

BruinIRB Overview

May 13, 2021



What is BruinIRB?

- Electronic IRB submission system
- Similar platform to current system (webIRB)
 - *webIRB is no longer supported by the vendor*
- Simplified system (fewer electronic pages to complete)
- Relies more on protocol upload
 - *Template protocols for different types of IRB submissions are part of the roll-out*

Who is involved in the development of BruinIRB?

- OHRPP & ORIS staff
- Faculty advisory committee
- Beta-testers from the research community
- Feedback from users in each phase (IRB members, investigators, research staff, OHRPP staff)

Overview of transition

Roll-out of new system is happening in phases

Phase 1

(as of April 5, 2021)

- Clinical use of HUD
- Emergency Use
- Expanded access
- Right To Try



Phase 1b

(later in 2021, date TBD)

- reliance applications



Phase 2

(late 2021 or early 2022, date TBD)

- all other new applications
- transition of existing studies from webIRB

Create A New Study

The screenshot shows the Bruin IRB system interface. At the top left is the Bruin IRB logo, followed by the UCLA Research Administration logo and a 'TEST' label in a yellow box. Below this is a navigation bar with 'Dashboard', 'IRB Home', and 'IRB' tabs. A 'Create' button is highlighted with a red box. A dropdown menu is open, showing 'IRB' as the parent category. Two options are listed: 'Create New Study' (highlighted with a red box) and 'Report New Information'. In the background, there is a 'My Inbox' section with tabs for 'My Inbox', 'Assignments', and 'In Process'. Below these tabs is a search bar with 'by ?' and 'ID' fields, and a table with columns 'Name' and 'ID'. The table contains three rows of data:

ID	Name
3-21-5013	Shenica 3.22
3-21-5011-4-001	Modification / Update # Example
IRB-21-5004	Test

Study Work Space

Pre-Submission

Last updated: 4/2/2021 8:30 AM

Next Steps

Edit Study

Printer Version

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

Add Public Comment

Copy Submission

Discard

IRB-21-5017: Staff Demo

Principal investigator: Joe Bruin

Submission type: Initial Study

Study type: Expanded Access/Compassionate Use

Primary contact: Lubabah Helwani

PI proxies:

IRB office: IRB

IRB owner:

```

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

History | Funding | Contacts | Documents | Reviews | Snapshots

Filter by Activity + Add Filter ✕ Clear All

	Activity	Author	Activity Date
	Guest List Updated	Helwani, Lubabah	3/31/2021 11:42 AM

BruinIRB – Manage Guest List

Pre-Review

Entered IRB: 3/11/2021 10:14 AM
Last updated: 3/11/2021 10:14 AM


Next Steps

[View Study](#)

[Printer Version](#)

- [Submit Pre-Review](#)
- [Request Pre-Review Clarification](#)
- [Assign Coordinator](#)
- [Assign Primary Contact](#)
- [Assign PI Proxy](#)
- [Assign IRB](#)
- [Manage Ancillary Reviews](#)
- [Manage Guest List](#)**
- [Add Related Grant](#)
- [Add Public Comment](#)
- [Add Private Comment](#)

Manage Guest List



The following people can view the details of this submission without being on the guest list:

Principal investigator:
Joe Bruin

Primary contact:
Joe Bruin

Study team members:
There are no items to display

Ancillary reviewers for organizations:
There are no items to display

Guest list for allowing additional people to view the submission:

...

First Name	Last Name	Employer	Title
There are no items to display			

BruinIRB Application – Basic Study Information – Part 1

The screenshot displays the BruinIRB application interface. At the top left, the BruinIRB logo is shown next to the UCLA Research Administration logo. A yellow 'TEST' badge is visible in the top right. The user's name, 'Hello, Lubabah Helwani', is displayed in the top right corner. Below the header, there are navigation options: 'Validate' and 'Compare'. The main content area is titled 'Basic Study Information' and shows the current study ID as 'IRB-21-5017'. The form contains four numbered sections: 1. 'Title of study' with a text input field containing 'Demo for Staff'; 2. 'Short title' with a text input field containing 'Staff Demo'; 3. 'Brief description' with a text area containing 'Go through entire application'; 4. 'What kind of study is this?' with radio button options for 'Multi-site or Collaborative study' and 'Single-site study', where 'Single-site study' is selected. At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue'.

BruinIRB | UCLA Research Administration | **TEST** | Hello, Lubabah Helwani

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: Staff Demo

Editing: IRB-21-5017

Go to forms menu Print Help

Basic Study Information

- * Title of study:**
Demo for Staff
- * Short title:**
Staff Demo
- * Brief description:**
Go through entire application
- * What kind of study is this?**
 Multi-site or Collaborative study
 Single-site study

Exit Save Continue

BruinIRB Application – Basic Study Information – Part 2

Validate Compare <<

Go to forms menu Print Help

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Drugs

Devices

Local Site Documents

5. * Will an external IRB act as the IRB of record for this study? ?
 Yes No [Clear](#)

6. * Local principal investigator: ?
Joe Bruin ... ✕

7. * Attach the protocol: ?

+ Add

Document	Category	Date Modified	Document History
Update Protocol(2)	IRB Protocol	4/2/2021	History ✕

8. * Select the IRB that you think best matches your research.

Name	Description
<input type="radio"/> Medical Institutional Review Board 1	MIRB1 reviews general and internal medicine, infectious diseases and ophthalmologic research.
<input checked="" type="radio"/> Medical Institutional Review Board 2	MIRB2 reviews oncology and hematology research.
<input type="radio"/> Medical Institutional Review Board 3	MIRB3 reviews neuroscience, neurology, psychiatric, drug abuse and dental research.
<input type="radio"/> North General Institutional Review Board	NGIRB reviews research from the College of Letters & Science and the Professional Schools.
<input type="radio"/> South General Institutional Review Board	SGIRB reviews social-behavioral research from the Schools of Public Health, Nursing, and Medicine.

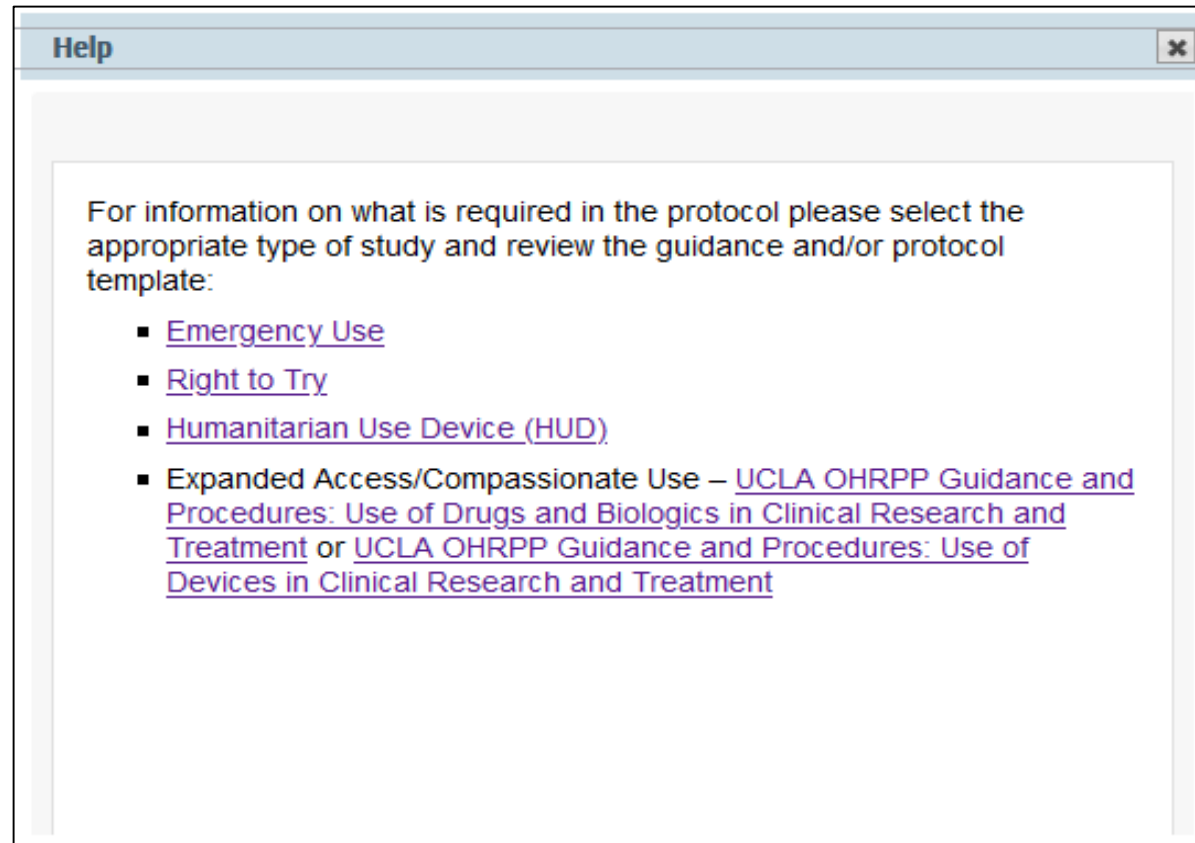
[Clear](#)

9. * Does the local principal investigator have a financial interest related to this research? ?
 Yes No [Clear](#)



✕ Exit Save Continue →

Help Text

All questions that contain the question mark icon  contain help text



The screenshot shows the BruinIRB application interface. At the top left is the BruinIRB logo and the UCLA Research Administration logo. A yellow 'TEST' badge is visible in the top right. The navigation menu on the left includes: Basic Study Information, Study Funding Sources (highlighted), Local Study Team Members, Study Scope, Local Research Locations, Drugs, Devices, and Local Site Documents. The main content area shows 'You Are Here: Staff Demo' and 'Editing: IRB-21-5017'. Below this is the 'Study Funding Sources' section with the instruction: '1. Identify each organization supplying funding for the study:'. There is an '+ Add' button and a table with the following data:

Funding Source	Sponsor's Funding	Grants Office ID	Attachments
 Update 100 WOMEN IN HEDGE FUNDS			Grant Application 

BruinIRB Application – Study Team Members

Validate Compare

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Drugs

Devices

Local Site Documents

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 Khoi Do	Co-Investigator	no	yes	Good Clinical Practice (OPTIONAL) — UCLA HIPAA <input checked="" type="checkbox"/> Completed: 4/14/2011 Human Subject <input checked="" type="checkbox"/> Expiry: 9/15/2022
Update Lubabah Helwani	Co-Investigator	no	yes	Good Clinical Practice (OPTIONAL) — UCLA HIPAA <input checked="" type="checkbox"/> Completed: 3/9/2020 Human Subject <input checked="" type="checkbox"/> Expiry: 3/9/2023
Update Jonathan Orin	Co-Investigator	no	yes	Good Clinical Practice (OPTIONAL) — UCLA HIPAA <input checked="" type="checkbox"/> Completed: 7/22/2013 Human Subject <input checked="" type="checkbox"/> Expiry: 8/21/2022

2. PI Training:

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

3. Will your study include any of the following:

- UCLA health sciences volunteers
- UCLA other volunteers
- UCLA medical students
- UCLA residents
- UCLA fellows
- Other

4. Non-UCLA Personnel information:

[+ Add](#)

BruinIRB | UCLA Research Administration **TEST**

Validate Compare

You Are Here: Staff Demo

Editing: IRB-21-5017

Study Scope

1. * 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](#)

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?
 Yes No [Clear](#)

3. Is your protocol one of the following?
 Right to Try
 Emergency Use
 Expanded Access/Compassionate Use
 None of the Above
[Clear](#)

a. * Select the type of Expanded Access/Compassionate Use:
 Single patient IND or IDE
 Intermediate size patient population
 Expanded access treatment protocol
[Clear](#)

b. * Indicate if you are requesting to use alternative IRB review procedures.
 Yes
 No
[Clear](#)

4. * 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](#)

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BruinIRB Application – Drug(s)

UCLA
Research Administration

TEST

Validate Compare

You Are Here: Staff Demo

Editing: IRB-21-5017

Drugs ?

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

[+ Add](#)

Generic Name	Brand Name	Attachment Name
5-Fluorouracil	5-FU; Adrucil	IB

[Update](#)

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

Yes No [Clear](#)

3. * Identify each IND:

[+ Add](#)

IND Number	IND Holder	Other Holder
1234567	Sponsor	

[Update](#)

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

[+ Add](#)

Document	Category	Date Modified	Document History
IND FDA confirmation(0.01)	Drug Attachment	3/31/2021	History

[Update](#)

BruinIRB UCLA Research Administration **TEST**

Validate Compare

You Are Here: Staff Demo

Editing: IRB-21-5017

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
Dissector, Surgical, General & Plastic Surgery	no	IFU

Update

2. * Device exemptions applicable to this study:

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

Clear

3. * Identify each IDE or HDE number:

+ Add

IDE / HDE Number	IDE / HDE Holder	Other Holder
9876543	Sponsor	

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

+ Add

Document	Category	Date Modified	Document History
FDA HDE confirmation(0.01)	Device Attachment	3/31/2021	History

Update

BruinIRB Application – Site Documents

BruinIRB | UCLA Research Administration | **TEST**

Validate Compare

You Are Here: Staff Demo

Editing: IRB-21-5017

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			

Suggested attachments:

- If applicable, provide the PI exception letter.
- Other site-related documents not attached on previous forms

Q: *Will have to submit a new application for an application that has already been approved in webIRB?*

A: No. As part of the plans in development for phase 2, OHRPP and ORIS are working on a way to move studies from one system to the other. Stay tuned for details on how this will be accomplished.

Q: *What if I'm submitting a study that already has a protocol? Will I have to re-write the protocol to match the OHRPP protocol template?*

A: No. If your existing protocol is missing some of the details requested in the OHRPP template, we will ask you to submit a supplement to the existing protocol to provide the required information.

OHRPP's [Electronic Submission Systems](#) page

- Updated information related to the roll-out
- Links to available template protocols
- Link to training guides
- Contact information to provide feedback or ask questions

“Human Research News” – subscribe via [ORA and Department News Subscription](#)

- Announcements relating to the BruinIRB roll-out