

# Revision History for the Institutional Assurance Statement

The table summarizes updates to the [Institutional Assurance Statement](#).

Revision Date	Description	Reason
August 20, 2025	Revised the fifth paragraph to clarify that use of a single IRB is at the institution's discretion.	Clarified that the use of single IRB is not required and will be used at the institution's discretion.
December 31, 2024	Revised the sixth paragraph to clarify when participants will be informed about Certificate protections and limitations.	Revised the statement to clarify when the investigator will inform participants about the Certificate protections and limitations and when there are any changes to those protections and limitations.
July 3, 2024	Revised the fifth paragraph to state that research will be conducted in accordance with 45 CFR 46 and relevant subparts.	Clarify the institutions responsibility to conduct research in compliance with 45 CFR 46 and the relevant subparts
November 1, 2023	Revised the second paragraph to add third party utilization language.	Ensure that institutions and investigators are aware of the potential for third party applications to release covered/protected data under forced disclosure.
November 1, 2023	Revised the third paragraph to remove references to 42 CFR 2a	Remove regulatory citation that conflicts with statute prohibiting voluntary disclosure of protected information, except under specific, limited circumstances.

Find more details on [Requesting a Certificate of Confidentiality for Non-NIH Funded Research](#).