Need to Know Information: Coming Changes to “the Common Rule”

Patricia M. Jones, Chair, Biomedical IRB
Rebecca Sandefur, Chair, Social/Behavioral IRB

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Federal Policy for the Protection of Human Subjects (aka “The Common Rule”)

Updated January 19, 2017
to go into effect January 2018
Four Major Changes

• New definitions of “research” and “human subject”
• New rules about Continuing Review
• New categories of Exempt Research
• New flexibility with Informed Consent
Definition of Human Subject Research

• **Now includes**
  • Information or bio-specimens obtained through interaction or intervention
  • Identifiable private information
  • Identifiable bio-specimens
Human Subject Definition

• Study of a living individual, from or about whom a researcher obtains the following for research purposes:

  • (i) information or biospecimens through intervention or interaction with the individual
  • OR
  • (ii) identifiable private information or identifiable biospecimens through some other means.
Continuing Reviews no longer required for

- Data analysis after data collection has concluded
- Expedited protocols or protocols with “limited IRB review”
New Categories of Exempt Research

• New exemption for secondary research involving identifiable private information

• New exemption for secondary research under “broad consent”
Updated Exemptions related to Education

• Research involving educational methods remains exempt if the research is not likely to adversely affect classroom instruction time or student performance.

• Educational testing remains exempt as long as
  • any recorded information is completely de-identified;
  • any disclosures of information would not place the subjects at risk of criminal or civil liability or financial or reputational harm; or
  • the recorded information cannot be de-identified and the procedures have been reviewed by an IRB.
Updated Exemption related to Benign Behavioral Interventions with Adults

• Research that involves benign behavioral interventions with adults in conjunction with collection of information or audiovisual recording is **exempt from IRB review** -- if at least one of the following criteria is met:
  • any recorded information is completely de-identified,
  • any disclosures of information would not place the subjects at risk of criminal or civil liability or financial or reputational harm, **or**
  • the recorded information cannot be de-identified and the procedures have been reviewed by an IRB.
New Exemptions for Secondary Research (1)

• Secondary research for which consent is not required: involving identifiable private information, which is regulated under HIPAA, or biospecimens collected by a researcher, if:
  • the identifiable information is already available to the public;
  • the information is not re-identified, and the researcher does not attempt to re-identify it;
  • the secondary research is already regulated under HIPAA; or
  • the secondary research is conducted by, or on behalf of, a Federal entity and involves the use of Federally-generated non-research information as long as the information remains covered under existing Federal privacy rules.
New Exemptions for Secondary Research (2)

• Secondary research and the storage and maintenance of identifiable private information or identifiable bio-specimens, provided that the subject or donor has given a **broad consent**.

• Any secondary research may be exempt if the broad consent was properly obtained and documented, and if an IRB determines that the secondary research is within the scope of the broad consent.
Broad Consent

• Broad consent seeks “prospective consent to unspecified future research” for “storage, maintenance, and secondary research use of identifiable private information and identifiable bio-specimens.”

• *Example*: A hospital has a generic “broad consent” form for patients who might want to donate their leftover biological materials to the hospital’s research biobank.
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Informed Consent

• Consent forms must be clearer and more focused

• Must include “sufficient detail relating to the research” to the prospective subject, or legally authorized representative, the reasons why one might or might not want to participate.
Informed Consent must now explicitly cope with:

• Collection of private information or identifiable biospecimens
• Biospecimens being used for commercial profit
• Disclosure of “clinically relevant” results to individual subjects
• Whole genome sequencing
Updated CITI Training

- https://about.citiprogram.org/en/final-rule-resources/