Office For Human Research Protections [OHRP]

Advanced Notice of Proposed Rulemaking
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### Data Security Protections

<table>
<thead>
<tr>
<th>Common Rule</th>
<th>Proposed Change</th>
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<tbody>
<tr>
<td>Present IRB rules do not include detailed specific security protections.</td>
<td>Specified data security protections, calibrated to the level of the information that will be collected, will be added to the regulations. (HIPAA ??)</td>
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Making the Common Rule
“Common To All”

Common Rule

- Current Regulations apply only to research directly funded by agencies that share the Common Rule. Application of the Common Rule to additional research is achieved by checking a box in Assurance Document.
- [Note: VCU ‘checks the box’ thereby extending the Common Rule to all research involving humans. Many institutions do not ‘check the box.’]

Proposed Rule

- Revised Rule would require new legislation extending the same rules to all research involving human subjects conducted in any institution that receives awards (of any kind) from any Common Rule Agency.
Biological Specimens

**Common Rule**

- Research using existing (de-identified) clinical or research biological data or specimens can be conducted without obtaining informed consent from subjects by stripping each specimen of identifiers.

**Proposed Rule**

- In the future, open ended consent (using a short form signed by persons 18 years and older) would be provided for most kinds of data and bio-specimens -- on condition that the consent forms are signed and collected after publication of revised rules. [Note: No provision made for data pertaining to children.]
Privacy and Confidentiality

**Current Rule:**
- Contains general (non-specific) requirements for privacy and confidentiality.
- IRB required to determine whether privacy protections are adequate and whether data will be confidential (including compliance with HIPAA).

**Proposed Rule**
- Will Specify data security. (HIPAA??)
- Will specify confidentiality protections. (HIPAA??)
- Fails to Provide Privacy Guidance.
Research Using Existing Specimens

**Current Rule**

- Current Regulations apply only to research funded by Common Rule Departments & Agencies.

- Rules are often extended to all research involving human subjects by checking the relevant box on the Assurance Document.

**Proposed Rule**

- Regulations would apply to all research -- regardless of funding source -- if it is conducted by a U.S. institution that receives any funding for the conduct of research involving human subjects from any Common Rule Agency.

- Note: Status of FDA in this regard is not clear.
Reporting Adverse Events

**Current Rule**

- Adverse events and unanticipated problems occurring in research are to be reported to multiple agencies – with differing time lines. No central database serves as a repository for such information.

**Proposed Rule**

- A single website would be created for electronic reporting of all such events. Reporting requirements would be harmonized to be consistent across Common Rule departments and agencies.

- Note: This can be accomplished without a change in the Common Rule.
Simplifying and Strengthening Informed Consent Documents

**Current Rule**
- Provides only basic information about the elements of informed consent; and how consent documents should be written. Current forms are too long and often fail to provide adequate information.

**Proposed Rule**
- Revisions would be made to provide greater specificity about contents of consent documents. Forms would be shorter, easier to understand, and provide better support for good decisions by prospective subjects.
Eliminating or Reducing Redundant Review by Several IRBs

Current Practice

• Studies conducted in multiple institutions frequently require IRB review in each institution that shares in the study. Although the Common Rule allows one IRB to review on behalf of many institutions, it is customary for many IRBs to review the same study.

Proposed Practice

• For all U.S. sites in a multi-site study, it is proposed that a single IRB be identified as the IRB of Record.
• [Note: This practice is permitted now. Institutional Legal Counsel in some institutions discourage the practice. This problem is not addressed in the ANPRM. Does this imply that an institution that conducts local review e.g. adds information to consent document would not be allowed to participate?]
### Guidance for Interpreting the Common Rule

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<td>Each Common Rule agency, plus the FDA, is authorized to issue its own guidance with regard to interpreting and implementing the regulations. That guidance may differ from one agency to another.</td>
<td>The NPRM does not propose a specific change, but seeks to determine whether differences in guidance are justified by differences in statutes or agency missions. The NPRM seeks advice on how to make federal guidance uniform.</td>
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<td>Research Involving More Than Minimal Risk</td>
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<tr>
<td><strong>Current Practice</strong></td>
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<tr>
<td>• Research involving more than minimal risk requires review by a convened IRB with a quorum of members present.</td>
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<td><strong>Proposed Change</strong></td>
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<td>• No change is proposed.</td>
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Research that Requires Full Board Review Also Requires At Least Annual Review

**Common Rule**
- Research that requires full Board Review by a convened IRB also requires re-review at least annually.

**Proposed Rule**
- Continuing review would not be required in cases where all subjects have completed study interventions and there remains only “standard of care” follow up.
Updating the List of Research Categories That Qualify for Expedited Review

**Common Rule**

- Research that poses no more than minimal list and appears on the list produced by OHRP may be reviewed by a single reviewer (expedited). The list of such categories was last updated in 1998.

**Proposed Rule**

- The list would be updated now and at regular intervals (Once each year? Once every five years?) in the future.
How Frequently Should Research That Qualifies for Expedited Review be Reviewed?

**Common Rule**
- Research that qualifies for expedited review is subject to continuing review at least annually.

**Proposed Rule**
- Continuing review would *not be* required of studies that qualify for expedited review unless the reviewer, *at the time of initial review*, recommends that it be re-reviewed at a later date.
Who should Decide Whether Studies On the Expedited Review List Involve No More Than Minimal Risk?

**Common Rule**
- A member of the IRB must determine that the study involves no more than minimal risk.

**Proposed Rule**
- The default position will be that any study that involves no procedures other than those described on the expedited review list is assumed to involve no more than minimal risk. However, a reviewer may determine that a study involves greater than minimal risk & may call for full board review.
Should Criteria for Expedited Review of a Study Be the Same as the Criteria for Full Board Review

**Common Rule**

- All studies – whether they qualify for expedited review or not--must meet the same criteria.

**Proposed Rule**

- ANPRM does not take a position on this issue. It seeks information & comment.
Exempt Categories

**Current Rule**

- Six categories of studies qualify as exempt from the regulations. This means that they do not have to comply with any requirements of the regulations.

**Proposed Rule**

- Such studies would no longer (fully) qualify for exemption. At a minimum they would have to meet data security criteria (mentioned above in Box 2). For biospecimens new consent requirements would apply.
Exempt Studies That Involve Human Subjects

**Common Rule**
- Studies in categories that may qualify as “exempt” are not clearly defined.
- Although not required to conduct “administrative review” most institutions (including VCU) follow OHRP recommendation to conduct review of studies that may or may not qualify for exemption.

**Proposed Rule**
- The recommendation that such studies be reviewed prior to initiation would be withdrawn.
- PIs would be allowed to file a brief “registration” form and commence their research immediately after filing.
- Institutions would conduct audits of a small percentage of such studies to ensure compliance.

[Note: It is not clear what would happen if a study is initiated and found, upon audit, not to qualify for exemption.]
Elimination of Exempt Category Number 2

**Common Rule**

- Exempt Category 2: Research is not exempt if it involves collection of data: (i) where information is recorded in a manner that identifies subjects; and (ii) disclosure of the information could place subjects at risk....

**Proposed Rule**

- The new data security section, if promulgated, will make this provision obsolete.
Should A New Category of Research Studies In the Social Sciences Qualify for Exemption?

**Common Rule**

- Some low risk studies that involve only well-understood procedures (e.g. word association studies) do not qualify for exemption. Should they be exempt?

**Proposed Rule**

- The ANPRM does not take a stand, but seeks to learn whether a broad subset of studies can be defined and identified so that they may qualify for exemption.
Revision of the Exempt Category for Data, Documents or Specimens

**Common Rule**

- Research involving existing data, documents or specimens, if they are publicly available, or if they exist at the time the research is initiated, and contain no identifiers, qualify for exemption.

**Proposed Rule**

- Investigators may use data documents or specimens if consent was obtained at the time the information was collected. A simple consent document to be used at the time of collection can be developed and utilized.