10. The advanced notice of proposed rulemaking (ANPRM) or 74 questions, but who's counting?

Ivor A. Pritchard
HHS, Office for Human Research Protections

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The Advance Notice of Proposed Rulemaking (ANPRM)

or

74 Questions, But Who’s Counting?

Ivor A. Pritchard, Ph.D.
Senior Advisor to the Director
Office for Human Research Protections

Ivor.Pritchard@hhs.gov

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Overview of Rulemaking Process

RFI → ANPRM → NPRM → Final Rule

public comment → public comment → public comment
Regulatory Jurisdiction

- “Research” “Quality Improvement” “Program” etc.?
- Should all biospecimens research be covered? [“Human Subject”?]
- Apply the regulations to all human subjects research at domestic institutions receiving Common Rule support?
3 levels of review, depending on risk + X

Convened IRB Review

Expedited Review

“Excused” or “Registered”
Convened IRB Review

• Should continuing review no longer be required if the research is in the analysis or follow-up phase?
• Should there be single IRB review of domestic sites of multi-site studies?
• Should accountability requirements be set for the site institutions and the single IRB?
Expedited Review

• Should there be single expedited review of domestic sites of multi-site studies?
• Revise the list of categories, and revise them again periodically?
• Presume that the identified research procedures are minimal risk?
• If eligible, should the research receive expedited review unless the reviewer refers it for a reason?
• Should any of the .111 criteria be omitted?
• Should continuing review occur only if and when it is appropriate?
“Excused” or “Registered” Research

- Registration Form Submitted
- Informed Consent (sometimes)
- Data Security and Information Protection Standards applied
- Sometimes audited retrospectively
- May be referred for expedited or convened IRB review, depending on …..[X]
Revising the scope of the existing exempt categories for “excused” or “registered” research

• Expand category .101(b)(2) by removing the anonymity & risky response conditions for research involving competent adults?
• Expand category .101(b)(4) by removing the “existing” & anonymous recording conditions?
• Add a new category of benign interventions research?
• Add other categories?
How to improve informed consent
Informed Consent

• How could the Informed Consent process be improved?

• Should written consent generally be required for research use of any biospecimens collected for clinical or research purposes?

• Should “oral consent” be employed for some studies, e.g. surveys with competent adults, and, if so, how?
Informed Consent (cont.)

• Should investigators assess subjects’ understanding?
• Should the criteria for waiver of informed consent be revised and clarified?
• Should the criteria for waiver of documentation of informed consent be revised?
Improving Informed Consent forms

• Identify appropriate specific content that must be included?
• Identify content that may not be included?
• Identify how information should be presented?
• Limit the acceptable length of various sections?
• Make standardized consent form template(s) available?
Research with Biospecimens
Research with Biospecimens

- What should the requirements be for research with specimens that already exist?
- Should secondary research with biospecimens be “excused” from review unless there is a waiver of informed consent or if individual results will be returned to subjects?
- Should research on de-identified biospecimens without consent or review be allowed?
Research with Biospecimens (cont.)

• What criteria should be used for waiver of consent for future research on biospecimens?
• Should open-ended consent for future research with bio-specimens be implemented?
• Should people be able to exclude certain types of future research with their biospecimens?
<table>
<thead>
<tr>
<th>Excused Research Involving Pre-Existing Information or Biospecimens</th>
<th>Identifiable info and all biospecimens</th>
<th>Limited data set (as defined in HIPAA Rule)</th>
<th>Deidentified Info (as defined in HIPAA Rule)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written IC req’d for future research w/material collected for non-research?</td>
<td>Yes, which could be obtained during initial collection</td>
<td>No consent required</td>
<td>No consent required</td>
</tr>
<tr>
<td>IC for future research w/material collected for research?</td>
<td>Yes, usually at time of consent for initial research (could be oral for data)</td>
<td>Yes (same rule as “Identifiable info and all biospecimens”)</td>
<td>Yes (same rule as “Identifiable info and all biospecimens”)</td>
</tr>
<tr>
<td>Standardized data protections?</td>
<td>Yes, Protections include encryption, authorized personnel, breach notification, audits</td>
<td>Yes (same rule as “Identifiable info and all biospecimens” + prohibition on reidentification)</td>
<td>Yes. Protection would include prohibition on reidentification</td>
</tr>
<tr>
<td>Registration of research w/IRB or research office?</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Prior review by IRB or research office?</td>
<td>No, unless PI plans to re-contact subjects w/individual research</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Harmony/Uniformity
Harmony/Uniformity

• Should there be harmony with other regulations, including Subparts B, C, D, HIPAA, FDA, etc.?
• Should we have a uniform set of Standards for Data Security and Information Protection, calibrated according to identifiability?
• Should there be uniformity of guidance from all of the Common Rule agencies?
• Should there be uniformity of information reported to the federal government?
ANPRM Comments due 10/26/11

Identify by docket ID number HHS-OPHS-2011-0005

- Federal eRulemaking Portal: 
  http://www.regulations.gov/

- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions] to: Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to 
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