Office for Human Research Protections
Notice of Proposed Rulemaking:
http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html

• Revisions to the federal regulations that control research with human subjects or
  the “Common Rule” (Department of Health and Human Services and 16 other federal agencies)
• Intent is to better protect human subjects involved in research, while facilitating valuable research
  and reducing burden, delay, and ambiguity for investigators

The Process

Proposed Changes!!!

• What’s REVISED?
  – 2° 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 the need for Broad Consent

Current regulatory environment:
• Research is performed with anonymous biospecimens every day
• Research with anonymous biospecimens not considered “human subject research” because cannot
  connect back to the individual person
  o No regulatory requirements
  o No Institutional Review Board (IRB) oversight
  o 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

Change to the regulations
• All research with biospecimens, regardless of how they are identified, will be considered research
  with human subjects, and
  o regulatory requirements
  o Limited IRB review
  o Written broad consent\(^1\) required for storage, maintenance, and future unspecified use of
    biospecimens or identifiable private information
  o When collected through research - Broad consent included with research consent

\(^1\) “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.
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When collected clinically – Broad consent obtained from the individual as part of clinical care.
  ▪ Adults: Broad consent required for anything existing and collected for the next 10 years.
  ▪ Children: Broad parental permission required for anything existing and collected for the next 10 years or until the child turns 18, whichever comes first

What does this mean??
• URMC will need to develop a mechanism to:
  o Obtain broad consent
  o Track and respect decisions
  o 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...
  o Signed at admission to the hospital or at front desk of PCP/Specialist?
  o Provided with a pile of other papers to sign/complete?
  o Provides generic information?
  o Possibly no one at the front desk to answer questions?
• Greater emphasis on respect for persons, while sacrificing beneficence and justice
• Will this potentially increase health disparities?
  o 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?
  o 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???

Possible 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
• If a consent mechanism is required, use an “opt out” approach
  o 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
  o Individuals with concerns can call get more information and have the ability to exclude their data and/or specimens.
  o Respects autonomy without sacrificing the valuable science that will benefit all society.
  o 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.
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Single IRB Review for Cooperative Research (more than 1 site)

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:
  o University of Rochester will continue to require institutional review (similar to current process)
• When RSRB is the Single IRB:
  o Lead PI takes on more responsibilities (e.g. coordination centers)
  o 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
  o 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”
  o Lead PI to create oversight plans to ensure compliance at other sites and to ensure responsibilities related to reporting
  o Lead PI responsible for gathering information related to continuing review for the Reviewing IRB, very similar to the characteristics of a coordination center.
• 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
  o Investigator could submit to 12 to 15 different IRBs, depending on the number of active research projects

Possible Alternative Approaches
• Mandate for 5 or more sites
• Include requirement for Single IRB review in funding requirements, leave unfunded research alone.