UCLA Research Administration

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 <u>every other week</u>*** to answer your questions

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

<u>Register once</u> and you can join any session.

Reminder - Subscribe to Human Research News

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

- ***To subscribe, visit ORA news subscription***

Any Questions?

Contact Information

OHRPP Website

http://ohrpp.research.ucla.edu/

Moore Rhys, OHRPP Asst. Director

Phone: x46339
Email: moore.rhys@research.ucla.edu