Social Behavioral Research and Key Changes to Common Rule

What Researchers Need to Know

Office for the Protection of Research Subjects

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Office for the Protection of Research Subjects (OPRS)

• Writes policies for IRB & researchers
• Creates educational materials
• Assures institutional compliance with regulations
• Maintains USC AAHRPP accreditation

oprs.usc.edu

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The “Common Rule” & Why it Matters

• Common Rule (45 CFR 46)
• Dictates what is reviewed by IRB and how the review is conducted
  ◦ human subjects research (HSR)
  ◦ HSR funded by HHS and other federal agencies (VA, Dept Ed, DOE, NASA, HUD, etc)
• IRB review is required by funding agencies and academic journal

Highlight of Common Rule Changes

• Definitions added for familiar concepts (intervention, clinical trial, vulnerable subject)
• Continuing review eliminated for expedited projects
• Consent has new required elements and required “key info” up front
• Exemption categories heavily revised
• Single IRB review required for multisite projects
• HHS will not exercise oversight of research not funded by HHS
“Nonresearch activities” (Not subject to IRB)

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship)
- Government research
  - Public health surveillance activities
  - Collection of information for criminal justice purposes
  - Operational activities for national security purposes

New Definitions in Common Rule

- **Benign behavioral intervention**: brief harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing
- **Intervention**: physical procedures/environmental manipulations by which information or biospecimens are gathered
New Definitions in Common Rule

- **Vulnerable Subjects**: participants vulnerable to coercion/undue influence
- **Clinical trial**: study in which human subjects are prospectively assigned to interventions to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- **Legally Authorized Representative**: individual/judicial/body authorized under applicable law to consent on behalf of prospective subject

Continuing Review Eliminated for Some Research

- Continuing review eliminated for
  - Expedited research
  - Full board projects once subject interaction is complete (data analysis or accessing follow-up clinical data)
- IRB can conduct continuing review when not required (rationale must be documented)
- If adverse event occurs or risk level is changed, PI must still submit change/event to IRB
- Investigators will receive annual reminders about submitting amendments, adverse events
Reminder: IRB Levels of Review

- **Full Board**
  - greater than minimal risk; e.g. drug study/domestic violence study
  - Reviewed by convened IRB committee

- **Expedited**
  - minimal risk; e.g. blood draw / alcoholism
  - Reviewed by IRB Chair/designee

- **Exempt**
  - not greater than minimal risk; e.g. blood pressure / educational tests
  - Reviewed by IRB Chair/designee/staff

- **Coded Data / Specimens**
  - e.g. analyzing discarded tissue
  - Reviewed by IRB Staff

- **Not Human Subjects Research**
  - doesn’t meet federal definition or is coded data
  - Reviewed by IRB Staff

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations or tests.

Changes to Exempt Categories
Overview of Exempt Categories

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<td>Exempt 8 Secondary research</td>
<td>New, requires “limited IRB review”</td>
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Exemption 1 – Education Research

- Normal educational practices in established or commonly accepted educational settings
- What’s new?
  - IRB must consider “adverse affects” on student learning or on assessment of educators
Exemption 2 – Surveys/Interviews/ Educational Tests/Observation of Public Behavior

What’s new?

- 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?

- Exemption is completely new
- Limited to verbal or written data collection
- Limited to research with adults

*Benign behavioral intervention

- Must obtain the subjects’ prospective agreement to the intervention and information collection
- No deception, except where the subject prospectively agrees (Debriefing still encouraged)
- No data collection via physical procedures (e.g. blood pressure, blood draw or saliva collection)
Examples of Benign Behavioral Interventions

• 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: Federal research or demonstration projects

Research designed to study, evaluate, improve, or otherwise examine public benefit or service programs

What’s new?

• Expanded to apply to such federally-supported research (no longer limited to federally-conducted research)

• Federal agencies must publish a list of projects covered by this exemption prior to research commencing

Exemption 6: Taste and food quality evaluation and consumer acceptance studies:

What’s new?  **NO CHANGE!**

• Exemption permitted if wholesome foods without additives are consumed, or

• Food contains food ingredient at or below the level and for a use are generally regarded as safe (GRAS)
New Exempt 7 – Storage and maintenance of identifiable material for which broad consent is required

What’s New?
IRB may exempt storage and maintenance of identifiable material for potential secondary research if...

• Consent was obtained for the primary research
• Broad consent was obtained
• IRB conducts a limited IRB review
• Investigators do not plan to return individual results to subjects

Exempt 8 – Use of identifiable data/specimens for which broad consent is required

IRB may exempt secondary research with identifiable info/specimens if:

• Consent was obtained for the primary research
• Broad consent was obtained
• IRB conducts a limited IRB review
• Investigators do not plan to return individual results to subjects
**Broad Consent for Future Research using Identified Data or Bio specimens (Exempt 7 & 8)**

- Broad consent is not necessary
- Gives subjects more control over research that might be done with their identifiable data
- Enables exemption of secondary research
- Necessitates an IT system to track individual biospecimens/data (refused/agreed or no response) to validate their inclusion in the study
- If subject declined to grant broad consent IRB cannot waive consent for secondary research

**Limited IRB Review**

- Mandatory for granting exemptions 7& 8 (secondary storage or use of research w/identifiable private info/specimens)
- Conducted by convened IRB (but IRB may use expedited review procedure)
- Continuing review not required after limited IRB review has been performed
Informed Consent Changes

- Must provide a “concise and focused presentation of key information” up front:
  - Voluntary participation
  - Summary of research procedures
  - Risks
  - Benefits
- Short consent (e.g. 4 pages) may not require key information section
- New USC consent templates provided
  oprs.usc.edu/hsirb/forms
Informed Consent: New Required Elements

• New element of consent (required as applicable)
  ◦ De-identified data or biospecimens may be shared for future research (or not)
• Biospecimens may be used for commercial profit (and whether the subject will share in that profit)
• Clinically relevant results will be returned (or not)
• Research will involve whole genome sequencing

Changes to Informed Consent Use

• Waiver of consent-- new criteria:
  ◦ For secondary use of data, must justify use of identifiers
• For federally-sponsored clinical trials*, a copy of an approved consent form must be posted on a “Federal website that will be established as a repository for such informed consent forms.”

*OHRP defines a clinical trial as: “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 effect of the interventions on biomedical or behavioral health-related outcomes.”
Consent Not Required for Screening

• No consent for screening, recruiting, or determining eligibility of prospective subjects if:
  ◦ information is obtained through oral or written communication OR;
  ◦ investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

*Single IRB (sIRB) Review Requirement

• *One IRB reviews for all participating sites in U.S.
• FDA no longer requires local IRB review of device trials
• sIRB Review required for multisite research funded by:
  ◦ NIH -effective January 25, 2018
  ◦ HHS -effective January 2020
• sIRB exceptions:
  ◦ If local IRB review is required by law (e.g., tribal law)
  ◦ If sponsor determines single IRB not appropriate
Research Eligible for Flexibility Policy* if all of the following:

- Not federally funded/federally regulated
- Research involves “minimal risk”
- Equivalent protections to Common Rule

*Flex exclusions: clinical trials, clinical interventions, research requiring ancillary reviews (rad safety, biosafety, conflict of interest, etc.)
New NIH Policy for Certificate of Confidentiality

• Cert of Confidentiality automatic condition of NIH award
• Applies to all NIH-funded research beginning December 13, 2016
• Limits disclosure “identifiable, sensitive” information
  ◦ Includes all identifiable human subjects data, biospecimens, individual level human genomic data, or other research data
  ◦ Information/biospecimens are also considered to be identifiable if there is a very small risk of deductive disclosure
• NIH will continue to issue CoCs for other non-NIH research falling under its mission

NIH Policy Changes—Clinical Trials

• Registration of research and reporting of results on ClinicalTrials.gov (effective 1/18/2017)
• Good Clinical Practice training requirement (effective 1/1/2017)
• Single IRB-of-Record requirement for multisite studies (effective 1/25/2018)
Common Rule Resources from USC

• Check the OPRS website for updates
  ◦ [https://oprs.usc.edu](https://oprs.usc.edu)
  ◦ Important dates
  ◦ Changes to institutional policies and procedures
  ◦ New informed consent templates
  ◦ Updated guidance materials

Common Rule Resources from Feds

• Federal Policy for the Protection of Human Subjects, Text of New Rule

• Secretary’s Advisory Committee on Human Research Protections, August 2, 2017, Letter to the HHS Secretary and Attachments, including:
  ◦ Attachment B, Recommendations on Benign Behavioral Intervention
  ◦ Attachment C, Recommendations for Broad Consent Guidance
  ◦ [https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html)
Questions

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