

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 upon the full 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 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).

Responsibilities during the conduct of the research:

- Maintain a 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. PIs may delegate responsibilities, but documentation of delegation is required and the PI must maintain oversight of all research activities.
- Conduct research in compliance with the finalized RSRB protocol, and submit any changes to the research (protocol, recruitment material/methods, or other study materials) 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 used as part of the research).
- Maintain adequate and accurate subject study records and documentation; changes should be traceable, should not obscure the original entry, and should be explained, if necessary.
- 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](#).