

RSRB GUIDANCE FOR INVESTIGATORS

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Scope and Purpose of the RSRB

This section has been replaced by new RSRB policies and guidelines. For information regarding the human research protection program and the RSRB scope and authority please refer to the following documents on the [OHSP Policies and Guidelines](#) website:

[RSRB Policy 102: University of Rochester Human Research Protection Program](#)

[RSRB Policy 103: Organizational Structure of the Human Research Protection Program](#)

[RSRB Policy 301: RSRB Scope and Authority](#)

Pre-Review Considerations

Before submitting a study to the RSRB for approval, consider the following questions:

Who can be a Principal Investigator?

This section has been replaced by new RSRB policies and guidelines. For information regarding criteria to serve as an Investigator and the responsibilities of this role, please refer to the following documents on the [OHSP Policies and Guidelines](#) website:

- [RSRB Policy 901: Investigator Responsibilities](#)
- Summary of Responsibilities for Investigators Conducting FDA Regulated Research
- Summary of Responsibilities for Investigators Conducting NON-FDA Regulated Research
- Summary of Responsibilities for Investigators Conducting EXEMPT Research

Does the project involve human subjects? Does the project involve research?

It's often easy to determine whether a project involves research -- a randomized trial, for example, or testing a drug for the first time in humans. But there are also times when it may be more difficult to tell whether an activity qualifies as research.

Before submitting your application to the RSRB, refer to the following guidelines on the [OHSP Policies & Guidelines](#) website to ensure you are engaging in human subject research:

- [Guideline for Determining Engagement in Research](#)
- [Guideline for Determining Human Subject Research](#)

Investigator Training

For details on the research education program, go to the [OHSP Policies & Guidelines](#) website and reference [Policy 201: Education Program](#) and the related guideline.

Who Reviews What?

For information on who is the IRB of record for industry-sponsored and industry initiated research, refer to the OHSP Policies & Guidelines website and reference the following:

- [Policy 401: Functions of the RSRB Office](#)
- [Guideline for Submitting to Central IRB](#)

Does the protocol qualify for Just-in-Time Review?

Most federally funded (and some foundation-funded) research qualifies for Just-in-Time review. This means that **RSRB review and approval are deferred until the Investigator receives verbal or written documentation from the funding agency that the study is within the fundable range.** If a score is not within a fundable range, or notice not yet received of a fundable score, wait to submit the ROSS application to the RSRB until that notification is received. Contact the funding agency if there are any questions as to whether the score is within a fundable range.

Is any member of the study team part of the University's covered entity?

This section has been replaced with [Policy 702 HIPAA Privacy Rule](#).

For additional information pertaining to the HIPAA Privacy and Security Rules, refer to the ["HIPAA Policies/Guidelines"](#) on the OHSP website.

Does the Study Need Data Monitoring?

This section has been replaced with [Policy 506: Data and Safety Monitoring](#).

Additional Approvals

(A) University Committees

This section has been replaced with [Policy 503 Ancillary Committee Reviews](#).

(B) Off-site Approvals

This section has been replaced with the following:

- o [Policy 504 RSRB Review Reliance](#)
- o [Guideline for Conducting International Research](#)

Is an Investigational New Drug (IND) or Investigational Device Exemption (IDE) required?

Research Involving Investigational Drugs:

This section has been replaced with [Policy 605 Research Using FDA Regulated Drugs, Biologics, and Supplements](#).

Research Involving Medical Devices:

This section has been replaced with [Policy 606 Research Using FDA Regulated Devices](#).

Is a Certificate of Confidentiality Needed?

This section has been replaced by [Policy 701 Informed Consent](#).

Do any members of the study team have a conflict of interest with the proposed research?

For more information regarding Investigator, study team or institutional conflict of interest with proposed research, refer to the following OHSP policies:

- o [Policy 104: Institutional Conflict of Interest](#)
- o [Policy 902: Investigator Conflict of Interest](#)



Stop . . . and take an inventory

Pre-submission checklist

Does your activity. . .

- Involve human subjects?
- Involve research?
- Need review by the RSRB? By WIRB?
- Qualify for Just-in-Time review?
- Need approval by other UR Committees?
- Need off-site approval(s)?
- Require an IND or IDE?
- Require Data & Safety Monitoring?
- Need a Certificate of Confidentiality?

Have the Investigators/Study team. . .

- Received certification for human subjects research through the Collaborative Institutional Training Initiative (CITI Program)?
 - Greater Than Minimal Risk Biomedical,
 - Greater Than Minimal Risk Behavioral, OR
 - Minimal Risk

Do any of the members of the research team. . .

- Have a conflict of interest?

Questions?

Call the RSRB office at (585) 275-2398.

Writing the Research Protocol

To ensure an effective review, the RSRB must be provided with a research protocol (study plan) that contains certain critical elements of information. The protocol needs to address these areas in detail. For any questions concerning protocol preparation, call an RSRB Human Subjects Protection Specialist at (585) 275-2398.

A protocol template can be found on the RSRB website: [Protocol Templates](#)

For additional information on conducting clinical trials in accordance with Good Clinical Practice (GCP), please refer to the [International Conference on Harmonization \(ICH\) Good Clinical Practice \(GCP\) Guidance](#).

NOTES:

- A grant proposal *does not* substitute for the RSRB protocol/study plan. For studies supported by grants, submit a *separate protocol*, based on the guidelines provided below.
- Make sure to date *each version* of the protocol as it is revised. This step is crucial in keeping track of any modifications as the protocol proceeds through the review process.



Stop . . . and take an inventory

Protocol Checklist

Is the protocol. . .

- Dated? Paginated (with version number or date)?
- A stand-alone document, separate from the grant application?

Does the protocol. . .

- Include all pertinent elements?
- Differentiate research from non-research activities?
- Need a data monitoring plan?
- Have sufficient sample size to address the objectives?
- Address the risks of the research?
- Involve deception? (applicable only to minimal risk studies)

Do the subjects. . .

- Have capacity to consent?
- Represent any vulnerable populations?

Does the investigator. . .

- Have routine, legitimate access to potential subjects (i.e., can he/she recruit subjects directly)?

Categories of Research and RSRB Review

Research involving vulnerable populations

The following descriptions are provided as additional considerations for investigators who plan to conduct research with vulnerable populations.

a) Research Involving Children

This section has been replaced by the RSRB policy on research involving children. Please refer to the following OHSP policies and guidelines:

- [Policy 601: Research Involving Children](#)
- [Guideline for Assessing Capacity in Children](#)
- [Guideline for SADCR Review](#)

b) Research Involving Pregnant Women and Fetuses

This section has been replaced by the RSRB policy on research involving pregnant women, fetuses, and neonates. Please refer to the following OHSP policy:

- [Policy 602: Research Involving Pregnant Woman, Fetuses and Neonates](#)

c) Research Directed Toward Pregnant Women as Subjects (45 CFR 46.207)

This section has been replaced by the RSRB policy on research involving pregnant women, fetuses, and neonates. Please refer to the following OHSP policy:

- [Policy 602: Research Involving Pregnant Woman, Fetuses and Neonates](#)

d) Research involving nonviable neonates and neonates of uncertain viability (45 CFR 46.209)

This section has been replaced by the RSRB policy on research involving pregnant women, fetuses, and neonates. Please refer to the following OHSP policy:

- [Policy 602: Research Involving Pregnant Woman, Fetuses and Neonates](#)

e) Research involving the dead fetus, fetal material or the placenta (45 CFR 46.210)

This section has been replaced by the RSRB policy on research involving pregnant women, fetuses, and neonates. Please refer to the following OHSP policy:

- [Policy 602: Research Involving Pregnant Woman, Fetuses and Neonates](#)

f) Research involving prisoners (45 CFR 46.302-306)

This section has been replaced by the RSRB policy on research involving prisoners. Please refer to the following OHSP policy:

- [Policy 603: Research Involving Prisoners](#)

Additional Research Considerations

1) Research Involving Genetic Testing

This section has been replaced by the OHSP policy on research involving genetic testing. Please refer to the following OHSP policy and guideline:

- [Policy 608: Research Involving Genetic Testing and Gene Transfer](#)
- [Guideline for Internal Review of Human Gene Transfer Research](#)

2) Research Involving HIV Testing and Subjects with AIDS

This section has been replaced by the [Guideline for Research Involving HIV Testing](#).

3) Research Databases

This section has been replaced by the [Guideline for Research Involving Repositories](#) and the RSRB [Protocol Template for Repositories](#).

4) Coordination Centers

This section has been replaced by the [Guideline for Coordinating Center Studies](#).

Levels of RSRB Review

This section has been replaced by the OHSP policy on the levels of RSRB review. Please refer to the following OHSP policy:

- o [Policy 501 Levels of RSRB Review](#)

Exempt Activities / Research (45 CFR 46.101(b))

This section has been replaced by the OHSP policy and guidelines on the levels of RSRB review. Please refer to the following OHSP policy and guideline:

- o [Policy 501 Levels of RSRB Review](#)
- o [Guideline for Determining Exempt Research](#)

Expedited Review – 45 CFR 46.110

This section has been replaced by the OHSP policy and guidelines on the levels of RSRB review. Please refer to the following OHSP policy and guideline:

- o [Policy 501 Levels of RSRB Review](#)
- o [Guideline for Expedited Review of Research](#)

Review at Convened Meetings

This section has been replaced by the OHSP policy and guidelines on the levels of RSRB review. Please refer to the following OHSP policy and guideline:

- o [Policy 501 Levels of RSRB Review](#)
- o [Guideline for Convened Board Review of Research](#)

Submitting Studies to the RSRB

This section has been replaced by the OHSP policy and guidelines on the types of RSRB submissions. Please refer to the following OHSP policy:

- o [Policy 502 Types of RSRB Submissions](#)

Responsibilities of the Principal Investigator for Research in Progress

For more information regarding Investigator responsibilities, refer to the following OHSP policy:

- o [Policy 901: Investigator Responsibilities](#) and related Responsibility Summary sheets

Reporting unanticipated problems -- adverse experiences and deaths

This section has been replaced by the OHSP policy on reporting research events. Please refer to the following documents:

- o [Policy 801: Reporting Research Events](#)

- [Guideline for Reporting Research Events](#)
- [Guideline to RSRB Categories of Reportable Events](#)

Non-Compliance

This section has been replaced by the OHSP policy on non-compliance. Please refer to the following documents:

- [Policy 802: Non-Compliance](#)
- [Guideline for Review of Allegations of Non-Compliance](#)

APPENDIX 1

University of Rochester Policy on Enrollment of Adult Decisionally Incapacitated Research Subjects and Permission of Authorized Representatives

This section has been replaced with the following OHSP policy and guidelines:

- [Policy 604: Research Involving Adults With Decisional Impairment](#)
- [Guideline for Assessing Capacity in Adults With Decisional Impairment](#)
- [Guideline for Institutional Review of Research Involving Adults With Decisional Impairment](#)
- [Advance Directive for Research Participation Form \(Research Proxy\)](#)

APPENDIX 2

Report of Emergency Use of Experimental Procedure Without RSRB Approval

This section has been replaced with the following OHSP policy and guidelines:

- [Policy 607 Emergency Use of Investigational Drugs, Biologics, and Medical Devices](#)
- [Emergency Use Physician Checklist](#)
- [Emergency Use Report to RSRB](#)
- [Emergency Use Follow Up Report](#)