Research Administration Forum

May 13, 2021
Welcome and Reminders

• This is NOT being recorded

• We will answer questions at the end of each segment as time permits

• Submit questions via Zoom Q&A window

• Use the “raise hand” option to ask a question verbally. You will be allowed to unmute.

• Slides will be posted on ORA website following the meeting
Agenda

• Welcome & Announcements – Marcia Smith

• Human Research Protection Program – Kristin Craun
  ◦ Bruin IRB Phase 1 Roll-out

• Extramural Fund Management – Robert De Jesus
  ◦ Effort Reporting Release
  ◦ Fiscal Closing Model

• Contract and Grant Administration – Kathy Kawamura
  ◦ NIH Updates

• Research Administration Hub and Spoke Model Initiative – Marcia Smith

• Q&A – Open Forum
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
Study Work Space

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
Pre-Review
IRB Review
Post-Review
Review Complete

Clarification Requested
Clarification Requested
Modifications Required

History
Funding
Contacts
Documents
Reviews
Snapshots

Filter by
Activity
Enter text to search for

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:**

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Employer</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</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
BruinIRB Application – Basic Study Information – Part 2

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

6. * Local principal investigator: 
   Joe Bruin

7. * Attach the protocol:
   
<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol1</td>
<td>IRB Protocol</td>
<td>4/2/2021</td>
<td>History</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Institutional Review Board 1</td>
<td>MIRB1 reviews general and internal medicine, infectious diseases and ophthalmologic research.</td>
</tr>
<tr>
<td>Medical Institutional Review Board 2</td>
<td>MIRB2 reviews oncology and hematology research.</td>
</tr>
<tr>
<td>Medical Institutional Review Board 3</td>
<td>MIRB3 reviews neuroscience, neurology, psychiatry, drug abuse and dental research.</td>
</tr>
<tr>
<td>North General Institutional Review Board</td>
<td>NGIRB reviews research from the College of Letters &amp; Science and the Professional Schools.</td>
</tr>
<tr>
<td>South General Institutional Review Board</td>
<td>SGIRB reviews social behavioral research from the Schools of Public Health, Nursing, and Medicine.</td>
</tr>
</tbody>
</table>

9. * Does the local principal investigator have a financial interest related to this research? 
   - Yes
   - No
   - Clear
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

You Are Here: Staff Demo

Editing: IRB-21-5017

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 Team Members
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?
   - [ ] Emergency Use
   - [ ] Expanded Access/Compassionate Use
   - [ ] None of the Above
   - a. * Select the type of Expanded Access/Compassionate Use:
      - [ ] Single patient IND or IDE
      - [ ] Interim data from patient population
      - [ ] Expanded access treatment protocol

4. * Is this a COVID-19 research proposal that falls under the following scope?
   - Yes [ ] No [ ]
   - 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 bioprecipitate collection of those patients.
   - d. Planning any clinical research intervention (medication or device) for those patients.
   - e. COVID Population-based studies that overlap the UCLA Health population or UCLA healthcare workers.
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.

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
BruinIRB Application – Drug(s)
BruinIRB Application – Device(s)

Devices

1. Select each device the study will use as an HED 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>Gastroscop, Surgical, General &amp; Plastic Surgery</td>
<td>Yes</td>
<td>IRU</td>
</tr>
</tbody>
</table>

2. Device exemptions applicable to this study:
- IDE number
- IDE number
- Claim of abbreviated IDE (non-significant risk device)
- Exempt from IDE requirements
- Clinical

3. Identify each IDE or HDE number:

<table>
<thead>
<tr>
<th>IDE / HDE Number</th>
<th>IDE / HDE Holder</th>
<th>Other Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>123456</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA IDE confirmation (DE)</td>
<td>Device Attachment</td>
<td>3/31/2021</td>
<td>History</td>
</tr>
</tbody>
</table>
BruinIRB Application – Site Documents

Local Site Documents

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

2. Recruitment materials: Add all materials to be seen or heard by subjects, including ads.

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.
Resources

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
• FY 2020-21 Fiscal Closing Activities
• Effort Report Release
FY20-21 Fiscal Closing Updates

Robert De Jesus
2020–21 Fiscal Year End Close Overview

• Business and Finance Solutions (BFS) has announced the Fiscal Year End (FYE) Closing Activities FY2020-21.

• EFM has compiled deadlines for campus to submit to EFM for review and processing

• EFM sent an announcement of FYE Close EFM deadlines on 05/07/2021.
  ◦ Email Subject: 2020-21 FYE Close - EFM Deadlines
What to do in May and continuing through FYE Close

• Review the fiscal closing letter and schedule to identify deadlines applicable to your area

• Conduct monthly reconciliation and ledger review:
  ◦ Verify that expenses booked to the ledger have been recorded to the appropriate FAU
  ◦ Process cost transfers for adjustments, if needed
  ◦ Submit vendor and subcontractor invoices to Accounts Payable in a timely manner
  ◦ Contact vendors and subcontractors for invoices billing for goods and services rendered during FY20-21
# FYE Close – Department Deadline for Submission to EFM

<table>
<thead>
<tr>
<th>Description</th>
<th>Deadline to Submit to EFM for Review/Processing</th>
<th>Deadline for EFM to Review, Approve, and Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payroll (UCPath) Direct Retro Expense Transfer</td>
<td>06/30/2021 @ 5:00 PM</td>
<td>07/06/2021 @ 5:00 PM</td>
</tr>
<tr>
<td>PPS Costs Transfer Journal Request</td>
<td>06/30/2021 @ 5:00 PM</td>
<td>07/13/2021 @ 5:00 PM</td>
</tr>
<tr>
<td>Intercampus Transfers</td>
<td>07/02/2021 @ 5:00 PM</td>
<td>07/13/2021 @ 5:00 PM</td>
</tr>
<tr>
<td>Accrual/Deferral Forms and Supporting Documents</td>
<td>07/06/2021 @ 5:00 PM</td>
<td>07/13/2021 @ 5:00 PM</td>
</tr>
<tr>
<td>NPEAR Non-Payroll Expense Adjustments</td>
<td>07/06/2021 @ 5:00 PM</td>
<td>07/13/2021 @ 5:00 PM</td>
</tr>
</tbody>
</table>
Treatment of Late Cost Transfer Submission

- Review and Approval of Late submission of Cost Transfers cannot be guaranteed by EFM

- Expense transfers that are not reviewed due to late submission will be reviewed and processed next fiscal year.
When accruals are required & why it matters:

- The Governmental Accounting Standards Board (GASB) requires the UC/UCLA financial statements to be prepared on an “accrual basis” where expenses incurred in a fiscal year are recorded to the year which goods and services were rendered.
- Submit Reimbursement Requests and Vendor Invoices to Accounts Payable by June 21, 2021 to be recorded as part of FY2020-21 Expenses
- If you missed the AP deadline of June 21, 2021, submit an Accrual Request to EFM by July 6, 2021
  - Complete the accrual Form E
  - Complete journal justification
  - Submit supporting documentation to EFM at EFMOperations@research.ucla.edu

**Note:** Accrual forms, justification template, and instructions will be published by BFS in June 2021
Effort Reporting Release

Robert De Jesus
# Effort Report Release Overview

The current progress projects Effort reports to be released on Monday, May 17, 2021 for the following periods:

<table>
<thead>
<tr>
<th>Reporting Period</th>
<th>Non-Academics and 11/12 Academics</th>
<th>9/12 Academics</th>
<th>Certification Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fall 2019</td>
<td>October – December 2019</td>
<td>July – October 2019</td>
<td>June 30, 2021</td>
</tr>
<tr>
<td>Fall 2020</td>
<td>October – December 2020</td>
<td>July – October 2020</td>
<td>July 31, 2021</td>
</tr>
</tbody>
</table>
Effort Report Release Overview

• In total **43,830** Effort Reports will be generated across the March 2019 – March 2021
  ➢ **3,260** Effort Reports (7.44% of Total Effort Reports) will have “Under Prelim Review” flag due to various UCPATH Defects which will block the ability to certify these reports.
• All payroll transactions through March 2021 are loaded in ERS so all direct retros processed through that period are reflected in the effort reports.
• General information on certifying effort reports can be found on the ERS section of the EFM website: [https://efm.research.ucla.edu/ers-overview/](https://efm.research.ucla.edu/ers-overview/)
Effort Report with “Under Preliminary Review” Flag

- As noted per the last Effort Report Release on October 2020, some reports have been flagged as “Under Preliminary Review” in ERS due to unresolved UCPath defects.
  - An Updated ERS Master Exception List of all effort reports flagged as “Under Preliminary Review” along with special instructions can be found on EFM’s website: https://efm.research.ucla.edu/ers-training/#specialinstructions
  - In addition, the “Under Preliminary Review” flag appears in two places in ERS:
    1. Under a separate column in the employee’s Report List
    2. On the effort report in the upper right corner with a red box
Effort Report with “Under Preliminary Review” Flag

• There are five unresolved UCPath issues that are being flagged in impacted effort reports. Additional issues may be added to the exception list if any are discovered.

• The specific issue impacting an effort report is noted in 1) the ERS Master Exception List Excel file and 2) under the “Comment Log” in the effort report in ERS:
# Effort Reports by the Numbers

## Effort Reports Generated Statistics Spring 2019 – Winter 2019*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Effort Reports Generated</td>
<td>43,830</td>
</tr>
<tr>
<td>Effort Reports with UCPATH Defect*</td>
<td>3,260</td>
</tr>
<tr>
<td>Affected Population %</td>
<td>7.44%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UCPATH Defect</th>
<th>Number of Reports affected</th>
<th>Required Campus Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earnings with Missing Hours</td>
<td>827</td>
<td>Review Supplemental file and job aid provided by EFM before certification</td>
</tr>
<tr>
<td>Pending Mass Leave Correction</td>
<td>1,031</td>
<td>Effort Reports should not be certified until EFM provides further instructions</td>
</tr>
<tr>
<td>Missing Payroll Lines</td>
<td>1,199</td>
<td>Effort Reports should not be certified until EFM provides further instructions</td>
</tr>
<tr>
<td>Missing Y-OTC or N-OTC Lines</td>
<td>471</td>
<td></td>
</tr>
</tbody>
</table>

*Effort Reports may be affected by one or more UCPATH Defect*

- Earnings with Missing Hours, Missing Payroll Lines and Missing Y-OTC or N-OTC Lines.
Review of UCPATH Defects affecting Effort Reports

- **Mass Leave Correction (MLC)** is correcting two issues related to exceptions taken (e.g., VAC, SKL) which has been discussed in detail during the November 2020 RAF [https://ora.research.ucla.edu/wp-content/uploads/RAF-2020-11-EFM.pdf](https://ora.research.ucla.edu/wp-content/uploads/RAF-2020-11-EFM.pdf)
  - The first batch of MLC was processed to address issues for transactions posted between September 2018 – June 2020
    - Effort Reports with corrected records will be unflagged and will be ready for certification
    - Effort Reports affected by MLC that failed the validation test will remain flagged
  - The second batch of MLC is scheduled for June 2021 and will address issues for transactions posted between July 2020 – January 2021
    - Effort Reports affected by the Leave issues for this period will be flagged with “Under Preliminary Review” citing “Pending Mass Leave Correction”
Any Questions?

Contact Information -

EFM Website
http://efm.research.ucla.edu

ERS Help Desk
Email: ershelp@research.ucla.edu

Robert De Jesus
Phone: X46997
Email: Robert.dejesus@research.ucla.edu
Q1: Would it be possible that RAF meetings to be recorded and posted to the site? These meetings sometimes conflict with deadlines and faculty meetings. It would be helpful to post the recordings as the RAF meetings provide more in-depth information and compliment the slides provided. Thank you for your consideration.

A1: Not at this time. I will discuss it with the team.

Q2: Why are you doing ERS reporting in the middle of fiscal closing? Why didn’t you wait until mid-July? Do you think fund managers have time to give their attention to this certification at this time?

A2: Just do the best you can. We have had a terrible time getting the reports out of the system. This has been outside of our control.

Q3: Can you please provide the links for retro and effort reports. The ones you referenced. Thanks


Q4: Investigators CAN use the new biosketch format though, if they want... right?

A4: Yes, and recommended so that we’re ready when it becomes required.