Summary of Responsibilities for Investigators Conducting EXEMPT Research

(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.
- Obtain a review determination to confirm exemption by the RSRB, including review of any recruitment materials and/or recruitment methods prior to use and/or implementation.
- 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).
- 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).

Responsibilities during the conduct of the research:

- Maintain a study site (regulatory) file to support RSRB determination, including at minimum, the finalized protocol, the RSRB application, and the RSRB letter regarding the exempt determination.
- Oversee the conduct of all research activities and ensure only IRB-approved research staff conduct the research. PIs may delegate responsibilities, but documentation of training to support this delegation is required, and the PI must maintain oversight of all research activities.
- Conduct research in compliance with the finalized RSRB protocol and submit all changes to the research (including the protocol and all other study documents) for review and confirmation of continued exempt determination by the RSRB prior to implementation.
- Use information letters (or consent forms) bearing a current RSRB watermark with the first page printed on UR letterhead.
    - While it is rare for an exempt study to require formal consent, if it does, maintain **all pages** of the **original** signed form(s) for at least 3 years after the research is completed (6 years if HIPAA Authorization is used as part of 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 with indelible ink).
- Ensure that any subject 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.