

Policy 901 – Investigator Responsibilities

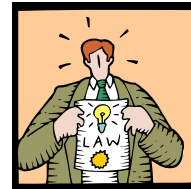
OHSP Seminar – 09/16/14
Kelley A. O'Donoghue, MPH, CIP
Director, Office for Human Subject Protection



UNIVERSITY of ROCHESTER

What do the regulations provide?

- Office for Human Research Protections (OHRP)
 - No regulations or guidance on Investigator Responsibilities, but *expect the Institution to ensure compliance with the regulations*
- Food & Drug Administration (FDA)
 - Investigator's Agreement (1572, device)
 - Good Clinical Practice



UNIVERSITY of ROCHESTER

Institution's responsibility

- Measures in place to educate and monitor Investigators:
 - Research Education
 - Quality Improvement
- How do Investigators know their responsibilities and what regulations apply?
 - In general...**Policy 901** with associated summary pages
 - By study...information will be on each **approval letter**



UNIVERSITY of ROCHESTER

Policy 901 - Purpose

- To ensure research is conducted in accordance with the Office for Human Subject Protection (OHSP) and University policies and guidelines, as well as federal regulations, as applicable.
 - To ensure the rights, safety, and welfare of research subjects are protected during the study and after the study is complete.
 - To ensure the integrity of the data collected.



UNIVERSITY of ROCHESTER

Policy 901 - Scope

- Applies to any individual designated as a Principal Investigator conducting human subject research governed by the Research Subjects Review Board (RSRB) under the University of Rochester Human Research Protection Program.
 - For research deferred to another IRB, Investigator responsibilities are also deferred to that IRB. However, UR institutional governed responsibilities still apply.

GOOD PRACTICE TO FOLLOW POLICY!!



UNIVERSITY of ROCHESTER

Policy 901- Definitions

- *Principal Investigator* – Individual who meets the qualifications and requirements outlined in the University of Rochester “Principal Investigator Eligibility Policy” and has full and final responsibility for study conduct.
 - Full-time Faculty, Senior Scientist, Scientist, Senior Research Associate, Senior Technical Associate, etc.
 - Individuals **not** meeting the criteria include: adjunct professors, residents, fellows, students or staff members; these individuals can serve as Co-PI
 - Exempt study – more flexibility (e.g., students)
- *Sponsor-Investigator* – UR Investigator holds the IND/IDE



UNIVERSITY of ROCHESTER

Policy - Format

- Policy broken down into 4 sections, responsibilities for:
 - All PIs
 - Exempt research = 1+2
 - Non-FDA regulated = 1+2+3
 - FDA regulated = 1+2+3+4



UNIVERSITY of ROCHESTER

What regulatory agencies are included?

| | Institutional policy and good practice | OHRP | FDA/Good Clinical Practice | OCR (HIPAA) |
|-------------------|--|------|----------------------------|-------------|
| Exempt | X | | | X |
| Non-FDA Regulated | X | X | | X |
| FDA Regulated | X | X | X | X |



UNIVERSITY of ROCHESTER

Summary Pages

- Policy is required to explain all requirements
- Problem: *Not very user-friendly*
- Single page “summary”
 1. Exempt
 2. Non-FDA Regulated
 3. FDA Regulated
- Each summary broken down by phase of the study
 - **Before** the research begins
 - **During** the conduct of the research
 - **After** the research is complete



UNIVERSITY of ROCHESTER

Examples of the types of research

Exempt

- Must be one of the 6 categories: surveys, focus groups, educational research, secondary use of de-identified pre-existing data

Non-FDA Regulated

- Almost all minimal risk research (expedited): non-invasive procedures, non-invasive collection of biological specimens, minimal blood draws, identifiable chart reviews
- Greater than minimal risk research with no investigational drugs (or supplements), biologics, devices: invasive procedures, significant amount of blood

FDA Regulated

- Investigational drugs (or supplements), biologics, devices
- FDA funded, regardless of study design



UNIVERSITY of ROCHESTER

Exempt - Before the research begins

- Obtain scientific review
- Provide a protocol (in addition to the grant)
- Obtain confirmation of exemption from the RSRB
- For sponsored research, ensure a fully executed contract before enrolling subjects
- Ensure and **document** appropriate education and training of research staff
- For faculty **mentoring** non-faculty Investigators (e.g., student, resident, fellow), ensure oversight and guidance during:
 - 1) protocol development and RSRB submission
 - 2) study conduct (including responsibilities of being an Investigator)



UNIVERSITY of ROCHESTER

Exempt – During the conduct

- Maintain a regulatory file to support RSRB 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 for review and confirmation of 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
 - If consent, maintain **all pages** of the **original** signed form(s) for at least 3 years after completed (6 years, if HIPAA Authorization)
- Ensure subject questions, concerns, and complaints are addressed and resolved, document in study records, report per guideline
- Report research events per Policy 801 Reporting Research Events



UNIVERSITY of ROCHESTER

Exempt Summary

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 submitted, in addition to the full grant proposal.
- Obtain a review determination to confirm exemption by the RSRB, including review of 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.
- 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, 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 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).
- 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.



UNIVERSITY of ROCHESTER

Non-FDA Regulated - Before

- All items on exempt summary
- Additional Items (or revisions):
 - Obtain RSRB **APPROVAL**, and any required ancillary committee approvals
 - Develop a budget, if applicable



UNIVERSITY of ROCHESTER

Non-FDA Regulated – During

- All items on exempt summary
- Additional Items
 - Maintain a regulatory file (see [OHSP Quality Improvement Study Documentation Tool Box](#) for guidance).
 - Oversee budget expenditure completeness and accuracy, and revenue realization
 - Conduct research in compliance with the finalized **RSRB approved protocol**, and submit any changes to the research 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)
 - Follow approved data and safety monitoring plan
 - Submit progress reports for continuing review
 - Notify the RSRB if departing the University (temporarily or permanently)



UNIVERSITY OF ROCHESTER

Non-FDA Regulated – After

- Submit a final continuing review report when the study is completed.
- 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.



UNIVERSITY OF ROCHESTER

Non-FDA Regulated

Summary of Responsibilities for Investigators Conducting **NON** FDA-Regulated 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 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).
- Oversees 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.
- Oversees 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 [OHSP regulations 41 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 901 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 closure of the budget.



UNIVERSITY of ROCHESTER

FDA Regulated - Before

All items on non-FDA Regulated summary

NO ADDITIONAL ITEMS



UNIVERSITY of ROCHESTER

FDA Regulated – During

- All items on non-FDA Regulated summary
- Additional Items
 - Conduct RSRB approved research in compliance with required regulations:
 - 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](#)]
 - 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) **, or for a longer term if required by FDA regulations or other contractual agreements.**
 - 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](#)].



UNIVERSITY of ROCHESTER

FDA Regulated – After

All items on non-FDA Regulated summary

NO ADDITIONAL ITEMS



UNIVERSITY of ROCHESTER

FDA Regulated

Summary of Responsibilities for Investigators Conducting FDA-Regulated 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 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 [CHSP 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: [41 CFR 101](#)
 - FDA regulations: [21 CFR 312](#) and [21 CFR 316](#) 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 316](#)).
- 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](#).
- 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.
- 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](#)).
- 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 closure of the budget.



UNIVERSITY of ROCHESTER

How to know what applies?

- Exempt determination letters and RSRB approval letters will reference Policy 901 Investigator Responsibilities, and have a link to the appropriate summary based on the applicable regulations.

EXEMPT

- *As the Principal Investigator, you are responsible for ensuring compliance with Policy 901 Investigator Responsibilities. A summary of responsibilities can be found at [Summary of Responsibilities for Investigators Conducting EXEMPT Research](#).*



UNIVERSITY of ROCHESTER

How to know what applies?

NON-FDA Regulated

- *This study was reviewed and approved under OHSP and UR policies, and in accordance with applicable Federal regulation 45 CFR 46 under the University's Federalwide Assurance (FWA00009386).*

As the Principal Investigator, you are responsible for ensuring compliance with Policy 901 Investigator Responsibilities. A summary of responsibilities can be found at [Summary of Responsibilities for Investigators Conducting NON FDA-Regulated Research](#).



UNIVERSITY of ROCHESTER

How to know what applies?

FDA Regulated

- *This study was reviewed and approved under OHSP and UR policies and in accordance with applicable Federal regulations: 45 CFR 46 under the University's Federalwide Assurance (FWA00009386) and the Food and Drug Administration (including Good Clinical Practice).*

As the Principal Investigator you are responsible for ensuring compliance with Policy 901 Investigator Responsibilities. A summary of responsibilities can be found at [Summary of Responsibilities for Investigators Conducting FDA-Regulated Research](#).”



UNIVERSITY of ROCHESTER

Policy 901 Disclaimer...

- This may not include everything an Investigator may be responsible for depending upon the type of research, but this is a comprehensive list of regulatory requirements, with some specific institutional considerations included.



UNIVERSITY of ROCHESTER

Office for Human Subject Protection

www.rochester.edu/ohsp



UNIVERSITY of ROCHESTER

QUESTIONS?



UNIVERSITY of ROCHESTER

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 submitted, in addition to the full grant proposal.
- Obtain a review determination to confirm exemption by the RSRB, including review of 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.
- 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, 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 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).
- 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.

Summary of Responsibilities for Investigators Conducting ***NON*** FDA-Regulated 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 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.

Summary of Responsibilities for Investigators Conducting FDA-Regulated 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 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 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*.
- 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.
- 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](#)].
- 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.