

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

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

Responsibilities before the research begins:

- Obtain scientific review from PI's IC prior to submission to the IRB. (See [this](#) OHSRP resource regarding scientific review)
- In collaboration with IC leadership, the PI should ensure sufficient resources exist to conduct the research (e.g., access to subjects, 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 [Templates and Forms](#)). The protocol is the "recipe" to be followed by the research team.
 - For multi-site research, see [Reliance Resources](#).
- Obtain IRB approval of the protocol and other study materials (e.g., 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 [OHSRP Recruitment Information Sheet](#).)
- If applicable, ensure that contracts for [CRADAs](#) and other required clinical trial agreements have been fully executed before enrolling subjects.

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 Policy](#).)
- The NIH PI 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, at all times the PI retains 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 amendment as the study progresses) and maintain documentation of this training in the

regulatory binder.

- Include information about recruitment, and how recruiting of subjects should be conducted and 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 subject 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 subject's questions, concerns, and complaints are properly addressed and resolution documented and retained in the study record. Report these per [Policy 104 Research Related Subject Complaints](#).
- Report research-related events per [Policy 801 Reporting Research Events](#), [Policy 802 Non-Compliance in Human Subjects Research](#) and the [Guidance: Reporting Research Events and Non-compliance](#).
- 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 [Policy 503, Data Safety and Monitoring](#).
- Submit Progress Report Forms for Continuing Review (CR) submissions, study closures and for institutional "check-in" required for protocols that have been determined by the IRB to not require CR. For those studies requiring continuing review, 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 subjects. For those studies that **do not** require continuing review, ensuring **timely** submission of the Progress Report Form (within 30 days of the due date is recommended).
- 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 the NIH PI, or the PI's Institute or Center (IC), must post one blank copy of an IRB-approved informed consent document used to enroll subjects in the research on a publicly available federal website that is established as a repository for such informed consent documents (e.g., [ClinicalTrials.gov](#) or [Regulations.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 subject, as required by the protocol.

- If departing the NIH and research activities are continuing at the NIH, the PI 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 their departure.

Responsibilities after research is complete:

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