3 years (F33: research training up to 2 years)

Thank you for participating as a reviewer.

- Additional materials can be found in Meeting Materials—IAR
 - Contact the SRO with questions

