Key Changes to the Common Rule

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Common Rule

- Federal Policy for the Protection of Human Subjects published in 1991 and codified in separate regulations by 14 Federal departments and agencies

DHHS	Dept of Commerce
NSF	Consumer Product Safety Commission
DOD	USAID
Dept of Justice	Dept of Housing and Urban Development
Dept of Agriculture	Dept of Education
Dept of Energy	Dept of Transportation
NASA	VA

State of Final Rule

- January 19, 2018 (Previous rule applies to research approved prior to 1/19/2018 and will not transition to the new rule)
- Trump administration issued an executive memorandum freezing all regulations that had been published but were not yet effective
- October 7, 2017 OMB received a proposal from the DHHS that, buy its title, seeks a 1-Year Delay of the General Implementation Date
- Formal delay not yet published by final rulemaking
- Final rule is ambiguous and lacks agency guidance/templates/FAQs to implement

Changes

- Broad changes
  - Scope
  - IRB Operations
  - Informed consent
  - Exemptions
  - Requires single IRB review of research involving external collaborators (effective 1/20/2020)

What's not Changing?

Minimal change to IRB review of projects that involve:

- More than minimal risk
- Drugs/biologics/medical devices (FDA-regulated)
- Collection of biospecimens
- Children
- Prisoners

Changes to Scope

- Definition of research
  - Defines what's not research, certain journalistic, public health surveillance, and criminal justice activities

- Definition of human subject
  - Expanded to clarify work with bio-specimens that are considered to be research activities. "includes research in which an investigator obtains, uses, studies, analyzes or generates identifiable bio-specimens or identifiable private information"

- Definition of clinical trial
  - "….one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

This definition to be used when determining what consent forms will need to be made publicly available.

Changes to IRB Operations

- Single IRB (sIRB) – for multi-site research, effective date 1/20/2020

- Formalization of reliance agreements
  - IRBs sign agreements with other institutions to accept/cede IRB approval

- Continuing review of research is not required for:
  - research that received expedited review
  - research that have completed data collection and are now only analyzing data (including analysis of identifiable private information or identifiable bio-specimens) or accessing follow up clinical data from standard clinical care procedures

Continuing Review

- Does not eliminate requirement for reporting adverse events, protocol deviations and amendments
- IRB will use annual notification for tracking purposes (remains ongoing vs closed)
  - Reminder to submit amendments, adverse events, etc.)
- Requires IRB to make determination

Informed Consent

- Consent must begin with a presentation of 'key information'
- Content, organization and presentation of information should facilitate a prospective subject's decision about whether to participate or not
- Additions to the 'basic' and 'additional' elements of consent

Consent: General Requirement

'Key Information'

Begin with "concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research"

This part of the consent must be organized and presented in a way that facilitates comprehension

§ ___.116(5)(i)

Key Information: Template

Here you will find a brief summary of key points to inform you about the research study you are being invited to participate in. You can find more detailed information throughout this document.

- You may be eligible to take part in a research study. Taking part in this study is *completely voluntary*. Even if you decide to join the study, you are free to leave at any time if you change your mind.

- List key information designed to assist the participant in deciding whether or not they would like to participate in the study. This information should include:
  - Why is the study being conducted
    - Summarize study's primary objective
  - What exams, tests, procedures, etc. are involved in the research?
  - What are my choices if I decide not to take part in this study?
  - What are the risks and benefits of taking part in this study?

- *Optional study components*
  - If your research includes an optional sub-study, briefly summarize here.

Informed Consent: Added Element

- When research involves collection of identifiable private information or bio-specimens the consent must include:
  - Whether identifiers might be removed, and
  - If information or bio-specimens could be used for future research without additional consent

Informed Consent: New Basic Element

Statement to be used when appropriate:

- Subject's bio-specimens may be used for commercial profit (and whether the subject will or will not share in the commercial profit)
- Whether clinically relevant research results, including individual research results, will be disclosed to subjects or not
- For research involving bio-specimens, whether the research will involve whole genome sequencing

How will we comply?

- Develop Informed Consent policies and procedures document
  - For use in assisting researchers in creating brief overview of summary key information
- Informed consent templates
- Update informed consent checklist
- QA oversight
  - Informed consent monitoring

Documentation of Informed Consent

Electronic formats are acceptable

- "informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the consent.

- Definition "*Written*, or *in writing*, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format"

- E-consent must meet FDA and HIPAA, as applicable

Informed Consent: Posting

- Applies only to **federally-conducted** or supported clinical trials

  - Reminder:

    "**Clinical trial** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

- Consent must be posted on a "**publicly available Federal Web site**"

Informed Consent- Posting

- Only one IRB-approved version used to enroll subjects is required
  - Even if multiple exist, multisite study, or different subject groups

- Posting can take place any time after recruitment closes but no later than 60 days after the last study visit by any subject

- Federal department or agencies may permit/require redactions to the posted information
  - e.g. confidential commercial information
  - could determine that the very existence of a particular clinical trial should not be publicly disclosed, in which case no posting would be required (rare)

Exemption Changes

Exemption 1 – Educational Exemption

What's new?

- Now must consider "adverse affects" on student learning of required educational content or on assessment of educators
  - Normal educational practices that are not likely to adversely impact (i) students' opportunity to learn required educational content, or (ii) assessment of educators who provide instruction

Exemption 2 – Surveys/Interviews/Educational Tests/Public Observation ONLY

What's new?

- Projects collecting **sensitive** and **identifiable** data may be exempt after "limited IRB review" (for privacy/confidentiality protections)
- Clarifies that the exemption **does not apply** to projects involving:
  - Interventions
  - Collection of biospecimens
  - Linking to additional personally-identifiable data
  - Children (except for educational tests or some public observations)

Exemption 3 – Benign Behavioral Interventions

What's new?

- NEW exemption
- Limited to research with adults

What is a benign behavioral intervention?

- Brief in duration
- Harmless and painless
- Not physically invasive
- Not likely to have a significant adverse impact on subjects
- Not offensive or embarrassing

Exemption 3 – Benign Behavioral Interventions

- Information is collected via
  - Verbal or written responses (surveys/interviews)
  - Data entry
  - Observation of subject (including audiovisual recording)
- Does not permit data collection via physical procedures
  - Physical sensors (e.g. blood pressure monitors, EEG, FitBits)
  - Minimally invasive procedures (e.g. blood draw or saliva collection)

Exemption 3 – Benign Behavioral Interventions

- Must obtain "prospective agreement to the intervention and information collection"
- **No deception**, except where the subject is told that they will be unaware or misled about the nature or purposes of the research and they agree
  - Debriefing still encouraged
- "Limited IRB Review" required for projects collecting sensitive and identifiable data

Examples

- Solving puzzles under various noise conditions
- Playing an economic game
- Being exposed to stimuli such as color, light or sound (at safe levels)
- Performing cognitive tasks

Exemption 4 – Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens

What's new?

- No longer limited to retrospective data review
- Permits secondary use of identifiable protected health information (PHI) (with HIPAA privacy board review)

Exemption 5 – Public Benefit/Service Programs Research /Demonstration Programs

- Expanded to apply to such federally-supported research; no longer limited to federally-conducted research

- Added requirement that Federal agency publish a list of projects covered by this exemption prior to commencing the research

Exemption 6 – Taste/Food Quality Evaluation

- Unchanged

- (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exemptions 7 & 8 – Storage and Secondary Use of Data/Biospecimens

Related new exemptions

- Exemption 7 covers the storage and maintenance of identifiable data and/or biospecimens for future research collected under broad consent
- Exemption 8 covers the use of secondary data/ biospecimens collected under broad consent

IRB will not use Exemptions 7 & 8

Single IRB (sIRB) Review Requirement

Requires that all federally-sponsored research with multi-institutional collaborators be reviewed by one designated IRB of Record

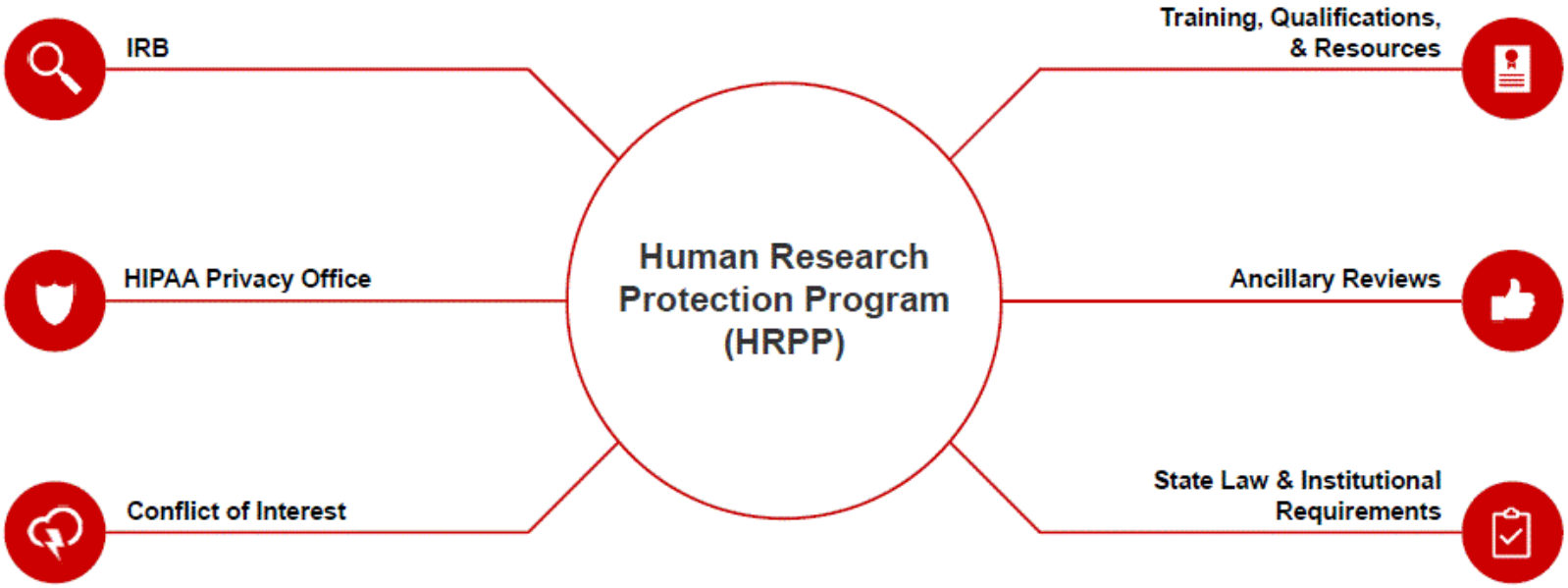
- Common Rule (compliance date 1/20/2020)
  - Applies to all federally supported multi-site studies, not limited to clinical research. Final rule seems to allow agencies to include certain broad types of research from requirements. No other information available.
- NIH (compliance date 1/25/2018)
  - Applies to all NIH sponsored multi-site studies
  - Applies only to domestic research studies conducting the same protocol
  - Does not apply to career development, research training or fellowship awards
  - Does not apply to studies involving more than one site and the sites have different roles in carrying out the research

- SMART IRB – Standard Reliance Agreement

sIRBs: Intended Benefits

- Reduces duplicative review across sites
- Reduces variability of the study design across sites
- Decreases cumulative review time
- Decreases burdens on local IRBs

Human Research Protection



sIRB NIH Policy: How To Comply?

Effective 1/25/2018

Currently, USA will not serve as the sIRB of IRB and will request to cede review to an external IRB.

- Finalize Policy and Procedures for Collaborative Research and External IRBs

- Research team completes IRB Reliance Request/Registration Form
  - Application for an External Institution to serve as IRB of Record

Attributions

- U-M website
  - http://research-compliance.umich.edu/human-subjects/common-rule-other-changes
- SACHRP Recommendations

  (Secretary's Advisory Committee on Human Research Protections)
  - https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html
- Common Rule
  - https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html