# Update to the Federal Policy for the Protection of Human Subjects

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# What is the common rule?

- The Common Rule has been in place since 1991 and governs all research that is conducted, supported or regulated by the federal government
- IRBs may also apply these regulations to non-federally funded research
- January 19, 2017 – 16 federal agencies including DHHS published a revision to the common rule – most provisions *were* to take **effect on January 20, 2018**
  - Notable exceptions: FDA and Dept. of Justice
- A one-year delay was implemented on January 18, 2018

# Why the Change?

- The changes are meant to address:
  - Advances in genetics and genomics
  - Concerns about privacy and autonomy and how biospecimens are procured, handled, and maintained
  - Greater need for "public" understanding during consent– through the use of the "reasonable person standard"
  - Single IRB review for multi-site studies
  - Reducing IRB process burden

# Which Regulation Applies?

- For research approved before January 20, 2019 – the old rule applies (now the called pre-2018 rule)
- For research approved after January 20, 2019 - the new rule applies (now called the post- 2018 rule)
- FDA and DOJ- regulated research remains under the old rule for now
  - Expectation is that the FDA and DOJ will eventually issue a revision (hopefully involving harmonization with the revised Common Rule)

# What changes might be important to social science and bio-behavioral researchers?

- New and revised definitions
- Revised exemption categories
- Single IRB review for multi-site research conducted in the U.S. – **effective January 20, 2020**
  - **Use of reliance agreements such as SMART IRB**
- No longer require congruency between IRB documents and grants
- Revised requirements for informed consent
- Changes to category of vulnerable subjects
- Changes to expedited review procedures

# Revised Human Subjects Definition

- The definition of human subject has been expanded to cover collection of "identifiable biospecimens"
  - Human subject means a living individual about whom an investigator conducting research obtains information *or biospecimens* through intervention or interaction with the individual, and uses, studies, or analyzes the information *or biospecimens* **or** obtains, uses studies analyzes or generates *identifiable private information or identifiable biospecimens*

# Revised clinical trial definition

- A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the interventions on biomedical or behavioral –related outcomes

# Vulnerable Subjects

- Changed to:
  - Children
  - Prisoners
  - Individuals with impaired decision-making capacity
  - Economically or educationally disadvantaged persons

# Changes to Exemptions

- Changes 5 of the exempt categories and added 3 new categories with a new type of review called "limited review"
- Limited review – used for studies that are:
  - minimal risk
  - exempt
  - maintain subjects' identifiable information or biospecimens
    - Limited review focuses on security, privacy, and confidentiality of identifiable private information

# Exemption Changes (cont.)

- Issues that may of be interest:
  - Research conducted in established **educational settings**
    - MUST DISCUSS IN YOUR APPLICATION: Can not have an adverse impact on student's opportunity to learn, required content or the assessment of educators who provide instruction
  - **Survey procedures, interview procedures** or **observation** of public behavior may be exempt if no identifiers are collected or may be subject to "limited review" if you plan to collect and retain linkage to identifiers
  - **Secondary research** - deidentified data – no linkages – researchers will not re-contact or be able to re-identify subjects

# Exemption Changes (cont.)

- Research involving **benign behavioral interventions** in "adults"
  - Benign behavioral interventions: brief in duration, harmless, painless, not physically invasive
- **Demonstration projects** that are supported by Federal department or agency – designed to study, evaluate or improve public benefit or service programs
  - (NEW: each agency must maintain a public list of these projects to be published prior to conducting research)

# Exemption Determinations

- Still
  - Must be determined by the IRB (not by individual investigators)
  - Need to submit an application to the IRB
  - The new rule –permits no continuing review for minimal risk studies - however each institution is allowed to set their own parameters on this
    - So need to check with your IRB on these issues

# Main Revisions to Consent

- Consent process will now use a **"reasonable person standard"**
  - Facilitate a persons understanding of the reasons why he/she might or might not want to participate in a particular research study
  - **KEY INFORMATION** section:
    - provides information that is essential to decision making and must appear at the beginning of the consent form and in the consent discussion = results in a revision to our informed consent template
    - What would a reasonable person need to know to make a decision whether he/she wanted to read further about the study?

# What must be included in the **key information** section?

- This is research
- Voluntary participation
- Purpose of the research
- Duration of participation
- Main procedures
- Reasonable risks and potential benefits
- Alternatives available
  - (the remaining part of the consent form will document the details)

# What else has been added as a consent requirement?

- Indicate whether data/specimens will be used or distributed for future research
- Whether specimens may or may not be used for commercial profit and whether there is potential for the subject to share in profit
- **If, How, and When research results will be disclosed to participants**
- Whether whole genome sequencing of biospecimens will be done

# Broad Consent

- Alternative to traditional study-specific consent (optional)
  - Applies only for storage, maintenance and secondary use of identifiable private information or identifiable biospecimens that **already exist** for non-research purposes (e.g., clinical data, leftover specimens …)
    - Requires an infrastructure that tracks patient responses and changes over time
    - Many institutions have a wait and see approach to this….

# Other Notable Changes

- Posting of consent form for clinical trial research;
- Electronic signatures allowed;
- Waive requirement for signed consents if subjects are members of a cultural group or community in which signing forms is not the norm;
- Eliminated continuing review for some minimal risk studies

# FYI

- Separate but related issue (effective October 2017):
  - NIH automatic issuing of **certificates of confidentiality** to all NIH-funded studies when identifiable sensitive information are being collected and/or linked with biospecimens
  - COC language in consent documents required

# Thank you – any questions?

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