

Human Research News

December 16, 2024

1) Just-In-Time Submissions – Reminders

Some sponsors, such as the NIH, use a “just-in-time” process to collect time-sensitive information (such as documentation of IRB review) after the proposal has received a fundable score but before making an award.

Researchers who are informed that their proposal may be funded should submit a BruinIRB application **as soon as possible**.

For NIH sponsored projects, please ensure that you upload [the NIH summary statement](#) with your submission.

Please contact gcirb@research.ucla.edu with any questions on this process or your submissions.

2) BruinIRB clarification regarding stamped documents for Amendments (AMs)

When an amendment is approved, only the consent forms and recruitment materials that have been newly added or updated as part of the amendment will receive a new IRB stamp in the document footer. All other documents will not receive a new stamp.

As a reminder, approved study documents remain valid until a revision is approved as part of a subsequent AM and a new version is released with an updated approval date.

Newly stamped documents can be found as links in the AM approval letter and are also listed in the BruinIRB study workspace Documents tab under “Site Approved Documents”.

3) BruinIRB updated on December 12, 2024

This update includes the following that impact study teams:

- **Devices SmartForm and Help Text**

Study questions were updated to apply both to studies that include a device that is FDA-approved and those that are investigational.

Study Scope Section

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

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)? **This may include diagnostics, software, off-label uses, unapproved devices and in some cases cleared or marketed devices used within their approved labeling.**
 Yes No REVISED

Devices Section

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

Device	Humanitarian Use Device	Attachment Name
There are no items to display		

1. * List each device that is the subject of the investigation: ? REVISED

Device	Humanitarian Use Device	Attachment Name
There are no items to display		

2. * Device exemptions applicable to this study: ? PREVIOUS VERSION

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

2. * Select the regulatory oversight for the proposed device: ? REVISED

- IDE number
- HDE number
- Claim of abbreviated IDE (nonsignificant risk device)
- Exempt from IDE requirements
- FDA approved device used according to approved indications

4) Reminder - Action Required on Pending webIRB Submissions by Dec 19th at 5pm

To complete the transition to BruinIRB, OHRPP is requesting that you take action on your pending application(s) in webIRB, as soon as possible, but **no later than 5:00 PM on December 19, 2024.**

Refer to the November 18th, 2024 [HRN](#) for details.

5) Reminder - OHRPP's Winter Holiday closure

In observance of the [UCLA Winter Holiday Closure](#), the Office of the Human Research Protection Program will be closed from Saturday, December 21st, 2024, through Wednesday, January 1st, 2025.

If you have a full-board study that will expire during the closure period, please submit the Continuing Review as soon as possible so it can be assigned to a [committee meeting](#). Please contact your IRB Administrator if you require assistance.

6) Updates to [BruinIRB Quick Guides and Resources](#)

Quick Guides

[Migration – Updating BruinIRB after Migration](#) (Updated)

- Updated the Devices section (Page 5) to align with the December 12th BruinIRB updates. See item 3 in this HRN for details on the SmartForm changes.

7) Updates to OHRPP [Policies and Guidance](#)

[Annual Assurance Quick Guide](#) (Updated – previously titled "Tip Sheet: Annual Assurance")

- Removed reference to exempt studies since they do not require Annual Assurances (Page 1)
- Added statement to clarify that Annual Assurance Reminder will also be sent on the anniversary date (Page 1)

8) OHRPP's Office Hours

[Register once](#) to join any session:

Upcoming Office Hours:

- December 19th, 2024, at 2pm
- January 2nd, 2025, at 2pm

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