



# Research Administration

## Human Research Protection Program

### Human Research News

June 4, 2024

#### 1) BruinIRB Training Presentations

OHRPP is moving forward with a transition to the BruinIRB system for IRB submissions. To support the research community during this transition, OHRPP has put together a schedule of trainings. All trainings will be recorded and available on [OHRPP's YouTube channel](#) shortly after each session.

#### Upcoming (all presentations are from noon-1pm)

Date	Presentation	Registration link
Thursday June 6, 2024	Learn at Lunch: <i>BruinIRB Protocol Uploads</i>	<a href="#">Link</a>
Tuesday June 25, 2024	Learn at Lunch: <i>Migration of Existing Studies from webIRB to BruinIRB</i>	<a href="#">Link</a>
Tuesday July 9, 2024	Learn at Lunch: <i>CR/AMs and AMs in BruinIRB</i>	<a href="#">Link</a>
Wednesday July 24, 2024	Learn at Lunch: <i>How to Submit New Studies in BruinIRB</i>	<a href="#">Link</a>
Wednesday August 7, 2024	Learn at Lunch: <i>CRAMs and AMs in BruinIRB (live repeat)</i>	<a href="#">Link</a>
Wednesday August 21, 2024	Learn at Lunch: <i>How to Submit New Studies in BruinIRB (live repeat)</i>	<a href="#">Link</a>

#### Passed

Date	Presentation	YouTube Link
Wednesday May 22, 2024	Learn at Lunch: <i>BruinIRB Phase 2 Roll-out Timeline</i>	<a href="#">Recording Available</a>

## 2) OHRPP's Office Hours

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

### Upcoming Office Hours:

- June 6, 2024, at 2pm
- June 20, 2024, at 2pm

## 3) Revised Post Approval Reporting (PAR) Guidance

The [PAR Guidance](#) and [Deviation Decision Tree](#) have been updated to remove the numeric threshold for reporting minor deviations which would otherwise not require reporting.

The updated guidance now states:

“If any individual deviation does not meet the above criteria, but multiple occurrences of the same type of minor deviation taken as a group suggest a pattern of non-compliance on the part of the study team (or ancillary staff) AND any of the following are met:

- pose increased risk to subjects or others
- has significant adverse impact on the rights or welfare of participants
- has significant adverse impact on the integrity of the data

Please note that procedures occurring out of window or missing the collection of routine vital signs would not require submission unless they posed an increase risk to the subject or had significant impact on the integrity of the study data”

## 4) Outside Training Opportunities and Resources (Live)

- [MCRT Sexual Orientation and Gender Identity \(SOGI\) Data in Clinical Research: Data and Privacy: Tools and Resources for LGBTQAI+ Inclusion by design](#)
  - Tuesday, June 11<sup>th</sup> 9am-10am (12pm ET)
  - The MRCT team will discuss key points from the SOGI Data Collection Checklist and SOGI Data Privacy Checklist, which will be released the same day, as part of the LGBTQIA+ Inclusion by Design in Clinical Research Toolkit. These tools build upon numerous efforts to develop guidance, test methodologies, and share lessons learned. Everyone should be able to see themselves in clinical research data and feel secure that their data is treated with respect and confidentiality.

## 5) Outside Training Opportunities and Resources (On Demand)

- [University of Minnesota's Annual Research Ethics Day Conference - Building Partnerships to Advance Ethical Research: Collaborators, Communities & Companies](#)
  - Interdisciplinary experts discuss the elements of successful collaboration that promote research integrity, inclusivity, mutual respect, and accountability in the conduct of research.
  
- [OHRP's Participant-Centered Informed Consent Training Program](#)
  - This interactive online program consists of 6 modules and delivers a comprehensive training for creating, designing, and reviewing consent forms or templates for the purposes of **ensuring that prospective research participants understand the content and appreciate how it relates to them.**
  
- [The MRCT at Brigham and Women's Hospital new clinical research glossary:](#)
  - This plain-language global standard has been developed at the [MRCT](#) in collaboration with [CDISC](#) for research participants **and anyone interested in developing easy-to-understand research materials.**
  
- [The Accessibility by Design \(AbD\) in Clinical Research Toolkit](#)
  - A comprehensive resource to support greater inclusion of people with disabilities in clinical research. It was developed by the [MRCT Center](#) in collaboration with people with disabilities, family caregivers, allies, disability rights advocates, and stakeholders working in clinical research.

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