



OHRPP Updates

August 13, 2020

OHRPP Updates

Guidance Updates/New
Guidance



Post Approval Monitoring -
update



Learn at Lunch



OHRPP Office
Hours



Human Research
News



Guidance Updates/New Guidance

Certificates of Confidentiality:

- [Tip Sheet: Certificates of Confidentiality](#)
- [Quick Guide: Certificate of Confidentiality \(CoC\) Applications for Non-Federally Funded Research](#)

Right to Try:

- [Right to Try Policy and Guidance](#)
- [Right to Try Consent Form template](#)



Guidance Updates/New Guidance

Reliance:

- [Consent Form Checklist for Reliance on External IRBs](#)
- [Steps to Rely on Another IRB – Flow Chart](#)
- [Relying Investigator Responsibility Checklist](#)
- [When UCLA Relies](#) information on ancillary reviews, amendments, and continuing reviews
- [Steps to serve as the Reviewing IRB – Flow Chart](#)
- [Reviewing Investigator Responsibility Checklist](#)
- [NCI CIRB reliance](#) information on ancillary reviews, amendments, and continuing reviews
- [NCI CIRB Boilerplate Consent Language Checklist](#)

Guidance Updates/New Guidance

Consent:

- [Deception or Incomplete Disclosure](#)
- [Obtaining and Documenting Informed Consent](#) Added table on types of informed consent allowable under FDA and DHHS regulations.

IRB submission and review:

- [Brief Overview of webIRB Submission Procedures](#)
- [Communication of Results of IRB Review](#)
- [List of Exemption Categories – 2018 Rule](#) Added information on exemption category 4(iii).
- [Tip Sheet: Minimal Risk](#)



Guidance Updates/New Guidance

Misc:

- [Funding Considerations for Federally-Funded and Industry Sponsored Human Research](#)
- [Genetics Research](#)
- [Use of Devices in Clinical Research and Treatment](#)
- [Family Educational Rights and Privacy Act \(FERPA\)](#)
- [Closure of Human Subjects Research studies](#)
- [Investigator Responsibilities](#)
- [Research Supported by the Department of Defense](#) Removed the requirement for medical monitors on greater than minimal risk research as it is no longer required.
- [DOD Checklist](#) Removed the requirement for medical monitors on greater than minimal risk research as it is no longer required.

Post Approval Monitoring

- Updated Post Approval Monitoring guidance will be posted early next week
- Routing monitoring now includes a tiered system and begins with an investigator self-assessment
- The focus of the monitoring is to provide investigators and their teams with the tools they need to meet their compliance responsibilities



OHRPP's "Learn at Lunch"

Topic: "Post Approval Monitoring"

Presenter: Moore Rhys, Asst. Director, OHRPP

Date: August 17, 2020, noon-1pm

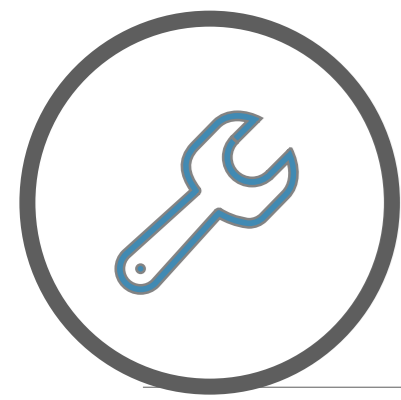
[Register in advance](#)



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, August 18, 2020 8:30am
 - Tuesday, September 1, 2020 8:30am

Register once and you can join any session.



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Any Questions?

Contact Information

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