2011

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

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The Advance Notice of Proposed Rulemaking (ANPRM)

or

74 Questions, But Who's Counting?

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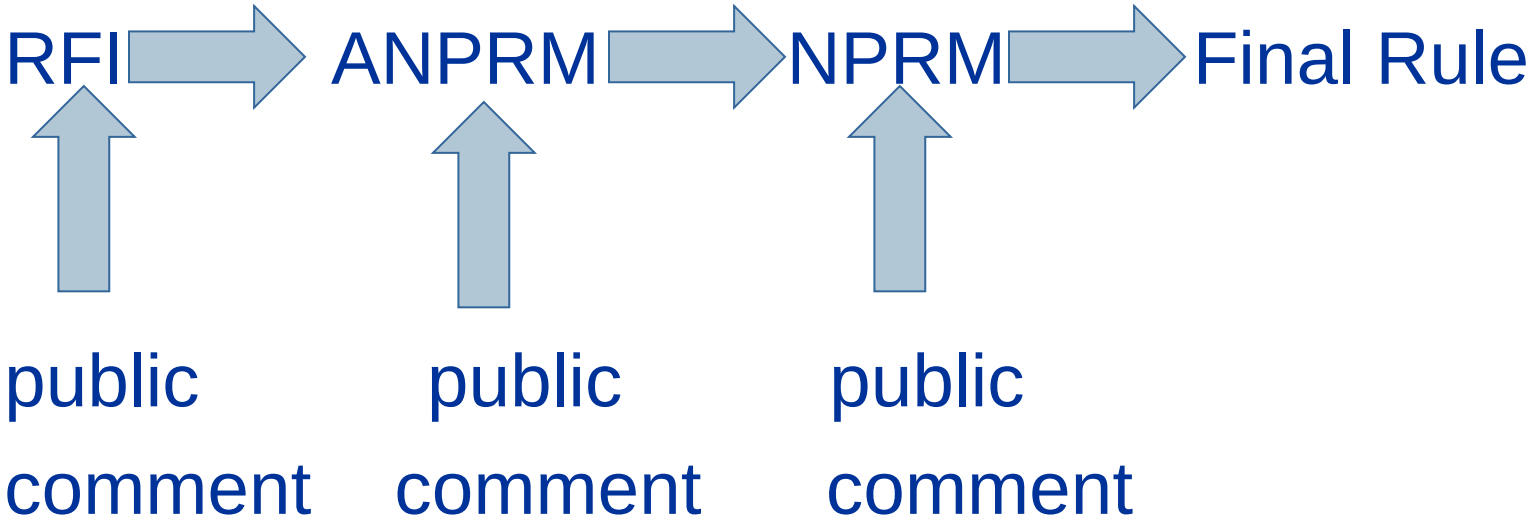
“Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators” (Federal Register July 26, 2011)

Office for Human Research Protections

Overview of Rulemaking Process



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

- 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?

Excused Research Involving Pre-Existing Information or Biospecimens	**Identifiable info and all biospecimens**	**Limited data set (as defined in HIPAA Rule)**	**Deidentified Info (as defined in HIPAA Rule)**
Written IC req'd for future research w/material collected for non-research?	Yes, which could be obtained during initial collection	No consent required	No consent required
IC for future research w/material collected for research?	Yes, usually at time of consent for initial research (could be oral for data)	Yes (same rule as "Identifiable info and all biospecimens")	Yes (same rule as "Identifiable info and all biospecimens")
Standardized data protections?	Yes, Protections include encryption, authorized personnel, breach notification, audits	Yes (same rule as "Identifiable info and all biospecimens" + prohibition on reidentification)	Yes. Protection would include prohibition on reidentification
Registration of research w/IRB or research office?	Yes	Yes	No
Prior review by IRB or research office?	No, unless PI plans to re-contact subjects	No	No

Harmony/Uniformity

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- 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 http://www.regulations.gov/