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 submitted, in addition to the full grant proposal.
- Obtain RSRB approval of protocol and other study 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.
- 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 OHRP regulations 45 CFR 46.
- For research requiring signed consent, 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) for at least 3 years after the research is completed (6 years if HIPAA Authorization used as part of the research)
- 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.
- Ensure timely submission of the progress report for continuing review 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.
- 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 continuing review 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.

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