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 on the entire grant proposal.
    - For multi-site research, a site-specific protocol addendum to address institution-specific requirements may be required.
- Obtain RSRB approval of protocol and other study materials (e.g., recruitment materials), as appropriate, and any required ancillary committee approvals.
- Ensure development of a compliant budget plan and budget, independent of the sponsor (if applicable), in accordance with UR policy.
- For sponsored research, ensure a fully executed contract is in place before enrolling any subjects.
- Ensure and document appropriate education and training of research staff and ensure only IRB-approved research staff conduct the research.
- Ensure sufficient resources to conduct the research (e.g., access to subjects, time to conduct and complete research activities, adequate staff and facilities).
- Ensure registration for all "applicable clinical trials" on www.ClinicalTrials.gov consistent with funding and regulatory requirements.
- 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 study site (regulatory) file of approved study materials (see OHSP Quality Improvement Study Documentation Tool Box for guidance).
- Oversee the conduct of all research activities and ensure only IRB-approved research staff conduct the research. 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 all changes to the research (including protocol and all other study documents) 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]
- Follow the RSRB-approved protocol for obtaining consent and obtain and document informed consent and HIPAA Authorization using documents bearing a current "RSRB Approval Date" watermark with the first page printed on UR department letterhead.
- Maintain all study records (e.g., study site files, data collection forms, source documentation) and **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 is used as part of the research)*** or for a longer term if required by FDA regulations or other contractual agreements.
- Maintain adequate and accurate subject study records and documentation to demonstrate compliance with the IRB-approved protocol; changes should be traceable, not obscure the original entry, and should be explained, if necessary (e.g., single-line through the original entry and initialed and dated with indelible ink).
- 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 and the Guideline for Reporting Research Events.
- Ensure an agreement (e.g., Material Transfer Agreement, Data Use Agreement) is executed before transmitting data/specimens to an external entity.
- Ensure the approved data and safety monitoring plan is followed and documented, including timely submission of reports, as applicable, per the Guideline for Reporting Research Events.
- Ensure **timely** submission of the progress report for continuing review (submit 6 to 8 weeks prior to study expiration) 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.
- Oversee the control of the investigational product (IP), ensuring the IP is dispensed/administered to enrolled subjects in accordance with the RSRB-approved protocol.
- For studies defined as a "clinical trial," ensure one consent form used to enroll subjects is posted on a publically available federal website after the clinical trial is closed to recruitment and no later than 60 days after the last study visit consistent with 45CFR46.116(h).
- 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.
- Ensure the submission of study results on www.ClinicalTrials.gov consistent with funding and regulatory requirements.
- 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.