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
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.
To be in the know when OHRPP releases updated guidance and offers training opportunities, please subscribe to Human Research News

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Any Questions?

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