

UC Irvine

Education and Guidance Documents

Title

IRB Navigator - Regulatory Background, Submission Standards, and Post-Approval Responsibilities

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Date of Last Revision: 07/22/19, 09/03/19

Audience: Researchers

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	DESCRIPTION
<p>Background and Significance of Human Subjects Research (HSR) Regulations</p>	<ol style="list-style-type: none"> 1. Regulation <ol style="list-style-type: none"> a. Timelines <ol style="list-style-type: none"> i. https://history.nih.gov/about/timelines_laws_human.html ii. https://www.niehs.nih.gov/research/resources/bioethics/timeline/ b. Belmont Report c. OHRP History <ol style="list-style-type: none"> i. 45 CFR 46 ii. Revised (2018) 45 CFR 46 <ul style="list-style-type: none"> ▪ Matrix of the revisions d. FDA History <ol style="list-style-type: none"> i. ICH GCP E6 R2 2. UCI's Mission Statement <ol style="list-style-type: none"> a. UCI Chancellor's Pillars b. UCI Vice Chancellor for Research's Strategic Plan 3. National Academy of Sciences (2019) <ol style="list-style-type: none"> a. Reproducibility and Replicability in Science – Improve Transparency and Rigor in Science 4. About UCI HRP and the IRB <ol style="list-style-type: none"> a. Policies b. Guidance for Researchers c. Contacts 5. About UCI Research Protection's Education and Quality Improvement Program (EQUIP)
<p>Activities that meet the definition of Human Subjects Research (HSR) require IRB review</p>	<ol style="list-style-type: none"> 1. The definition of HSR inclusively meets both parts of this definition: <ol style="list-style-type: none"> a. 45 CFR 46.102(e)(1) and 45 CFR 46.102(l) 2. Additional definitions <ol style="list-style-type: none"> a. Clinical Investigation of a Drug (or, Biologic) b. Clinical Investigation of a Device <ol style="list-style-type: none"> i. Stepwise Method to Determine Medical Device Research Regulatory Status c. OHRP Guidance for Engagement of Institutions in HSR 3. When in doubt, you may submit a Request for Determination of Non-Human Subjects Research form to the IRB 4. Other considerations: <ol style="list-style-type: none"> a. Conducting a Case Report

- b. [Quality Improvement \(QI\) Projects vs QI-Research Activity](#)
- c. Transferring Research
 - i. [OHRP](#)
 - ii. [FDA](#)
- d. International Research
 - i. [OHRP](#)
 - ii. [OHRP Domestic and International Social Behavioral research standards](#)
 - iii. [International Clinical Regulations Database \(ClinRegs\)](#)
 - iv. [International Research Ethics Online Training \(World Health Organization\)](#)
 - v. [Family Health International Research Ethics Training Curriculum](#)
 - vi. [EU GDPR](#)
 - vii. University of California
 - [UC Global Research \(UC ECAS Policy\)](#)
 - [UC Global Operations \(UCGO\)](#)
 - UCI Administrative [policy](#) and [procedures](#) for *Student International Activities*
 - viii. [Data Protection Laws](#)
 - ix. [CIOMS](#)
 - x. ISBN 10:0-7637-3049-1 (Chapter 10)

CITI Training is required to conduct HSR

- Lead Researcher
- Research Personnel interacting with subjects and/or have access to identifiable data

1. Webpage: <https://www.citiprogram.org/?pageID=668>
 - a. Login through: University of California, Irvine
 - b. [Complete](#) your registration/profile; **or**, if you have an existing CITI profile/record from another institution, please [affiliate](#) with UCI and update your primary email address to your UCI email address
 - c. Choose and complete one of the following
 - i. Basic HRP Course for Biomedical Investigators
 - ii. Basic HRP Course for Social & Behavioral Investigators
 - iii. Note: Biomedical Research vs Behavioral Research
 - OHRP IRB Guidebook (1993): [Chapter 5](#)

[Lead Researcher Eligibility](#)

Determine whether you may serve in a Lead Researcher role, or whether you require a Faculty Sponsor

Two Types of HSR

- Minimal Risk Research
- Greater than Minimal Risk Research

A. Minimal Risk Research

1. Definition of minimal risk research
 - a. 45 CFR 46.102(i)
 - b. When research involves prisoners as subjects [[OHRP definition](#)]
 - c. Understanding "minimal risk"
 - i. 2007 SACHRP ([pages 6-7](#)) ([appendix](#))
2. **Minimal Risk Research: 2 types (Exempt, and Expedited)**
 - a. **[Exempt](#) Research: 3 distinct paths**
 - i. [categories](#)
 - ii. [Undergraduate Exempt Research \(UROP Review\)](#)
 - iii. [Exempt Self-Determination](#)
 - iv. Note: to qualify for an Exempt path, your research in its entirety (scope, procedures, risks) must inclusively meet the criteria(s) for one of the path above
 - b. **Categories of Research that may be reviewed through the [Expedited Review Procedure](#): 1 path**
 - i. [categories](#)

- ii. Note: to qualify for the Expedited Research path, your research in its entirety (scope, procedures, risks) must inclusively meet the criteria(s) for one (or more) of the Expedited Research categories

c. Notes

- i. [Comparing Expedited Research Category 7 and Exempt Research Categories 1, 2, 3](#)
- ii. [Detailed overview of the Exempt categories of research](#)

B. Greater than Minimal Risk Research

- 1. HSR activities that exceed the above definition of minimal risk research

Two Levels of IRB Review

- Expedited Review of Minimal Risk Research
- Full Committee Review of Greater than Minimal Risk Research

1. **Minimal Risk** Research are reviewed on a weekly basis (an “*expedited review*”) [45 CFR 46.110]; minimal risk research do not require a review by a full committee of the IRB

2. **Greater than Minimal Risk** Research are reviewed on a monthly basis by a full committee of the IRB

- a. [Calendar](#)

3. Additional considerations

- a. Biomedical Research vs Behavioral Research

- i. OHRP IRB Guidebook (1993): [Chapter 5](#)

- b. UCI Committees

- i. IRB Full Committee, Biomedical: [IRB A, IRB B](#), Web-Based (WB) IRB

- ii. IRB Full Committee and Minimal Risk Research, Social Behavioral and Education: [IRB C](#)

- iii. IRB Minimal Risk, Biomedical: [Team D](#)

- iv. IRB Unanticipated Problems and Serious/Continuing Non-Compliance: [IRB E](#)

- v. IRB Reliances: [sIRB](#)

- vi. IRB Undergraduate Research Opportunities Program ([UROP Review](#))

- vii. [hSCRO](#) Committee

- c. [Ancillary Committees](#)

- i. PRMC

- ii. CRB

- iii. COIOC

- iv. IBC

- v. RDRC

- vi. Radiation Safety Committee Review

- vii. Scientific Review

- viii. Environmental Health and Safety

- ix. Epidemiology and Infection Prevention (EIP) Committee

IRB Application and Submission

- Submission standards
- Criteria for IRB approval
- Quality of your application

1. [Guidance page for researchers](#)

- a. [Submission Guidance](#)

- b. [FAQs](#)

- c. [Common submission errors](#)

- d. [Preparation Checklist](#)

- e. [Applications and Forms webpage](#) (*Human Research Protections*)

- i. Common required forms

- Appendices
- Application

- Consent forms
 - HIPAA Documents
 - Protocol Narrative
 - Recruitment materials
 - Other supporting materials [other sites, collaborators, Sponsor, FDA, data collection form, questionnaires, additional materials regarding procedure(s), etc]
- ii. Complete the online IRB Application form as accurately as possible; the application will generate a list of required ancillary reviews and required forms to download and complete
 - iii. The UCI IRB forms (consent, narratives) are templated and designed to ensure *usability and compliance* with regulations and policies; complete required materials as accurately as possible

2. Criteria for IRB approval of Research

- a. 45 CFR 46.111
- b. Additional guidance/recommendation
 - i. Quality of your submission
 - 2019: [DOI 10.17226/25303](https://doi.org/10.17226/25303)
 - Ensure your materials/documents have [internal congruence](#)
 - When applicable, work with your faculty sponsor on the *research design and statistical methods*; or, acquire guidance from the [UCI Center for Statistical Consulting](#), or [UCI ICTS BERD](#)

[Post-Approval Investigator Responsibilities](#)

1. [Guidance/Worksheet](#)

- a. Use the worksheet to help you with *compliance* with your post-approval responsibilities, and to ensure your *research records* are *audit-ready*

2. When applicable

- a. [ClinicalTrials.gov Registration and Results Submission](#)
- b. [Posting an Informed Consent Form for Federally Supported Clinical Trials](#)
- c. [NIMH Data Sharing Policy](#)
- d. [NIH Policy for the Management of Genomics Summary Results Access](#)
- e. [EU GDPR](#)
- f. [International Data Protection Laws](#)
- g. [UCI Data Security Policies](#)
- h. [OHRP Informed Consent FAQs \(additional consent guidance\)](#)
- i. [OHRP guidance for researchers \(list\)](#)
- j. [SACHRP recommendations \(database of topics\)](#)

3. Visit the Office of Research [News and Announcements](#) page to stay current on regulatory requirements

- a. Subscribe by sending a blank email to the following groups
 - i. [HRP](mailto:or-irb-hrp-join@department-lists.uci.edu): or-irb-hrp-join@department-lists.uci.edu
 - ii. Contracts and Grants: cg-news-join@uci.edu
 - iii. [ERA](mailto:or-era-join@department-lists.uci.edu): or-era-join@department-lists.uci.edu