



OHRPP Updates

February 11, 2021

OHRPP Updates

Introducing New MIRB 2 Administrator



Reminder - CITI Updates



New BRUIN IRB – Phase I



New IRB Administrator Melissa Nowicki to lead MIRB 2



- **Melissa Nowicki – MIRB 2 Administrator**
- melissa.nowicki@research.ucla.edu

Updates to OHRPP's CITI training for Human Subjects:

- OHRPP will now accept either GCP or HS training courses to fulfil the requirement for human subjects protection training.
 - o GCP training is required for key personnel conducting NIH-funded research that meets the NIH definition of a clinical trial.

Updates to OHRPP's CITI training for Human Subjects:

- The HS training course in CITI has been made more flexible:
 - o For initial training, researchers may select any 8 modules to complete the course. For refresher training, any 4 elective modules may be selected.

 - o The Biomedical and Social/Behavioral courses have been combined. The course includes both types of modules. Researchers may select any modules relevant to the type of research they conduct.

Updates to OHRPP's CITI training for Human Subjects:

- The path to select UCLA training in CITI under “add a course” now includes a skip pattern, so you’ll only see training relevant to the type of research you conduct.

Question 1

SECTION ONE: DETERMINING THE TRAINING REQUIRED In order to determine which course(s) you may need to take, please indicate which of the following categories apply to you (check all that apply)

This question is required. Choose all that apply.

- I conduct human subjects research/Realizo investigaciones con sujetos humanos ["OHRPP" \[SECTION TWO\]](#)
- I conduct animal research ([RSAWA](#)) [SECTION THREE]
- I conduct research that involves using hazardous biological material or recombinant or synthetic nucleic acids ([IBC](#)) [SECTION FOUR]
- I conduct research that meets the definition of [Dual Use Research of Concern \("DURC"\)](#). ([RSAWA](#)) [SECTION FIVE]
- I was instructed to take a course by [Research Policy and Compliance](#) in order to meet the Responsible Conduct of Research training requirements of the agency funding the research [SECTION SIX]
- I have a special role (OHRPP Staff, IRB member, IACUC member, IBC member, DURC committee member, Institutional Official) in the research enterprise at UCLA that requires me to take training. [SECTION SEVEN]

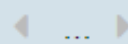
New BRUIN IRB – Phase I - My Inbox

Create ▾

Study Expiration Dates

Enter search terms to

No pending items to do.



Recently Viewed

STUDY00000024: My First Study

My Inbox Assignments In Process

My Inbox

Filter by ID Enter text to search for + Add Filter x Clear All

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY00000024	My First Study	2/3/2021 1:03 PM	2/3/2021 2:08 PM	Pre-Submission	

1 items

page 1 of 1

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New BRUIN IRB – Phase I - Protocol Workspace

»
Dashboard
IRB Home
IRB

Submissions
Meetings
Reports
Library
Help Center

Pre-Submission

Last updated: 2/3/2021 2:08 PM

Next Steps

Edit Study

Printer Version

- [Submit](#)
- [Assign Primary Contact](#)
- [Assign PI Proxy](#)
- [Manage Ancillary Reviews](#)
- [Manage Guest List](#)
- [Add Related Grant](#)
- [Add Comment](#)
- [Copy Submission](#)
- [Discard](#)

STUDY00000024: My First Study

Principal investigator: Joe Bruin **IRB office:** IRB

Submission type: Initial Study **IRB coordinator:**

Primary contact: Joe Bruin

PI proxies:

```

graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[IRB Review]
    C --> D[Post-Review]
    D --> E[Review Complete]
    B --> B1[Clarification Requested]
    B1 --> B
    C --> C1[Clarification Requested]
    C1 --> C
    D --> D1[Modifications Required]
    D1 --> D
          
```

History
Funding
Contacts
Documents
Reviews
Snapshots

Filter by Activity Q + Add Filter x Clear All

	Activity	Author	Activity Date
	Study Created	Bruin, Joe	2/3/2021 1:03 PM

(IRB - STUDY - In review)

New BRUIN IRB – Phase I - Basic Study Information Page

Validate Compare <<

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Drugs

Devices

Local Site Documents

You Are Here: My First Study

Editing: STUDY00000024

Basic Study Information

- * Title of study:**
- * Short title: ?**
- * Brief description: ?**
- * What kind of study is this? ?**
 Multi-site or Collaborative study
 Single-site study
[Clear](#)
- * Will an external IRB act as the IRB of record for this study? ?**
 Yes No [Clear](#)
- * Local principal investigator: ?**
Joe Bruin

New BRUIN IRB – Phase I - Study Funding Sources

☰ Validate Compare <<

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

You Are Here: 📁 My First Study

Editing: STUDY00000024

Study Funding Sources

1. Identify each organization supplying funding for the study:

	Funding Source	Sponsor's Funding	Grants Office ID	Attachments
<input type="button" value="✎ Update"/>	NIH - NATIONAL INSTITUTES OF HEALTH	1234		My Grant Application <input type="button" value="✕"/>

New BRUIN IRB – Phase I - Study Team Members

Validate
Compare

Go to forms menu
Print
Help

You Are Here: My First Study

Editing: STUDY00000024

Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research: ?

+ Add

	Name	Roles	Financial Interest Review Status	Involved in Consent	Training						
Update	Michael Yuan	Co-investigator	no	yes	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Good Clinical Practice (OPTIONAL)</td> <td style="width: 33%;">UCLA HIPAA</td> <td style="width: 33%;">Human Subject</td> </tr> <tr> <td>Completed: 10/18/2018 Expires: 10/17/2021 ✓</td> <td>Completed: 10/3/2018 Expires: - ✓</td> <td>Completed: 10/3/2018 Expires: 10/2/2021 ✓</td> </tr> </table>	Good Clinical Practice (OPTIONAL)	UCLA HIPAA	Human Subject	Completed: 10/18/2018 Expires: 10/17/2021 ✓	Completed: 10/3/2018 Expires: - ✓	Completed: 10/3/2018 Expires: 10/2/2021 ✓
Good Clinical Practice (OPTIONAL)	UCLA HIPAA	Human Subject									
Completed: 10/18/2018 Expires: 10/17/2021 ✓	Completed: 10/3/2018 Expires: - ✓	Completed: 10/3/2018 Expires: 10/2/2021 ✓									

2. PI Training:

Good Clinical Practice (OPTIONAL)	UCLA HIPAA	Human Subject
—	—	—

3. External team member information: ?

+ Add

Name	Training/Qualifications and Study role(s):
There are no items to display	

New BRUIN IRB – Phase I - Study Scope

Validate Compare <<

You Are Here: My First Study

Editing: STUDY00000024

Go to forms menu Print Help

Study Scope ?

- * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**
 Yes No [Clear](#)
- * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**
 Yes No [Clear](#)
- Is your protocol one of the following?**
 - Right to Try
 - Emergency Use
 - Expanded Access/Compassionate Use[Clear](#)
- Is this a COVID-19 research proposal that falls under the following scope:**
 - a. Access to the suspected and confirmed UCLA Health COVID-19 patients.
 - b. Access to the electronic medical record chart or data of those patients.
 - c. Access to the remnant or research biospecimen collection of those patients.
 - d. Planning any clinical research interventional trial (drug/device) for those patients.
 - e. COVID Population-based studies that overlap the UCLA Health population or UCLA healthcare workers. Yes
 No
[Clear](#)

New BRUIN IRB – Phase I - Research Locations

☰ Validate Compare <<

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

You Are Here: 📄 My First Study

Editing: STUDY00000024

◀ Go to forms menu 🖨️ Print ▾ ? Help

Local Research Locations

1. * Indicate the locations where any research activities will be performed by the UCLA research team with participants and/or private information obtained.

Check all that apply: ?

- UCLA Sites or UCLA Health System Sites (Does not include Harbor-UCLA Medical Center, Olive View-UCLA Medical Center, or Orthopaedic Institute for Children)
- Off Campus (in California)
- Outside California (in the U.S.)
- Outside the United States
- Internet

New BRUIN IRB – Phase I - Drug Information

Validate Compare

You Are Here: My First Study

Editing: STUDY00000024

Drugs ?

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:

+ Add

Generic Name	Brand Name	Attachment Name
<input type="text"/>	<input type="text"/>	<input type="text"/>

Update Drug Name Drug Brand Name

2. * Will the study be conducted under any IND numbers? ?

Yes No [Clear](#)

3. * Identify each IND:

+ Add

IND Number	IND Holder	Other Holder
<input type="text"/>	<input type="text"/>	<input type="text"/>

IND1234 Sponsor

4. Attach files: (such as IND or other information that was not attached for a specific drug) ?

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

New BRUIN IRB – Phase I - Device Information

Validate Compare

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Drugs

Devices

Local Site Documents

You Are Here: My First Study

Editing: STUDY00000024

Devices ?

1. * Select each device the study will use as an HUD or evaluate for safety or effectiveness:

+ Add

Device	Humanitarian Use Device	Attachment Name
<input type="checkbox"/> Update Device Name	no	<input type="checkbox"/>

2. * Device exemptions applicable to this study: ?

- IDE number
- HDE number
- Claim of abbreviated IDE (nonsignificant risk device)
- Exempt from IDE requirements

[Clear](#)

3. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device) ?

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

New BRUIN IRB – Phase I - Local Site Documents

Validate Compare

Basic Study Information

Study Funding Sources

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Local Research Locations

Drugs

Devices

Local Site Documents

You Are Here: My First Study

Editing: STUDY00000024

Local Site Documents

1. Consent forms: (include an HHS-approved sample consent document, if applicable) ?

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads) ?

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

3. Other attachments:

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

i Suggested attachments:

- If applicable, provide the PI exception letter.
- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms



Learn at Lunch – upcoming session

February 24, 2021, noon-1pm

***“Obtaining consent under special circumstances:
Bill of Rights, Short Form, and Surrogate
Consent”***

presented by Moore Rhys, OHRPP

➤ [Register](#) for this event on zoom



OHRPP's "Office Hours"

- OHRPP Quality Improvement Unit staff are hosting *half-hour open Q/A sessions every other week* to answer your questions
- *Upcoming sessions*
 - Tuesday, February 16, 2021 8:30am
 - Tuesday, March 2, 2021 8:30am

Register once and you can join any session.



Subscribe to *Human Research News*

To be in the know when OHRPP releases updated guidance and offers training opportunities, please subscribe to *Human Research News*

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Any Questions?

Contact Information

OHRPP Website

<https://ohrpp.research.ucla.edu>

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