

Summary of Responsibilities for Investigators Conducting FDA-Regulated Research When the RSRB is the Reviewing IRB

(Summarized from Policy 901 Investigator Responsibilities)

Responsibilities before the research begins

- Obtain scientific review from PI's department prior to submission to the RSRB.
- Provide a protocol document with sufficient information for RSRB review (see [RSRB Protocol Templates](#)).
 - For funded studies, a separate protocol must be created based upon the full grant proposal.
- Obtain RSRB approval of protocol and other study materials (e.g., recruitment materials), as appropriate, and any required ancillary committee approvals.
- Ensure a budget is developed, independent of the sponsor (if applicable), in accordance with UR policy.
- For sponsored research, ensure a fully executed contract is in place before enrolling subjects.
- Ensure and document appropriate education and training of research staff.
- Ensure sufficient resources to conduct the research (e.g., access to subjects, time to conduct and complete research activities, adequate staff and facilities).
- Comply with UR requirements for reporting and disclosure of conflicts of interest.
- For faculty members mentoring a non-faculty Investigator (e.g., student, resident, fellow), ensure procedures are in place to maintain appropriate oversight and guidance during: 1) protocol development and RSRB submission, 2) study conduct (including responsibilities of being an Investigator), 3) study closure.

Responsibilities during the conduct of the research:

- Maintain a regulatory file of approved study materials (see [OHSP Quality Improvement Study Documentation Tool Box](#) for guidance).
- Oversee the conduct of all research activities. PIs may delegate responsibilities, but documentation of delegation is required and the PI must maintain oversight of all research activities.
- Oversee budget expenditure completeness and accuracy, and revenue realization (as applicable).
- Conduct research in compliance with the finalized RSRB approved protocol, and submit any changes to the research (protocol or other study materials) for review and **approval** by the RSRB prior to implementation.
- Conduct RSRB approved research in compliance with required regulations:
 - OHRP regulations [45 CFR 46](#)
 - FDA regulations [21 CFR 50](#) and [21 CFR 56](#) and “[Guidance for Industry – Investigator Responsibilities](#)”
 - Oversee (or delegate as appropriate) the control of drugs, biologics or medical devices under: drugs or biologics [[21 CFR 312](#)], devices [[21 CFR 812](#)]
- Obtain and document informed consent and HIPAA Authorization using documents bearing a current “RSRB Approved” watermark with the first page printed on UR department letterhead.
 - Maintain **all pages** of the **original** signed form(s) in the study file for at least 3 years after the research is completed (6 years if HIPAA Authorization used as part of the research), or for a longer term if required by FDA regulations or other contractual agreements.
- Ensure the subjects' questions, concerns, and complaints are properly addressed and resolution documented and retained in the study record. Report per the [Guideline for Reporting Research Events](#).
- Report research events per [Policy 801 Reporting Research Events](#).
- Ensure approved data and safety monitoring plan is followed, including timely submission of reports, as applicable, per the [Guideline for Reporting Research Events](#).
- For those studies requiring continuing review, ensure **timely** submission of the progress report (6 to 8 weeks prior to study expiration is recommended) to ensure continued RSRB approval during the conduct of the study. If RSRB 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 annual update (within 30 days of the study update due date is recommended).
- Investigators with the role of sponsor-investigator (UR PI holds the IND/IDE) will comply with the requirements for both the “Investigator” and “Sponsor” defined by the FDA [[21 CFR 312](#)] and FDA [[21 CFR 812](#)].
- Notify the RSRB if departing the University (temporarily or permanently) and follow additional procedures according to the [Guideline for Investigators Leaving the Institution](#).

Responsibilities after research is complete:

- Submit a final progress report when a study is completed or closed.
- When new information or findings related to subject safety or welfare are identified after a study has closed, provide the RSRB with a report of the new information/findings.
- Ensure timely programmatic and financial closeout of the budget.