UCI Office of Research
Research Administration

Quarterly Research Administration Meeting

December 11, 2024

Agenda

- Welcome
- ERA Updates
- Huron for IRB and HSCRO
- C&G Accounting Updates
- Q&A and Closing

Breakouts

Would you rather travel to a beach destination or ski resort?

Would you rather travel to space or travel to the past?

Would you rather live in a remote destination or the heart of a metropolitan city?

ERA Updates

KR PD Route Log Tips

Pending Action Requests hide

	Action	Requested Of	Time/Date	Annotation
show	IN ACTION LIST COMPLETE	Lew, Jonathan	01:26 PM 11/20/2024	DOCUMENT RETURNED: Review Notes: fix the problem section; Mission documents.

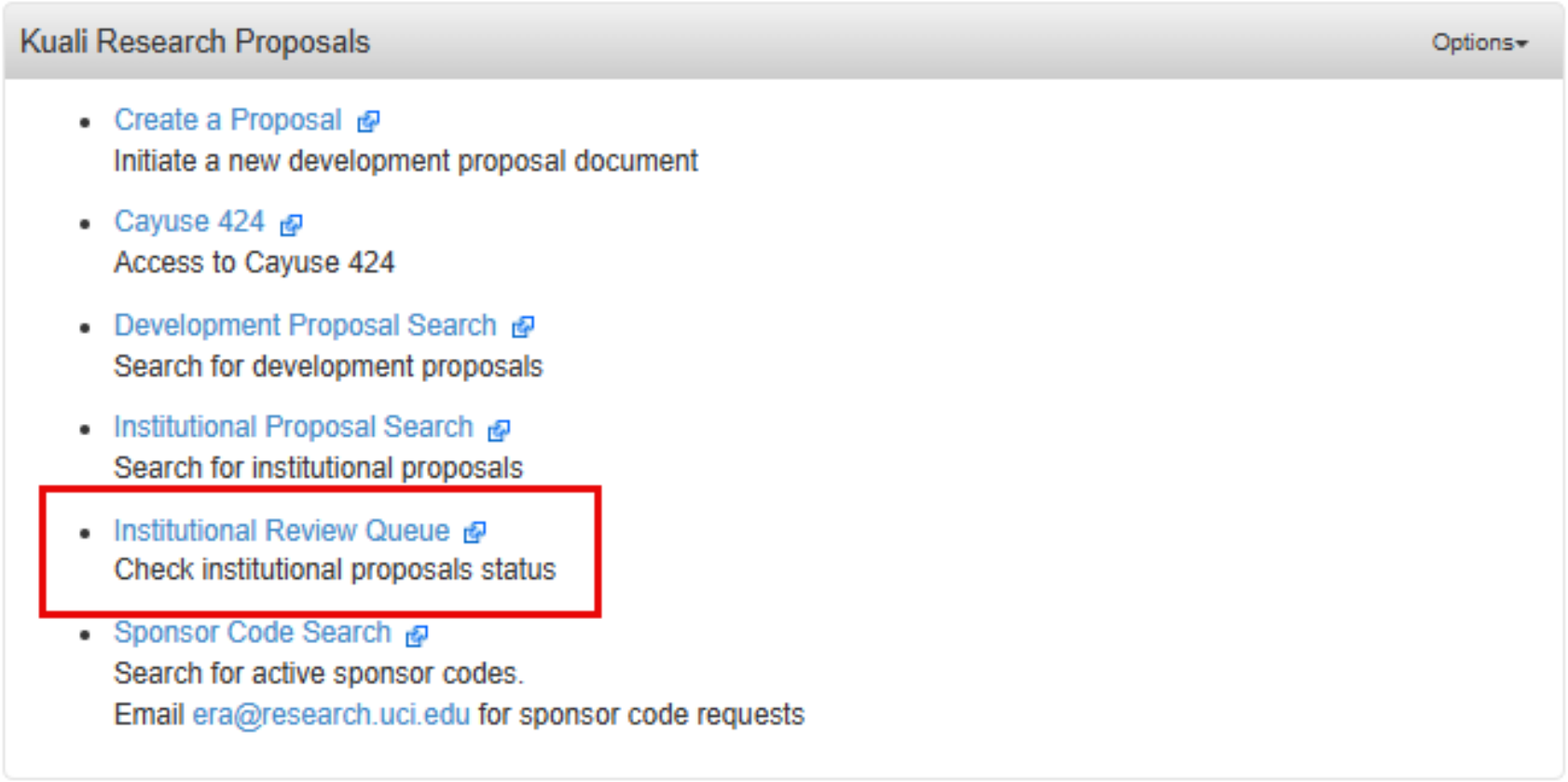
Future Action Requests hide

	Action	Requested Of	Time/Date	Annotation
show	PENDING FYI	Non-Federal Officers	01:36 PM 11/20/2024	PeopleFlow Name: Non-Federal Officers Approvers
show	PENDING APPROVE	Anteater, Peter	01:37 PM 11/20/2024	Role: KC-PD PI from PeopleFlow Name: Proposal Development Standard Workflow
show	PENDING APPROVE	Byrnes, Holly (Chair Approval) Digman, Michelle (Chair Approval)	01:37 PM 11/20/2024	Role: KR-WKFLW Chair Approval from PeopleFlow Name: Chair Approval PeopleFlow
show	PENDING APPROVE	Mcclyde, Kara (Dean Approval) Muylle, Cynthia (Dean Approval)	01:37 PM 11/20/2024	Role: KR-WKFLW Dean Approval from PeopleFlow Name: Dean Approval PeopleFlow
show	PENDING APPROVE	Non-Federal Officers	01:37 PM 11/20/2024	PeopleFlow Name: Non-Federal Officers Approvers

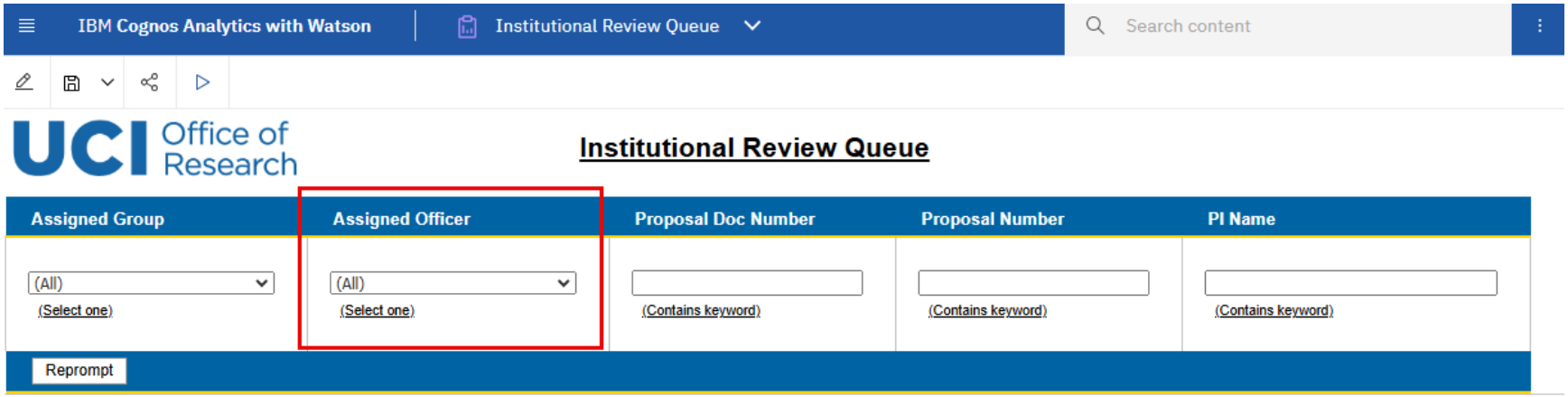
KR KSAMS Roles – What do they mean?

KR – Proposal Creator	Create proposals for assigned Lead Unit(s)
KR – Administrative Contact	Access ALL proposals created under the assigned Lead Unit(s) to assist in editing

Institutional Review Queue (IRQ)



Institutional Review Queue (IRQ)



Institutional Review Queue (IRQ)

(7 result(s) found)

SPA Arrival Date	Proposal Number	Proposal Doc Number	Sponsor Deadline Date	Sponsor Deadline Type	Sponsor Deadline Time	PI Name	Proposal State	Assigned Officer	Reviewing Officer	Sponsor Name	Unit Name	Project Title
11-23-2024 6:59:16 AM	232919	2734870	11-27-2024	Receipt		Kristin Turney	Revisions Requested	Madison Spiva		NATIONAL SCIENCE FOUNDATION	SOCIOLOGY	Deaths During and After Jail Incarceration
12-01-2024 9:01:18 PM	232735	2732685	12-04-2024	Receipt	5:00 PM	An Do	Approval Pending	Madison Spiva		NATIONAL SCIENCE FOUNDATION	NEUROLOGY	BRING-SynBio:Closed Loop Control of Neuroregeneration After Stroke
12-06-2024 3:19:40 PM	233020	2735914	12-08-2024	Receipt		Isabel Almeida	Revisions Requested	Madison Spiva		NATIONAL INSTITUTES OF HEALTH CENTER FOR SCIENTIFIC REVIEW	LANGUAGE SCIENCE	Effects of acculturation and social support on birth outcomes in Mexican American women
12-03-2024 11:58:58 PM	232979	2735390	12-10-2024	Receipt		Darci Trader	Revisions Requested	Madison Spiva		NIH/MISCELLANEOUS AGENCIES & DEPARTMENTS	PHARMACEUTICAL SCIENCE	Monitoring and Manipulating the Activity of the Immunoproteasome with Small Molecules.
12-03-2024 11:59:23 PM	232978	2735387	12-10-2024	Receipt		Darci Trader	Approval Pending	Madison Spiva	Submitted - Lourdes	NIH/MISCELLANEOUS AGENCIES & DEPARTMENTS	PHARMACEUTICAL SCIENCE	Development of Proteasome Substrate Labeling Assays
12-05-2024 9:56:25 PM	232980	2735406	12-10-2024	Receipt	5:00 PM	Ulrike Luderer	Revisions Requested	Madison Spiva	Cindy Lam	NIH/MISCELLANEOUS AGENCIES & DEPARTMENTS	ENVIRONMENTAL & OCCUPATIONAL HEALTH	Is Adolescence a Sensitive Window for Cannabinoid-Induced Ovarian Toxicity?
12-05-2024 10:02:36 PM	232982	2735427	12-10-2024	Receipt		Michael Demetriou	Revisions Requested	Madison Spiva	Cindy Lam	NIH/MISCELLANEOUS AGENCIES & DEPARTMENTS	NEUROLOGY	N-acetylglucosamine as a biomarker and therapeutic in multiple sclerosis

Questions?

Current and Pending Support

Preview and feedback

Upcoming in early 2025

- **ERA support will move to Service Now**
- Replacing era@research.uci.edu for support requests
- User friendly Kuali Build form -> Service Now
- ERA will communicate via Service Now

- **Why?**
  - Increase in support requests
  - Increase in ERA support team
  - To limit back and forth, obtain all necessary info up front
  - Transparency
  - Metrics
  - Workload
  - Knowledge Base

Questions?

Breakouts

What is your superpower?

**something you do extraordinarily well with little effort and high impact*

WE ALL HAVE ONE!

Agenda

- Welcome
- ***ERA Updates***
- Huron for IRB and HSCRO
- C&G Accounting Updates
- Q&A and Closing

Questions

Agenda

- Welcome
- ERA Updates
- ***Huron for IRB and HSCRO***
- C&G Accounting Updates
- Q&A and Closing

Huron IRB / hSCRO at UCI

Topics

- What we're doing
- Why
- Timeline
- Scope
- How and when you can help
- Sneak Peek
- Q&A

Huron IRB and Safety

- Replacing Kuali Research Protocols (KRP)
- Implementing Huron for IRB and hSCRO
- Software as a Service (SAAS) version 10.X
  - Limited customizations
  - Automatic Updates
- HRP Toolkit

Why are we making this change?

- 2021: HRP transitioned to KRP
  - Replacing a 20-year-old home grown system (HPS) that was becoming unstable. KRP was the most cost-effective option at the time.
  - Since implementation, KRP has presented the UCI research community with performance issues.
- Performance gaps that directly impacted the facilitation of research:
  - From 2021 – 2023, unpredictable lagging was noted by both HRP and faculty.
    - In early 2023, lagging resulted in cancelation of subcommittee, delaying IRB review for 6 protocols.
    - HRP continues to perform administrative processes, such as a manual document version check, and manual processing of the IRB approval and consent forms.
    - Numerous ERA and OIT solutions were created to address underdeveloped areas of the system (e.g., IRB approval letters, reports, even a functional IRB agenda).
    - KRP's performance is inconsistent.
- Users desire more transparency in the IRB review process.

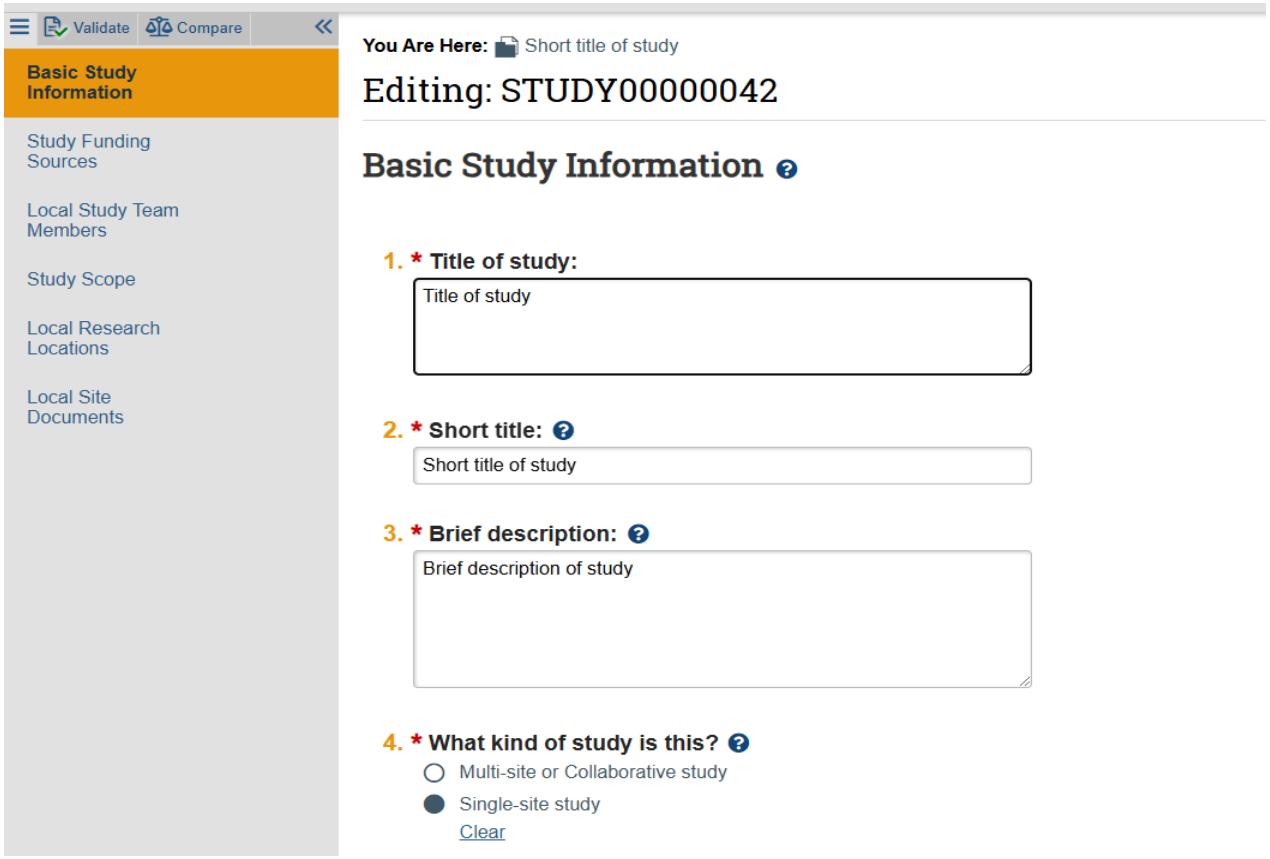
Huron IRB is widely used by research intensive institutions of higher education, including UCLA, USC, CHLA, and soon, UCSF. Other key clients include our commercial IRB partners and Carnegie Mellon, Cedars Sinai, Cleveland Clinic, Fred Hutchinson, Harvard, Johns Hopkins, Mayo Clinic, MD Anderson, Univ. of Michigan, and more.

Users characterize Huron IRB as stable, reliable and efficient. UCI will implement a more cost effective, robust, reputable, cloud-based product that will require less workarounds.

Scope of Implementation

- Smartform
- Toolkit
  - Investigator Manual
  - Protocol Template
  - SOPs
  - Worksheets
  - Checklists

Smartform


Validate
Compare
Basic Study Information
Study Funding Sources
Local Study Team Members
Study Scope
Local Research Locations
Local Site Documents
You Are Here: Short title of study
Editing: STUDY00000042
Basic Study Information
1. * Title of study:
Title of study
2. * Short title:
Short title of study
3. * Brief description:
Brief description of study
4. * What kind of study is this?
Multi-site or Collaborative study
Single-site study
Clear

Investigator Manual

Scope

Throughout this document "institution" refers to University of California, Irvine.

What is the purpose of this manual?

This document, HRP-103 - INVESTIGATOR MANUAL, is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to this institution.

General information regarding Human Research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see below: "What training does my staff and I need in order to conduct Human Research?"

What is Human Research?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN defines the activities that this institution considers to be "Human Research." An algorithm for determining whether an activity is Human Research can be found in HRP-310 - WORKSHEET - Human Research Determination, located in the IRB Policies & Procedures section of the IRB Web site. Use this document for guidance as to whether an activity meets either the DHHS or FDA definition of Human Research, keeping in mind that the IRB makes the ultimate determination in questionable cases as to whether an activity constitutes Human Research subject to IRB oversight.

You are responsible not to conduct Human Research without prior IRB review and approval (or an institutional review and determination of exempt Human Research). If you have questions about whether an activity is Human Research, contact the IRB Office who will provide you with a determination. If you wish to have a written determination, provide a written request to the IRB Office.

What is the Human Research Protection Program?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN describes this institution's

Table of Contents

Protocol Template

PROTOCOL TITLE:

INSTRUCTIONS[i]:

- *Use HRP-503 - TEMPLATE PROTOCOL to prepare a document with the information from following sections.*
- *Depending on the nature of your study, some sections may not be applicable to your research. If so mark as "NA". For example, research involving a retrospective chart review may have many sections with "NA." For subsections, like 1.x or 8.x, you can delete it if it's not applicable.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.*
- *For submission of a protocol specific to a participating Site as part of a Multi-Site Study, use HRP-508 – TEMPLATE - SITE SUPPLEMENT*

PROTOCOL TITLE:

Include the full protocol title.

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

REVISION HISTORY

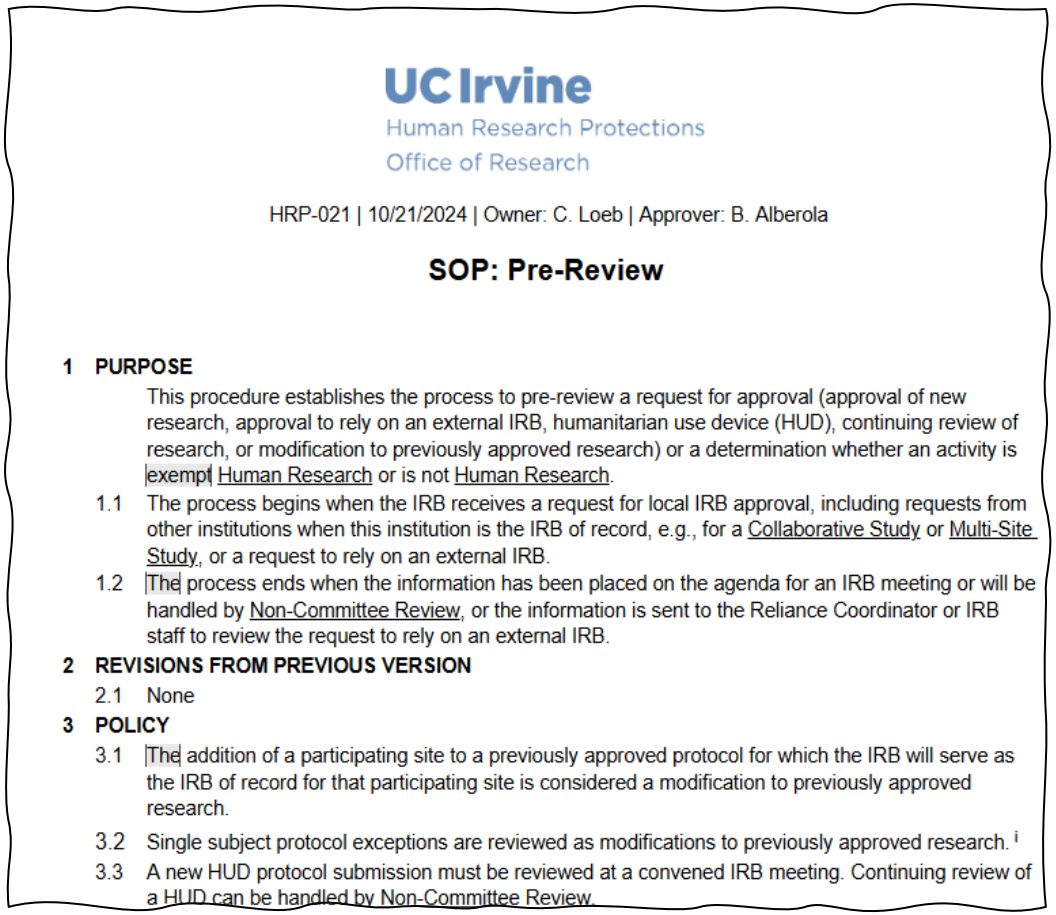
Revision #	Version Date	Summary of Changes	Consent Change?

Table of Contents

Current Document
Ctrl+Click to follow link

SOPs

- HRP-001 - SOP - Definitions.docx
- HRP-012 - SOP - Observation of Consent Pr...
- HRP-013 - SOP - LARs, Children, and Guard...
- HRP-020 - SOP - Incoming Items.docx
- HRP-021 - SOP - Pre-Review.docx
- HRP-023 - SOP - Emergency Use, Compassi...
- HRP-024 - SOP - New Information.docx
- HRP-025 - SOP - Investigations.docx
- HRP-026 - SOP - Suspension or Terminatio...
- HRP-027 - SOP - Emerg Use, Comp Use, In...



UC Irvine
Human Research Protections
Office of Research

HRP-021 | 10/21/2024 | Owner: C. Loeb | Approver: B. Alberola

SOP: Pre-Review

1 PURPOSE

This procedure establishes the process to pre-review a request for approval (approval of new research, approval to rely on an external IRB, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research.

1.1 The process begins when the IRB receives a request for local IRB approval, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study, or a request to rely on an external IRB.

1.2 The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review, or the information is sent to the Reliance Coordinator or IRB staff to review the request to rely on an external IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The addition of a participating site to a previously approved protocol for which the IRB will serve as the IRB of record for that participating site is considered a modification to previously approved research.

3.2 Single subject protocol exceptions are reviewed as modifications to previously approved research. [i]

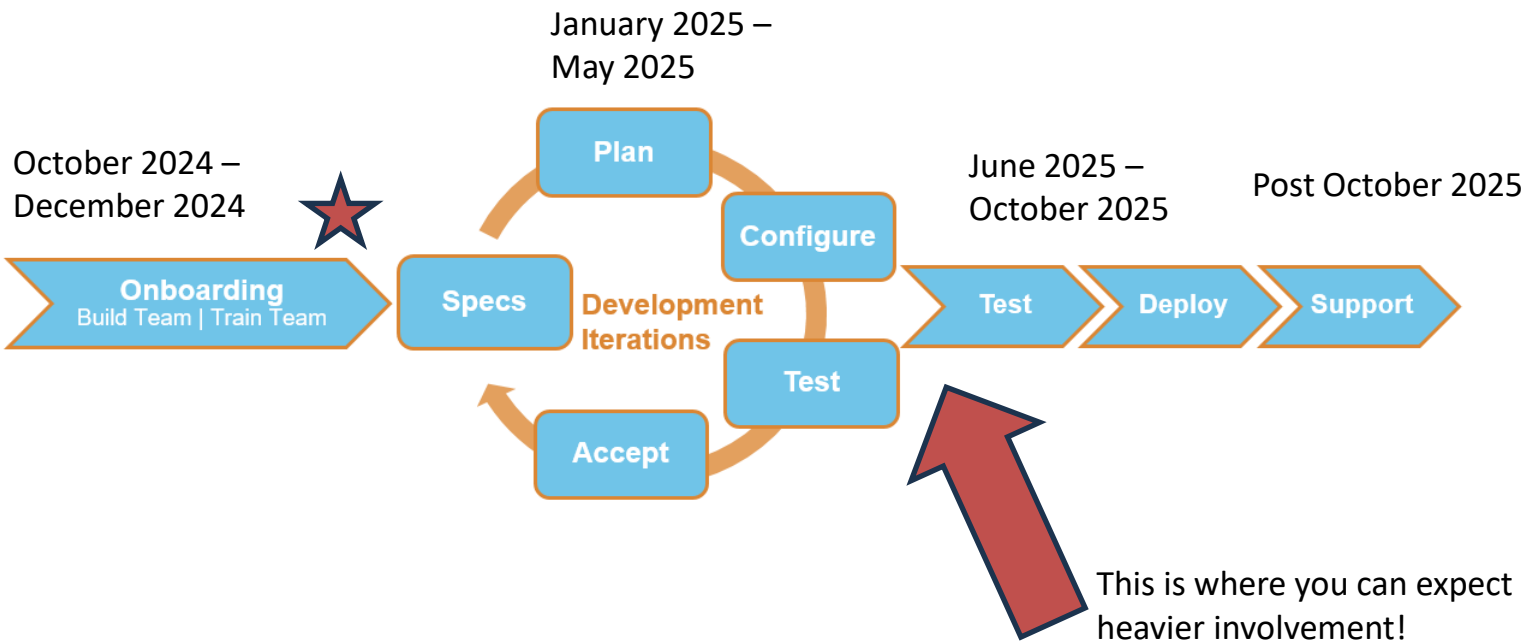
3.3 A new HUD protocol submission must be reviewed at a convened IRB meeting. Continuing review of a HUD can be handled by Non-Committee Review.

Worksheets and Checklists

- HRP-301 - WORKSHEET - Review Materials....
- HRP-302 - WORKSHEET - Approval Interval...
- HRP-303 - WORKSHEET - Communication ...
- HRP-304 - WORKSHEET - IRB Composition....
- HRP-305 - WORKSHEET - Quorum and Exp...
- HRP-306 - WORKSHEET - Drugs and Biolog...
- HRP-307 - WORKSHEET - Devices.docx
- HRP-308 - WORKSHEET - Pre-Review.docx
- HRP-309 - WORKSHEET - Ancillary Review ...
- HRP-310 - WORKSHEET - Human Research ...
- HRP-311 - WORKSHEET - Engagement Det...
- HRP-312 - WORKSHEET - Exemption Deter...

- HRP-401 - CHECKLIST - Pre-Review.docx
- HRP-402 - CHECKLIST - Non-Committee Re...
- HRP-410 - CHECKLIST - Waiver or Alteratio...
- HRP-411 - CHECKLIST - Waiver of Written ...
- HRP-412 - CHECKLIST - Pregnant Women.d...
- HRP-413 - CHECKLIST - Non-Viable Neonat...
- HRP-414 - CHECKLIST - Neonates of Uncert...
- HRP-415 - CHECKLIST - Prisoners.docx
- HRP-416 - CHECKLIST - Children.docx
- HRP-417 - CHECKLIST - Cognitively Impaire...
- HRP-418 - CHECKLIST - Non-Significant Ris...
- HRP-419 - CHECKLIST - Waiver of Consent ...
- HRP-430 - CHECKLIST - Investigator Quality...

Overall Timeline



Screenshots

Validate Compare

Basic Study Information
Study Funding Sources
Local Study Team Members
Study Scope
Local Research Locations
Drugs
Devices
Local Site Documents

Editing: STUDY00000050

Basic Study Information

1. * **Title of study:**
Barbara's test

2. * **Short lay language title:**
Barbara's Test

3. * **Brief description:**
This is a test.

4. * **What kind of study is this?**
○ Multi-site or Collaborative study
● Single-site study
Clear

5. * **Will an external IRB act as the IRB of record for this study?**
○ Yes ● No Clear

6. * **Local principal investigator:**
Rebecca Simms (pi) ···

7. * **Does the local principal investigator have a financial interest related to this research?**
○ Yes ● No Clear

8. * **Attach the protocol:**
+ Add

	Document	Category	Date Modified	Document History	
Update	InstructionalCalendar_2024-25.pdf(0.01)	IRB Protocol	12/6/2024	History	

Pre-Submission

STUDY00000050: Barbara's Test

Last updated: 12/6/2024 12:57 PM

Principal investigator: Rebecca Simms (pi)
Submission type: Initial Study
Primary contact: Rebecca Simms (pi)
PI proxies:

IRB office: Human Research Protections
IRB coordinator:

Next Steps

Edit Study

Printer Version

Submit

Assign Primary Contact

Committee Review

MOD00000005: Modification / Update #1 for Study IRB RP 2024-10-07 B ST

Entered IRB: 10/22/2024 11:53 AM
Last updated: 10/25/2024 4:08 PM

Principal investigator: Rebecca Simms (pi)
Submission type: Modification / Update
Primary contact: Rebecca Simms (pi)

IRB office: Human Research Protections
IRB coordinator: Orlando Max (irbc)
Regulatory authority: 2018 Requirements

Next Steps

View Modification/CR

Printer Version

Manage Ancillary Reviews

Approved

STUDY00000047: 11/13/2024 test YS

Entered IRB: 11/26/2024 11:24 AM
Initial approval: 11/26/2024
Initial effective: 11/26/2024
Effective: 11/27/2024
Approval end: 11/25/2025
Last updated: 11/27/2024 5:15 PM

Principal investigator: Rebecca Simms (pi)
Submission type: Initial Study
Primary contact: Rebecca Simms (pi)
PI proxies:

IRB office: Human Research Protections
IRB coordinator: Orlando Max (irbc)
Letter: Correspondence_for_STUDY00000047.pdf(0.01) ...
Regulatory authority: 2018 Requirements

Next Steps

View Study

Printer Version

Create Modification/CR

Report New Information

Assign Primary Contact

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

History | Funding | Contacts | Documents | Follow-on Submissions | Reviews | Snapshots

Filter by Activity | Enter text to search | Add Filter | Clear All

Activity	Author	Activity Date
Modification MOD00000009 review complete: Approved Modification: MOD00000009	Max (irbc), Orlando	11/27/2024 5:15 PM
Modification MOD00000009 Opened	Simms (pi), Rebecca	11/27/2024 5:05 PM

Poll: What should we name Huron for IRB and hSCRO?

Questions?

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- ***C&G Accounting Updates***
- Q&A and Closing

UCI Office of Research
Research Administration

Contracts & Grants Accounting

Alice Han

Director, Extramural Funds Accounting

Agenda

- Contracts and Grants Accounting staff update
- C&G accounting training

Staff Update

- Effective 11/4/2024: New Contracts and Grants Manager- Vivian Situ
- Open position: Contracts and Grants Accounting Accountant IV and Compliance analyst

C&G Training

COURSE #1 (CGS 1) Introduction to Fund Management
Thursday, January 30, 2025, 10:30 a.m. – 12 p.m.

COURSE #2 (CGS 2) Direct vs. F&A
Tuesday, February 4, 2025, 10:30 a.m. – 12 p.m.

COURSE #6 (CGS 6) Ledger Reading and Award Closeout
Thursday, February 6, 2025, 10:15 a.m. – 12 p.m.

Available in UCLC as an e-Course

COURSE #3 (CGS 3) General Error Correction (GEC)/Cost Transfers
COURSE #4 (CGS 4) Payroll Certification
COURSE #5 (CGS 5) Cost Sharing

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A Reminder About the Winter Administrative Recess

- The Office of Research will be closed during the UCI Winter Administrative Recess *(Tuesday, December 24, 2024 through Wednesday, January 1, 2025, with the campus reopening Thursday, January 2nd).*

- Lead Researchers and administrative contacts should be mindful of this closure when planning proposal submissions, or submissions to UCI regulatory committees.

- Should you have any questions regarding funding opportunities with proposal submission deadlines that fall during the Winter Administrative Recess, please contact the Contract and Grant Officer(s) assigned to your unit as soon as possible.

- For dates related to IRB, IACUC or hSCRO submissions, please check the various committee calendars at the following links: IRB Calendar, IACUC Calendar, HSCRO Calendar.

Happy Holidays