UC Irvine
Education and Guidance Documents

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

Permalink
https://escholarship.org/uc/item/0bg3q1b0

Author
Estanol, Laverne

Publication Date
2019-07-01

Copyright Information

Title: IRB Navigator – Regulatory Background, Submission Standards, and Post-Approval Responsibilities
Date of Last Revision: 07/22/19, 09/03/19
Audience: Researchers
Citation: https://escholarship.org/uc/item/0bg3q1b0

	DESCRIPTION

Background and Significance of Human Subjects Research (HSR) Regulations	1. Regulation
	   a. Timelines
	      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
	      i. 45 CFR 46
	      ii. Revised (2018) 45 CFR 46
	         ▪ Matrix of the revisions
	   d. FDA History
	      i. ICH GCP E6 R2
	
	2. UCI's Mission Statement
	   a. UCI Chancellor's Pillars
	   b. UCI Vice Chancellor for Research's Strategic Plan
	
	3. National Academy of Sciences (2019)
	   a. Reproducibility and Replicability in Science – Improve Transparency and Rigor in Science
	
	4. About UCI HRP and the IRB
	   a. Policies
	   b. Guidance for Researchers
	   c. Contacts
	
	5. About UCI Research Protection's Education and Quality Improvement Program (EQUIP)

Activities that meet the definition of Human Subjects Research (HSR) require IRB review	1. The definition of HSR inclusively meets both parts of this definition:
	   a. 45 CFR 46.102(e)(1) and 45 CFR 46.102(l)
	
	2. Additional definitions
	   a. Clinical Investigation of a Drug (or, Biologic)
	   b. Clinical Investigation of a Device
	      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:
	   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(j)
	        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
         - **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: or-irb-hrp-join@department-lists.uci.edu
	        ii. Contracts and Grants: cg-news-join@uci.edu
	        iii. ERA: or-era-join@department-lists.uci.edu