Auditing in a Post-Common Rule World

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Objectives

- Understand the retroactive application of the revised Common Rule
- Highlight key areas where pre and post rules will make a difference when auditing study and IRB committee files
- Discuss potentially high compliance risk areas to focus audit activity in post–Common Rule world

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Agenda

Topics:

- Applicability & Transition
- Continuing Review
- Informed Consent
- Broad Consent
- Exempt Research
- sIRB

For each topic we will:

- Discuss changes under the revised Common Rule
- Discuss possible related compliance risk
- Propose strategies to mitigate compliance risk

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Revised Common Rule Effective & Compliance Date

- Publication Date: January 19, 2017
- Initial Effective & Compliance Date: January 19, 2018
- Interim Final Rule Published January 17, 2018: Delayed effective and compliance Date: July 19, 2018
- Compliance Date for Single IRB: January 20, 2020
- NPRM published April 19, 2018: Intent is to delay effective and compliance date to January 21, 2019 – *next slide*

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Revised Common Rule Effective & Compliance Date

- Propose to delay the general compliance date for the revised common rule an additional 6 months until January 21, 2019
- Proposes to permit institutions to implement (effective July 19,2018) three "burden reducing" provisions in the 2018 requirements:
  1. **the revised definition of "research," which deems four categories of activities not to be research;**
  2. **the allowance for no annual continuing review of certain categories of research; and**
  3. **the elimination of the requirement that institutional review boards (IRBs) review grant applications or other funding proposals related to the research.**
- Accepting comments until May 21, 2018

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Applicability and Transition

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Applicability & Transition

Current Common Rule (terms of FWA)

- Provides an option for organizations to voluntarily chose to apply the requirements of the Common Rule and subparts B,C, and D to all research regardless of the source of funding.

Revised Common Rule

- Common Rule applicability only to non-exempt human research conducted or supported by federal agencies that have signed the Common Rule.

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Applicability & Transition

if April 19 NPRM becomes final

Before July 19, 2018	After July 19, 2018	After January 21, 2019
» Current Common Rule Regulations » FDA Regulations » Institutional Policies for non-federally funded studies	» Current Common Rule Regulations » Three burden reducing provisions » FDA Regulations » Institutional Policies for non-federally funded studies	» Revised Common Rule Regulations » Studies approved with the "old" common rule regulations plus the 3 burden reducing provisions » Pre-January 21, 2019, Current Common Rule Regulations » FDA Regulations » Institutional Policies for non-federally funded studies

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Applicability & Transition

Applicability:

- Will your organization apply the Common Rule to all studies regardless of funding source?
- Will your organization apply the Common Rule to only federally funded studies and maintain a separate set of requirements for non-federally funded studies?

Transition:

- Does your organizations transition plan require applying the requirements of the Updated Common Rule to:
  - Only studies approved after the effective date of January 19, 2018,
  - All studies regardless of when they were approved, or
  - All studies approved after the effective date and some studies approved prior to the effective date.

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Continuing Review

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Continuing Review

Current Common Rule

- The convened IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year……(§46.109(e))

Revised Common Rule

- The convened IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, and except as described in §46.109(f)…..

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Continuing Review

Revised Common Rule

§46.109(f).

- Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:
  - Research eligible for expedited review
  - Research reviewed by the IRB in accordance with the limited IRB review
  - Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

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Continuing Review

Operational Considerations:

- Follow requirements of the revised Common Rule?
- Require continuing review (CR) of all non-exempt studies and exempt studies approved through limited IRB review?
- Require a formal, annual "check-in" in lieu of a formal CR?

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Informed Consent

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Informed Consent

Requirements Related to Informed Consent

- Changes to informed consent process
- Changes to requirements within informed consent documents
- Changes to wavier/alteration of informed consent
- Broad consent
- Screening, recruitment, and determining eligibility
- Posting of informed consent documents

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Informed Consent

Requirements Related to Informed Consent Process

- Informed consent must begin with a concise and focused presentation of key information about the study and the information must be organized and presented in a way that facilitates comprehension.

- Key information (from the preamble):
  - the fact that consent is being sought for research and that participation is voluntary;
  - the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
  - the reasonably foreseeable risks or discomforts to the prospective subject;
  - the benefits to the prospective subject or to others that may reasonably be expected from the research; and
  - appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

- The investigator must present information in sufficient detail relating to the research, and must be organized and presented in a way that facilitates understanding of the reasons why one may or may not want to participate in the study.

§__.116(a)(5)(i)(ii)

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Broad Consent

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Broad Consent

Current Common Rule

- No provision for broad consent

Revised Common Rule

- Option for the broad consent for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens

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Broad Consent

Broad Consent permitted as an alternative to traditional informed consent if:

- Certain requirements of §46.116 are included,
- General description of future use (reasonable person standard),
- Description of what identifiable information might be used and who it will be shared with,
- Description of how long the identifiable information will be stored and used for research purposes,
- Statement that participants will not be informed (or will be informed) of future use,
- Statement that future research results will not be disclosed to participants, and
- Contact information about subject rights, storage and use, and research-related injury.

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Broad Consent

- If an individual *refuses to provide broad consent*, the IRB cannot waive consent for storage, maintenance, or secondary research use of identifiable tissue/data

- If an individual refuses to give broad consent, an organization can:
  - Destroy tissue/data
  - De-identify tissue/data to make available for future use
  - Retain identifiable tissue/data and allow only for non-research purposes or for research that was deemed beyond the scope of the broad consent

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Broad Consent

Considerations:

- How will refusal to consent be defined?
- How will your organization track broad consent (including refusals)?
- Who are the parties bound by refusal to give broad consent?
- What must be included in the description of the types of future research?
- What are the responsibilities of the reviewing IRB when broad consent has used obtained at another institution?

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Exempt Research

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Exempt Research

Current Common Rule

- Six exempt categories §46.101(b)(1-6)
- Exempt research activities are not subject to Common Rule requirements

Revised Common Rule

- New restrictions added to previously listed exempt categories 1-5 (category 6 is unchanged)
- New exempt categories created
- Limited IRB review as a condition of exemption for categories 2, 3, 7, and 8 (whenever recorded information is directly or indirectly identifiable).
- Broad consent as a condition of exemption for categories 7, and 8.

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Exempt Research

Considerations

- Will your organization provide exemptions under categories 7 & 8?
- If so, under will restrictions be imposed?
- Limit exemption to category 8 only if the identifiable private information or identifiable biospecimens were collected at another institution

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sIRB

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Single IRB Review of Multisite Research

- U.S. institutions engaged in cooperative research must rely upon approval by a single IRB.
- The reviewing IRB is to be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
- The requirement for single IRB review is not required whenever this requirement is precluded by law or whenever a Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
- Compliance with this requirement is January 20, 2020.

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Single IRB Review of Multisite Research

Considerations when institution cedes IRB review:

- Local review requirements
- Local compliance oversight
- Others

Considerations when institution serves as IRB of record:

- Resources
- Alliance agreements
- Compliance oversight
- Others

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Discussion

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