Current Landscape in Human Subject Protections

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Current Landscape

- ANPRM
- Standards of Care
  - SUPPORT Study
  - Comparative Effectiveness
- Incidental Findings
- BIG Data

ANPRM

- Advance Notice of Proposed Rulemaking
  - Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators
    - Posted on July 26, 2011, comments to be submitted by September 26, 2011 (extended to October 26, 2011)

ANPRM: Key Topics

- **Protecting Subjects from Informational Risk** (Session 1)
  - Adoption of HIPPA as universal standard
    - Use of data
      - De-identified data collected for non-research purpose, no need for consent other than that obtained at collection
      - Data collected for research purposes, with or without identifiers, consent required

ANPRM: Key Topics (cont')

- Calibrating IRB review to level of risk
  - Revise and simplify approach to Expedited review
    - Eliminate requirement for continuing review
  - Replace category of Exempt research with new category of Excused research
    - Report by PI, audit by IRB

ANPRM: Key Topics (cont')

- **Utilization of a single IRB of record for domestic sites of multisite studies** (Session 6)
  - Multiple reviews fail to improve protection of human subjects
  - Diversion of valuable resources

NIH Funding Announcement (2/14/14): Empirical Research on Ethical Issues Related to Central IRBs and Consent for Research Using Clinical Records and Data

ANPRM: Key Topics (cont')

- **Improvement of consent forms and process** (Session 2)
- Establishment of an improved, more systematic approach for the collection and analysis of data on unanticipated problems and adverse events

ANPRM: Key Topics (cont')

- Extension of federal regulatory protections to all research regardless of funding source, conducted at institutions in the US that receive some federal funding from a Common Rule agency for research with human subjects
- Improvement and harmonization of regulations and related agency guidance

ANPRM: Response

- Advance Notice of Proposed Rulemaking
  - Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators
    - Received 1,142 comments

ANPRM: Response

- Joint Comment
  - American Association for Cancer Research
  - American Society for Clinical Oncology
  - Association of American Cancer Institutes

ANPRM: Response

- Joint Comment
  - General Support
    - Need to delineate responsibilities of IRB of record
  - Overarching Concerns
    - Disagree with Adoption of HIPPA as universal rule for privacy protection
    - Consideration needed regarding consent requirements for de-identified data

ANPRM: Response

- Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the **Behavioral and Social Sciences**, National Research Council Board on Behavioral, Cognitive, and Sensory Sciences
  - Phase 1: Workshop March 2013
  - Phase 2: Report January 2014

ANPRM: Response

- Primary Recommendations
  - Redefine “human-subjects research” to provide criteria for what types of research should be considered not human-subjects research
  - Endorse adoption of new category of “Excused” research
  - Operationalize procedures for implementing “Excused” research

ANPRM: Response

- Specific Critique
  - Adoption of HIPPA as universal standard is bad idea
  - Consent should not be required for use of de-identified data regardless of source

ANPRM: Next Steps

- Advance Notice of Proposed Rulemaking
  - Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators
    - Notice of Proposed Rulemaking *expected* 10/2013 (OMB)
      - Request for Public Comment
    - Review and Approval by 15 Federal Agencies

ANPRM: Status

- "Sadly, recent proposals to modify the Common Rule have become stalled, at least in the foreseeable future, if not permanently. Given the current political climate and the often divergent interests of the seventeen agencies that adhere to the rule, meaningful systematic modernization of the Common Rule is not likely to occur any time soon."
  - Tom Puglisi, Director of the Office of Research Oversight in the Department of Veterans Affairs in *Hastings Center Report* 45(1) 2013: S40-42.

Standards of Care

- Notice of a Department of Health and Human Services Public Meeting and Request for Comments on Matters Related to the Protection of Human Subjects and Research Studying Standard of Care Interventions
  - Public Meeting on August 28, 2013

Standards of Care

- SUPPORT Study
  - Surfactant, Positive Pressure, and Oxygenation Randomized Trial
    - Does targeting oxygen saturations measured by pulse oximetry (85% and 95%) result in better outcomes for very preterm infants?
- Comparative Effectiveness
  - Learning Health Systems

Incidental Findings

PCSBI Overall Recommendations:

- Informing Persons Tested
- Evidence-Based Practice Guidelines
- Additional Empirical Research
- Educating Stakeholders
- Justice and Fairness and Health Inequities

Classification of Individualized Results of Medical Tests

Clinical Recommendations
Research Recommendations
DTC Recommendations

Genetic Sequencing
Biological Sampling
Medical Imaging

BIG Data

- Explosion of Digital Data on human populations
  - Internet search data
  - Social Media (Facebook, twitter etc..)
  - E-mail data
  - GPS data
  - Cell phone records