

Summary of Responsibilities for Investigators Conducting **NON-FDA-Regulated Research** When the NIH is the Reviewing IRB

(Also see [Policy 300 Investigator Responsibilities](#))

As PI, your responsibilities **before** the research begins:

- Obtain scientific review from your Institute or Center (IC) prior to submission to the IRB. (See [OHSRP webpage for Scientific Review](#).)
- In collaboration with IC leadership, you should ensure sufficient resources exist to conduct the research (e.g., access to participants, time to conduct and complete research activities, adequate staff, and facilities).
- Complete required education and ensure training of research staff. (See [Policy 103 Education Program](#))
- Comply with NIH requirements for reporting and disclosure of conflicts of interest. (See [Policy 102 Institutional and Investigator Financial Conflict of Interest in Human Subjects Research](#).)
- Provide a protocol document with sufficient information for IRB review. (See [Protocol Templates](#)). The protocol is the “recipe” to be followed by the research team.
- For multi-site research, see on the [OHSRP webpage, Multi-Site Research](#).
- Obtain IRB approval of the protocol and other study materials (e.g., consent form recruitment materials), as appropriate, and any required ancillary committee approvals. (See [Policy 106 Ancillary Reviews](#) and, for recruitment information, see [Policy 302 Subject Recruitment and Compensation](#) and [302-Guideline-Recruitment Plan, Recruitment Materials and Screening Plan for NIH IRP Protocols](#) (downloads as a pdf)).
- If applicable, ensure that contracts for [CRADAs](#) and other required clinical trial agreements have been fully executed before enrolling participants.

As PI, your responsibilities **during** the conduct of the research:

- Maintain a regulatory file with current and accurate records of all study documentation as required by applicable regulatory requirements. (See [NIH Manual Chapter 1743 – Managing Federal Records](#), the [NIH Intramural Records Retention Schedule](#), and the [NIH Privacy Act](#).)
- You may assign responsibility for specific aspects of the conduct of the research to appropriately qualified individuals consistent with the IRB-approved protocol and the NIH policy requirements (See [Policy 300 Investigator Responsibilities](#).) However, as PI, at all times you retain overall responsibility for the conduct of the research and must ensure both the protocol and the research team’s actions are compliant with law, regulation, and policy.
- Train the study staff about how to implement the protocol (at the beginning and with each

modification as the study progresses) and maintain documentation of this training in the regulatory binder.

- Include information about recruitment, how recruiting of participants will be conducted, and who has responsibility for recruitment.
- For research requiring signed consent (which also refers to parental permission in this document) or assent, obtain and document informed consent/assent using the current NIH IRB approved consent/assent documents. (See [Policy 301 Informed Consent](#).)
- Conduct research in compliance with the final IRB approved protocol and submit any changes to the research (protocol or other study materials) for review and approval by the IRB prior to implementation.
- Conduct IRB approved research in compliance with [OHRP regulations at 45 CFR 46](#) as well as other applicable regulations and policies, including [NIH HRPP policies](#), that apply to the research.
- Maintain adequate and accurate participant study records and documentation to demonstrate compliance with the IRB-approved protocol. Changes should be traceable, should not obscure the original entry, and should be explained, if necessary (e.g., single line through the original entry, and initialed and dated).
- Ensure the participant's questions, concerns, and complaints are properly addressed and resolution documented and retained in the study record. Report these per [Policy 104 Managing Research Related Subject Complaints](#).
- Report research-related events per [Policy 801 Reporting Research Events](#), [Policy 802 Non-Compliance in Human Subjects Research](#) and [801-Guideline-Reporting Research Events and Non-compliance](#) (downloads as a pdf).
- Ensure the approved data and safety monitoring plan in the IRB approved protocol is followed and documented, including timely submission of reports, as applicable, per [Poli 503, Data Safety and Monitoring](#).
- For those studies requiring continuing review (CR), ensure **timely** submission of the progress report (4 to 6 weeks prior to study expiration is recommended) to ensure continued IRB approval during the conduct of the study. If IRB approval expires, ensure all research activities are stopped, including recruitment, enrollment, interventions, interactions, and data analysis on current participants.
- Unless the convened IRB or designated reviewer determines and documents otherwise, CR is not required in the following circumstances for research subject to the 2018 Common Rule, and the approval period for these studies will continue until the date the study is closed:
 - Research eligible for expedited review.
 - Research reviewed by limited IRB review.
 - Research that has progressed to the point that it involves only one or both of the following:
 - Data analysis of identifiable information and/or identifiable biospecimens.

- Access to follow-up clinical data from procedures that participants would undergo as part of clinical care.
- For clinical trials subject to the 2018 Common Rule, if the NIH is the only site, or in the case of multi-center research when NIH is the lead site, then you, or your IC, must post one blank copy of an IRB-approved informed consent document used to enroll participants in the research on a publicly available federal website that is established as a repository for such informed consent documents (e.g., [ClinicalTrials.gov](https://www.clinicaltrials.gov)). The document must be posted after the trial is closed to recruitment, and no later than 60 days after the last study visit by any participant, as required by the protocol.
- If departing the NIH and research activities are continuing at the NIH, you should revise the protocol and obtain IRB approval of a new PI who is suitably qualified to be responsible for the conduct of the research prior to your departure.

Responsibilities after research is complete:

- Submit a final Continuing Review Report Form to the IRB when a study is being closed.
- As applicable, ensure the submission of study results on [www.ClinicalTrials.gov](https://www.clinicaltrials.gov) consistent with regulatory requirements as noted above.
- If new information or findings related to participant safety or welfare are identified after a study has closed, provide the IRB with a report of the new information/findings.