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.
  
  - 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:
  - For initial training, researchers may select any 8 modules to complete the course. For refresher training, any 4 elective modules may be selected.
  - 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.
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.
New BRUIN IRB – Phase I - My Inbox

Dashboard | IRB Home | IRB

Create

Study Expiration Dates

Enter search terms

No pending items to do.

Recently Viewed

STUDY00000024: My First Study

My Inbox

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Date Created</th>
<th>Date Modified</th>
<th>State</th>
<th>Coordinator</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY00000024</td>
<td>My First Study</td>
<td>2/3/2021 1:03 PM</td>
<td>2/3/2021 2:08 PM</td>
<td>Pre-Submission</td>
<td></td>
</tr>
</tbody>
</table>

1 items

Page 1 of 1

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New BRUIN IRB – Phase I - Protocol Workspace
New BRUIN IRB – Phase I - Study Funding Sources

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>NIH - NATIONAL INSTITUTES OF HEALTH</td>
<td>1234</td>
<td></td>
<td>My Grant Application</td>
</tr>
</tbody>
</table>
New BRUIN IRB – Phase I - Study Team Members

### Local Study Team Members

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Financial Interest Review Status</th>
<th>Involved in Consent</th>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michael Yuan</td>
<td>Co-investigator</td>
<td>No</td>
<td>yes</td>
<td>Good Clinical Practice (OPTIONAL)</td>
</tr>
</tbody>
</table>

   - Completed: 10/10/2012
   - Expires: 10/17/2021

2. PI Training:
   - Good Clinical Practice (OPTIONAL)
   - UCLA HIPAA
   - Human Subject

3. External team member information:

   - Name
   - Training/Qualifications and Study role(s):

There are no items to display
New BRUIN IRB – Phase I - 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?
   - Right to Try
   - Emergency Use
   - Expanded Access/Compassionate Use

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 intervention trial (drug/device) for those patients.
   e. COVID Population-based studies that overlap the UCLA Health population or UCLA healthcare workers.
   - Yes
   - No
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

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**Drugs**

1. *List all drugs, biologics, foods, and dietary supplements to be used in the study:*
   
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Attachment Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. *Will the study be conducted under any IND numbers?*
   
   - Yes
   - No
   - Clear

3. *Identify each IND:*
   
<table>
<thead>
<tr>
<th>IND Number</th>
<th>IND Holder</th>
<th>Other Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>IND1234</td>
<td>Sponsor</td>
<td></td>
</tr>
</tbody>
</table>

4. **Attach files:** (such as IND or other information that was not attached for a specific drug)
   
<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
New BRUIN IRB – Phase I - Device Information

You Are Here: My First Study
Editing: STUDY0000024

Devices

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Humanitarian Use Device</th>
<th>Attachment Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Add</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. * Device exemptions applicable to this study:

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

3. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device)
New BRUIN IRB – Phase I - 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)
   - 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)
   - Document  Category  Date Modified  Document History
   - There are no items to display

3. Other attachments:
   - Document  Category  Date Modified  Document History
   - There are no items to display

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

➢ *To subscribe, visit* [ORA news subscription](#)
Any Questions?

Contact Information

OHRPP Website
https://ohrpp.research.ucla.edu

Kristin Craun, OHRPP Director
Phone: x33150
Email: kristin.craun@research.ucla.edu