

## Human Research News

February 5, 2025

### 1) OHRPP Learn at Lunch Presentation –

#### ***Document management and other tips for IRB submissions***

Presenter: Moore Rhys, Assistant Director, OHRPP

This presentation will review what is and isn't needed for IRB submissions, tips from OHRPP staff and IRB Chairs, and how to manage revised documents over the life of the study.

Date: **Tuesday, February 25<sup>th</sup>, 2025**

Time: **Noon-1pm**

Location: **Zoom** ([Register](#) for this meeting)

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

#### Quick Guides

##### [Assurances – Annual Assurances Required for Principal Investigator and Faculty Sponsor \(Updated\)](#)

- Updated to provide more information to guide PIs through the annual assurance process.

##### [Follow-on Submissions – Create and Submit a CR, AM, CRAM \(Updated\)](#)

- Clarified that multiple AM submissions can be created but that only one AM can be created for each Amendment Scope.

##### [Devices - Completing the Device Section in BruinIRB \(New\)](#)

- This is a new document to assist with the Device section of BruinIRB.

### 3) Updates to OHRPP Website

### [Human Subjects Protection Certification via CITI:](#)

- Updated to include instructions for identifying completed training in BruinIRB. The instructions for webIRB have been removed.

## **4) Updates to OHRPP [Policies and Guidance](#)**

### [Communication of Results of IRB Review](#) (Updated)

- Clarified that the approval period for research requiring Full Committee review is based on guidance from the Office for Human Research Protections (OHRP) and from the Food and Drug Administration (FDA).
- Clarified that except for FDA and Department of Justice (DOJ) regulated studies that require annual review, the approval period for research reviewed under expedited review procedures will not require a continuing review, unless there is adequate justification confirmed by the expedited reviewer.

### [IRB Review Type – Continuing Review](#) (Updated)

- Added Federal Reporting section to clarify that the expiration of IRB approval is not considered suspension or termination of research and will not be reported to OHRP or FDA.
- Included the requirement for the completion of PI Annual Assurances for research that relies on the approval of an external IRB (reliance)

## **5) OHRPP's Office Hours**

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

### **Upcoming Office Hours:**

- February 13<sup>th</sup>, 2025, at 2pm
- February 27<sup>th</sup>, 2025, at 2pm

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