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
IRB-21-5017: Staff Demo

Principal Investigator: Joe Brun
Submission type: Initial Study
Study type: Expanded Access/Compassionate Use
Primary contact: Lubabah Helwani
PI proxies:

Pre-Submission

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

History
- Funding
- Contacts
- Documents
- Reviews
- Snapshots

Filter by
- Activity
- Enter text to search for

Activity
- Activity Date
- Guest List Updated
- Helwani, Lubabah

Pre-Submission

Pre-Review

IRB Review

Post-Review

Review Complete

Clarification Requested

Modifications Required
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:

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Employer</th>
<th>Title</th>
</tr>
</thead>
</table>

There are no items to display
BruinIRB Application – Basic Study Information – Part 1

Basic Study Information

1. * Title of study:
   Demo for Staff

2. * Short title:
   Staff Demo

3. * Brief description:
   Go through entire application

4. * What kind of study is this? 
   - Multi-site or Collaborative study
   - Single-site study
5. * Will an external IRB act as the IRB of record for this study? *
   - Yes
   - No

6. * Local principal investigator: *
   - Joe Brain

7. * Attach the protocol: *
   - Document: IRB Protocol
     - Date Modified: 4/2/2021

8. * Select the IRB that you think best matches your research. *
   - Medical Institutional Review Board 1
   - Medical Institutional Review Board 2
   - Medical Institutional Review Board 3
   - North General Institutional Review Board
   - South General Institutional Review Board

9. * Does the local principal investigator have a financial interest related to this research? *
   - Yes
   - No
All questions that contain the question mark icon contain help text.

Help Text

For information on what is required in the protocol please select the appropriate type of study and review the guidance and/or protocol template:

- Emergency Use
- Right to Try
- Humanitarian Use Device (HUD)
- Expanded Access/Compassionate Use – UCLA OHRPP Guidance and Procedures: Use of Drugs and Biologics in Clinical Research and Treatment or UCLA OHRPP Guidance and Procedures: Use of Devices in Clinical Research and Treatment
BruinIRB Application – Funding

Study Funding Sources

1. Identify each organization supplying funding for the study:

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Sponsor’s Funding</th>
<th>Grants Office ID</th>
<th>Attachments</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 WOMEN IN HEDGE FUNDS</td>
<td></td>
<td></td>
<td>Grant Application</td>
</tr>
</tbody>
</table>
BruinIRB Application – 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

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

3. Is your protocol one of the following?  
   - Research
   - Emergency Use
   - Expanded Access/Compassionate use
   - None of the Above
      - Single patient IND or IDE
      - Interim size patient population
      - Expanded access treatment protocol

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 these patients.
   c. Access to the specimen or research biopsies collection of these patients.
   d. Planning any clinical research interventional trial (drug/device) for those patients.
   e. COVID Population-based studies that enroll the UCLA Health population or UCLA healthcare workers.
      - Yes
      - No
BruinIRB Application – Research Location(s)

Editing: IRB-21-5017

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.

- 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
BruinIRB Application – Drug(s)
BruinIRB Application – Device(s)
BruinIRB Application – Site Documents

Local Site Documents

1. Consent forms: Include an IRB-approved sample consent document, if applicable

2. Recruitment materials: Include all material to be seen or heard by subjects, including audio

3. Other attachments:

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

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- Announcements relating to the BruinIRB roll-out