Regulatory Changes Human Research Protection

AU SPAN Meeting

October 23, 2017

NIH Certificate of Confidentiality (CoC) Policy

Effective Date: October 1, 2017

Retroactive : December 13, 2016

NIH Funded Projects

- NIH CoCs protect identifiable, sensitive information or identifiable biospecimens collected or used for research purposes
- NIH may issue certificates for NIH funded or non-NIH funded research (no change to non-NIH funded)
- Transfer of information or biospecimens requires notice to the recipient that a certificate of confidentiality exists

NIH Funded Projects

- Change in process for NIH funded projects
- PI no longer applies to NIH for CoC
- PI requests CoC in IRB protocol and includes CoC language in consent(s)
- AU IRB determines, as part of protocol review, if CoC Policy applies and consent language is appropriate
- "Deemed Certificate" – No document issued by NIH
- Compliance with the COC Policy is a condition of award

NIH Single IRB (sIRB) Policy

Effective Date: January 25, 2018

Applicability

- Domestic sites of NIH funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research

- **Proposal must include (sIRB) Plan** for ethical review required by 45 CFR 46

- Applies to:
  - cooperative agreements, contracts, and NIH intramural research program
- Does not apply to:
  - career development, research training, or fellowship awards.

sIRB

"IRB of Record" or "Reviewing IRB"

- Conducts ethical review (45 CFR 46)
- Works with Awardee to implement communication mechanism between sIRB and participating sites
- Executes Authorization (Reliance) Agreements
  - Documents respective authorities, roles, responsibilities, and communication between sIRB and participating sites
- May include direct costs for sIRB in proposal budget
  - Cost must be justified, reasonable, and consistent with cost principles

Participating Site

"Relying Institution"

- Relies on sIRB ethical review - 45 CFR 46
- Provides information on local context or state/local regulations to sIRB
- Meets other regulatory obligations
  - Oversees implementation of approved protocol
  - Conducts post approval monitoring
  - Reports problems and study progress to sIRB
  - May serve as HIPAA Privacy Board
- Sites are not prohibited from duplicating sIRB review

sIRB Process

- AU PI completes and submits sIRB Form to AU ORC
  - Submission must be at least 3 weeks before proposal deadline
- AU ORC works with AU PI and External Compliance Programs to develop a proposed sIRB Plan
- AU IRB reviews and approves sIRB Plan and Form
- Project PI includes IRB approved sIRB Plan in proposal to NIH

Revised Common Rule

Effective Date: January 19, 2018

Effective Date for Cooperative Research: January 20,2020

Transition

- Protocol approvals and exempt determinations prior to January 19, 2018 may continue under the pre-2018 Rule.
  - IRB may choose to apply the Revised Common Rule on or after January 19, 2018 on a protocol by protocol basis
- Protocol approvals and exempt determinations on or after January 19, 2018 will be reviewed in accordance with the Revised Common Rule.

Significant Changes

- Definition of Human Subject Research
- Required Elements and Format of Informed Consent
- Public Posting of Some Consent Forms
- New Broad Consent Requirement
- Limitations on Waiver or Alteration of Consent
- Review of Research for Vulnerable Populations
- New and Revised Exempt Categories
- New Limited IRB Review for some Exempt Research
- Use of Stored Identifiable Data or Biospecimens
- Elimination of continuing review for some studies
- Cooperative Research (January 20, 2020)

Implementation Plan

In Process

Communication

- **AU Compliance Office – Complete**
- **Institutional Official (VPRED) – Complete**
- **Sponsored Programs Administration – Complete**
- **IRB Joint Meeting – Complete**
- **Associate Dean for Research Meeting – October 19**
- **AU SPAN – October 23**
- Faculty Research Committee – October 26

Investigator Resources

- **Open Forum**
  - October 26 – OIT 1st Floor Meeting Room – 3:30 pm – 4:30 pm
  - November 29 – CASIC 1st Floor Meeting Room - 3:30 pm – 4:30 pm
- **"What's New" Human Research Webpage**
  - ORC - Human Research (IRB) - What's New
    - NIH CoC Policy Summary Table
    - NIH CoC Process Flowchart
    - NIH sIRB Policy Summary Table
    - NIH sIRB Process Flowchart
- **CITI Training**
  - Updated for regulatory changes

Implementation Tasks

- **Policies & Procedures**
  - Revise Existing Policies and Procedures
  - Draft New Policies and Procedures
- **Forms**
  - Revise Current IRB Submission Forms
  - Develop sIRB Form
- **Sample Documents**
  - Revise Existing Consent Templates
  - Develop Broad Consent Template
- **Investigator Tools and Resources**

How can you help?

- Notify investigators that changes are in process
- Check the What's New webpage for updates
- Inform investigators of tools and resources
- Be aware of proposal requirements
- Encourage attendance at Open Forum