Town Hall

Review of Notice of Proposed Rulemaking (NPRM)
What is the NPRM?

• **Notice of Proposed Rulemaking:**
  – Revisions to the Common Rule for the Department of Health and Human Services and 16 other federal agencies

  – Revisions intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators

  [http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html](http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html)
The Process

Fall 2011
- Advanced Notice of Proposed Rulemaking (ANPRM)
- 90-day comment period and then OHRP review of comments

Fall 2015
- Notice of Proposed Rulemaking (NPRM)
- 120-day comment period and then OHRP review of comments

FINAL RULE
- Comments Due 1/6/2016

Proposed Changes!!!

• What’s REVISED?
  – Secondary Use of Biospecimens/Data
  – Exemptions
  – Elements of Consent
  – Waivers of Consent
  – Continuing Review
  – Minimal Risk Definition/Expedited Review
  – IRB Operations
  – IRB Review of Grant Applications

• What’s NEW?
  – Exclusions
  – Privacy Safeguards
  – Broad Consent
  – Public Posting of Consent Forms
  – Single IRB Review for Multi-Site Research
  – Extend the Common Rule to all Clinical Trials
Secondary Use of Specimens and Broad Consent

Current regulatory environment:
• Research with anonymous biospecimens happens every day
• It is not considered “human subject research” because cannot connect back to the individual person
  – No regulatory requirements
  – No Institutional Review Board (IRB) oversight
  – No consent needed, but...
    • When collected for research - consent to store and be used in the future
    • When collected clinically – no specific consent needed; hospitals, clinics, etc. have different requirements
<table>
<thead>
<tr>
<th><strong>Current</strong></th>
<th><strong>NPRM</strong></th>
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<tr>
<td>Human subject means a living individual about whom an investigator</td>
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<td>(whether professional or student) conducting research obtains:</td>
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<td>1) Data through intervention or interaction with the individual</td>
<td>1) Obtains data through intervention or interaction with the individual,</td>
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<td>2) Identifiable private information</td>
<td>and uses, studies, or analyzes the data;</td>
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<td></td>
<td>2) Obtains, uses, studies, analyzes, or generates identifiable private</td>
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<td>information;</td>
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<td>3) Obtains, uses, studies, or analyzes biospecimens</td>
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Secondary Use of Specimens and Broad Consent

Change to the regulations

- All research with biospecimens, regardless of how they are identified, will be considered **research with human subjects**, and
  - regulatory requirements
  - Limited IRB review
  - **Written broad consent** required for storage, maintenance, and future unspecified use of biospecimens or identifiable private information
    - When collected through research - Broad consent included with research consent
    - When collected clinically – Broad consent obtained from the individual as part of clinical care.
Written Broad Consent

• NPRM Proposal
  – “Broad Consent” means an individual must agree to allow biospecimens (e.g., blood, urine, tissue, saliva, plague, hair samples) to be stored, maintained, and used for future research, but the nature of the research would not be specified.
  – **Written** broad consent required for biospecimens
  – **Oral** for private information (DATA)

• Why?
  – Respect for Persons: “Research” to show individuals want to decide what happens with their biospecimens or information
Written Broad Consent

• Limited IRB review of the consent process in the non-research context ("Institutional protocol")

• Must require the possibility to withdraw consent, when feasible

• Public posting of non-identifiable data
  – When relevant, individuals would be given an option to consent or refuse to consent to the inclusion of their data, with the removal of certain identifiers, in a publicly available database
Written Broad Consent

• Initially created through research
  – Research consent will include HHS template for broad consent

• Initially created clinically
  – Adults: Broad consent required cover what is currently existing and anything for the next 10 years.
  – Children: Broad parental permission required cover what is existing and anything for the next 10 years or until the child turns 18, whichever comes first
What does this mean?

URMC will need to develop mechanism to:
• Obtain broad consent (written and oral??)
• Track and respect the individual’s decision
• Maintain forms

But…every hospital, clinic, etc. that contributes biospecimens for anonymous research **must have** a process for broad consent, or will not be able to contribute biospecimens.
Concerns

• Significant cost and effort required to implement

• Does “Broad Consent” achieve purpose or “respect for persons”, when…
  – Signed at admission to the hospital or at front desk of PCP/Specialist?
  – Provided with a pile of other papers to sign/complete?
  – Provides generic information?
  – Possibly no one at the front desk to answer questions?
Concerns

• Greater emphasis on respect for persons, while sacrificing beneficence and justice

• Will this potentially increase health disparities?
  – Cost prohibitive for many small hospitals, clinics, etc. to implement, will not be able to contribute specimens to basic research

• Are we sacrificing valuable research?
  – Exclude certain de-identified tumor biospecimens originating from specific populations in a particular area because their local hospital does not have a process for obtaining broad consent

• Other examples???
Alternative Approaches

• Leave de-identified samples as not “human subject research” - no change to the regulations

• Leave de-identified samples as not “human subject research” – add sanctions to researchers who attempt to re-identify
Alternative Approaches

• If a consent mechanism is required, use an “opt out” approach
  – Institutions required to publicize that research is conducted with specimens and data, e.g. posters, brochures, handouts, etc. IRB’s review and approve publicity campaign
  – Individuals with concerns can call get more information and have the ability to exclude their data and/or specimens.
  – Respects autonomy without sacrificing the valuable science that will benefit all society.
  – While this will still have some financial burden and may exclude some information from research, it will remove the costly generation and storage or written consent forms to be managed and tracked, while still allowing for those with concerns to be heard and respected.
Cooperative Research: Single IRB Review

• Current regulatory environment:
  – IRBs can decide to perform local institutional review or defer to another IRB

• Change to the regulations
  – Mandate all institutions in the US engaged in cooperative research (more than one site) rely on a single IRB
  – Reviewing IRB selected by the funding agency or, if no funding, by the lead institution conducting the study
  – Only applies to studies undergoing convened or expedited review
What does this mean?

• When RSRB defers:
  – University of Rochester will continue to require institutional review (similar to current process)

• When RSRB is the Single IRB:
  – [OHSP Policy 504 - RSRB Reliance for Review](#)
  – Lead PI takes on more responsibilities (e.g. coordination centers)
  – Oversight plans to ensure compliance at other sites, responsibilities related to reporting
Concerns

• Mandate across all multi-site research does not recognize the complexity and variation of research
  – 3 or 4 sites, expedited review - may be quicker and less burdensome to perform local review, rather than to set up the infrastructure required to have a Single IRB

• Pushes the burden and the work to the “lead PI”
  – Lead PI to create oversight plans to ensure compliance at other sites and to ensure responsibilities related to reporting
  – Lead PI responsible for gathering information related to continuing review for the Reviewing IRB, very similar to the characteristics of a coordination center.
Concerns

• Reasonable for larger studies with funding, but small collaborative research a lead PI might not have the time to take on this added responsibility to manage IRB review for the other sites or to maintain oversight of those sites.

• Local Investigators have to deal with unfamiliar IRBs
  – Investigator could submit to 12 to 15 different IRBs, depending on the number of active research projects
Alternative Approaches

• Mandate for 5 or more sites

• Include requirement for Single IRB review in funding requirements, leave unfunded research alone.
• Comments can be submitted through www.regulations.gov

• Until 5 pm EST on Wednesday, January 6th, 2016.

• To obtain additional information about the proposed changes or for instructions on how to submit a comment, click the link below:

  http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html
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• OHRP Website: NPRM for Revisions to the Common Rule
  (http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html)

• "Not Just Another Acronym: What the NPRM Could Mean For You" it was recorded and there video and slide presentation are available on the OHSP Research Education and Training website under “Seminars”