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 C FR 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.
  o 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