NCI CIRB: COMMON RULE UPDATE & AUDIT REPORTING

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AMANDA PUTNICK, CIP
DIRECTOR, CENTRAL OPERATIONS
NCI CIRB OPERATIONS OFFICE

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FOR THE NATIONAL CANCER INSTITUTE

STATUS OF THE COMMON RULE REVISIONS

- 19-April-2018 – HHS released an NPRM proposing a delay in the compliance date for the revised Common Rule to January 21, 2019
    - Previously postponed from 19-January-2018 to 19-July-2018, the NPRM would push back the compliance date an additional 6 months
- NPRM proposes permitting implementation of three "burden-reducing" provisions from the new rule prior to compliance date
- Changes impact:
    - Scope
        - Definitions
        - Exemptions
    - IRB Operations
    - Informed Consent

WHAT'S CHANGING?

Scope and Definitions

- "Burden-reducing" provision #1 Refines definition of research (what's not included)
- Refines definition of human subjects to include information or biospecimens obtained through intervention/interaction, OR identifiable private information or identifiable biospecimens
- Defines clinical trial
- Defines identifiable biospecimen/identifiable private information
    - Definition to be reviewed within 1 year of implementation and every 4 years thereafter
- Revises definition of vulnerable populations (removes pregnant women and "handicapped" individuals)
- Addresses applicability of tribal law
- "Burden-reducing" provision #2: No IRB review of grant applications related to research

WHAT'S CHANGING?

IRB Operations

- Requires use of a Single IRB for multicenter research (includes flexibility for research where this may not be appropriate)
    - ✓ 4 NCI CIRB's serve as the single IRB for NCTN, ETCTN, NCORP, DCP Consortia, PTBC, ABTC, and CITN
- "Burden-reducing" provision #3: No continuing review required for research eligible for expedited review, limited IRB review, or research that continues for data analysis or accessing follow-up data on usual clinical care
    - ✓ CIRB implementation pending final determination re: 18-April NPRM

WHAT'S CHANGING?

Informed Consent (content)

- *New* requirement for clarity and focus of consent content to facilitate understanding.
- Requires a concise summary of study activities, risks and benefits, as an introduction to the consent form.
- New elements of consent:
    - Collection of identifiable private information, identifiable biospecimens
    - Commercial profit disclosure
    - Return of research results (clinically relevant) and whole genome sequencing
- Permits "broad consent" for storage, maintenance, and secondary use of identifiable private information and biospecimens.
    - ✓ NCI Informed Consent Template updated 12-December-2017

WHAT'S CHANGING?

Informed Consent

- No need for waiver of informed consent for recruitment screening
- Requires online posting of consent form for some clinical trials
- Gives the OK for electronic consent (requires written copy be provided)
- Affirms use of Legally Authorized Representative (if no law, institution may designate a representative)

WHAT'S CHANGING?

Exempt Research

- Refines existing categories of exempt research
- Adds new exemption for behavioral interventions that are considered benign
- Introduces "limited IRB review" for two categories of exemption (surveys/interviews, and benign behavioral interventions) where there may be risk to subjects if research data was disclosed to others (i.e. risk of criminal or civil liability or negative impact on financial standing, employability, etc.)
    - ✓ CIRB's scope does not include exempt research.

WHAT TO DO?

Just keep swimming...

- Continue to comply with current Common Rule
- Consent form changes can be implemented now (nothing in current regulations would preclude their implementation)
- CIRB Ops Office has draft SOPs ready for release upon compliance date (once confirmed)
- Full impact of some changes still debated in the IRB world (broad consent, biospecimen issues)
- Guidance from OHRP?

RESOURCES

PRIM&R: https://www.primr.org/commonrule/

- Resources for IRB and Research Professionals (much is publicly available)
- Includes:
    - Summaries of changes
    - Tools developed by different institutions
    - Impact analysis
    - News/Updates

AUDIT REPORTING

Overview of the process:

AUDIT REPORTING

Before you begin:

- Collect the following for submission to the CIRB:
  - audit report
  - response to the audit report
  - the management plan that outlines how the findings will be addressed and future occurrences prevented

AUDIT REPORTING

Follow these steps for reporting an audit finding:

1. **PI OR DESIGNEE REVIEWS AUDIT REPORT**
   - The report is reviews the audit report
2. **PI OR DESIGNEE IDENTIFIES MAJOR AUDIT FINDINGS**
   - There are two categories of audit findings: major and minor.
   - Major finding based on the CTMB guidelines should be submitted to the CIRB as potential serious noncompliance. Any finding that had been documented in a previous audit report should be submitted to the CIRB as potential continuing noncompliance.
3. **PI OR DESIGNEE COMPLETES THE UNANTICIPATED PROBLEM(UP) AND/OR NONCOMPLIANCE WORKSHEET**
   - The PI or designee submits any findings using the UP and/or Noncompliance Worksheet available in IRBManager.

AUDIT REPORTING

Follow these steps for reporting an audit finding:

4. CIRB OPERATIONS OFFICE CONDUCTS ADMINISTRATIVE REVIEW

- The Worksheet is reviewed by the CIRB Operations Office which typical takes two weeks. There may be requests for additional information. Revisions to the Worksheet are completed in IRBManager.

5. CIRB LOCAL CONTEXT COMMITTEE CONDUCTS REVIEW

- The Worksheet is sent to the CIRB Local Context Subcommittee for review whicy typically takes five days. There may be requests for additional information. Revisions to the Worksheet are completed in IRBManager.

6. CIRB SENDS DETERMINATION LETTER TO INSTITUTION

- After the CIRB Local Context Subcommittee approves the Worksheet, the CIRB Operations Office sends a determination letter to:
  - the PI, the person submitting the Worksheet, the Signatory Institution Primary Contact(s), and OHRP and FDA if the event is determined to be reportable.

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