Common Rule Changes
Effective date is January 21, 2019

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Transition Provisions- Upstate IRB

- Research approved by the IRB or determined to be exempt, on or after 21 January 2019 must comply with the Revised Common Rule (2018 requirements)
- Research approved by the IRB or determined to be exempt before January 21, 2019 are “grandfathered” and are not required to comply with the changes

Transition Provisions- WIRB

- Federally funded research approved by the IRB on or after 21 January 2019 must comply with the Revised Common Rule (2018 requirements)

- FDA regulated research is not required to comply with the Revised Common Rule (at this time).

Summary of Main Changes

- Definitions
- Informed Consent
- Posting consent forms
- Continuing review
- Exemptions
- Limited IRB Review
- Single IRB-of-record (January 2020)

Definitions

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Definitions

The following activities are deemed not to be research:

(1) Certain scholarly and journalistic activities,

(2) Certain Public health surveillance activities,

(3) Collection and analysis of information, specimens, or records by or for a criminal justice agency for certain criminal justice or criminal investigative purposes, and

(4) Certain authorized operational activities for national security purposes.

Definitions

Public Health Authority: means “an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Definitions

- **Clinical Trial:** “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 their interventions on biomedical or behavioral health-related outcomes.

- **Subjects vulnerable to coercion or undue influence**, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

Note: no changes to the subparts were made.

Informed Consent

Several Major changes:

- Informed consent must give prospective subjects the information that a reasonable person would want to have in order to make an informed decision about whether to participate.
- the information needs to be presented in sufficient detail and organized and presented in a way that facilitates an understanding of why one might, or might not, want to participate (informed consent should not merely be a list of isolated facts).
- **key information** about the study must be provided, in a concise and focused manner, at the beginning of the discussion and form (the aim is to put the really important information up front).

Informed Consent

One New Basic Element – must include whether participants' information or biospecimens collected as part of the current research might or might not be stripped of identifiers and used for other research in the future.

Examples:

- Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent or
- Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

Note: that this is only about future research use of information and biospecimens that will be stripped of identifiers.

Informed Consent

Three New Additional Elements (all notices): include only if applicable:

- notice about possible commercial profit,
- notice about whether clinically relevant research results will be returned to the subjects,
- notice about whether research activities will or might include whole genome sequencing.

Informed Consent

Key Information:

- For example: purpose, the risks, the benefits, and alternatives, and it will explain to the person how to think about these pieces of information in terms of making a decision.

- If information included in the key information section also satisfies the elements of informed consent, this information need not be repeated later in the body of the informed consent.

Informed Consent

Screening, recruiting, or determining eligibility

- An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility without the informed consent if either of the following conditions are met:
  - The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
  - The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

This option does not apply to FDA-regulated research.

Posting Consent Forms

- One IRB approved version of a consent form, that has been used to enroll subjects, must be posted on a public federal website designated for posting such consent forms.
- The form must be posted after recruitment closes, and no later than 60 days after the last study visit.
- Federal departments or agencies may permit or require redactions as appropriate.

Note: this applies to clinical trials conducted or supported by a federal dept. or agency. Refer to the definition of clinical trial for determining which studies require posting

Continuing review

Continuing IRB review will NOT be required (in most cases) for:

- Research that is eligible for expedited review,
- Exempt research conditioned on limited IRB review,
- Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable,
- Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

***Note*: Researchers are still required to maintain human subjects training, submit all changes, unanticipated problems or complaints, closure reports, etc.**

Exemptions

Exemption 1 - Education:

- Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular or special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemptions

Exemption 2 - Surveys, Interviews, Observation:

- Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria are met:

  (Only: 1. the use of educational tests and 2. observation of public behavior when the investigator(s) do not participate in the activities being observed apply to research involving children and conditions i or ii are met).

  i. The information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

  ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

  iii. Where identifiable information (even if sensitive) is recorded, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study.

  (This option does not apply to research involving children)

Exemptions

Exemption 3(i) - Benign Behavioral Interventions: *(NEW)*

- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of following criteria is met:
  - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
  - Any disclosure of human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; or
  - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through Identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

Exemptions

Exemption 3 - Benign Behavioral Interventions:

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

-examples: playing an online game, solving puzzles under various noise conditions, or deciding how to allocate a nominal amount of received cash between themselves and someone else.

Not applicable to biomedical research.

Exemptions

Exemption 4- secondary research:

Secondary use of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly, or through identifiers linked to subjects, the investigator does not contact subjects, and the investigator will not re-identify subjects;
- The investigator's secondary use of the identifiable private information is regulated under HIPAA as "healthcare operations," "research," or "public health."
- The secondary research is conducted by, or on behalf of a federal department or agency, using data collected or generated by the government for nonresearch purposes, and the information is subject to federal privacy standards and other requirements specified in the exemption.

Exemptions

Revised exemption #4

- eliminates the requirement that the data exist at the time of the exempt determination; data may be collected prospectively.
  - ✓ for example, a research study that proposes to analyze samples or information that will be collected for clinical purposes in the future could qualify for this exemption if it meets at least one of the applicability provisions.

Exemptions

Exemption 5- Demonstration Projects:

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

1. Public benefit or service programs;
2. Procedures for obtaining benefits or services under those programs;
3. Possible changes in or alternatives to those programs or procedures; or,
4. Possible changes in methods or levels of payment for benefits or services under those programs.

Exemptions

Exemption 6-Taste and Food Quality:

Taste and food quality evaluation and consumer acceptance studies:

- If wholesome foods without additives are consumed, or

- 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.

Limitation on Exemptions

Prisoners: Exemptions do not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Children: Most of the exemptions apply for research involving children with some exceptions, as noted on the slides.

FDA regulated research: Research activities regulated by the FDA are generally not eligible for exemption (except emergency use of a test article and Taste and food quality evaluations and consumer acceptance studies).

Regulations include 2 additional categories for exempt research which Upstate has determined not to use due to additional regulatory requirements.

Limited IRB Review

The IRB Chair/Vice Chair must determine that the privacy of subjects and the confidentiality of data in the proposed research are appropriate.

Researchers need to be familiar with the following Upstate Policies:

1. UW I-06- Information Security Policy: This policy defines the data security principles associated with computer and information systems.
2. UW-M-01- Device and Media Controls Policy: This policy establishes the security protection requirements for all devices and media used to store, process and send electronic patient, research subject, employee, student and/or other proprietary information at Upstate Medical University.
3. UW E-09 - Laptop/MacBook Encryption Policy: This policy defines the requirements for laptop/MacBook encryption to protect patient, research subject, financial, and/or student information.

Single IRB (sIRB) Mandate-NIH

The National Institutes of Health (NIH) implemented a Single IRB-of-Record policy on January 25, 2018. This policy applies to:

- NIH-sponsored multi-site studies conducted in the US, where the same protocol is used at multiple sites.

Exceptions:

- Types of awards (e.g., Career development, research training, or fellowship awards (“K”, “T”, and “F” grants)
- Types of Sites (e.g., VA sites, tribal nations, where the law (federal, tribal or state) prohibits it; where there is a compelling justification)

Single IRB (sIRB) Mandate-DHHS

The revised common rule requires Single IRB review for federally funded studies where the same protocol will be conducted at more than one domestic site **- starting January 20, 2020.**

- At the present time, there is no existing or pending FDA regulation requiring single IRB review of FDA regulated multi-site research.
  - FDA is interested in harmonization with the Common Rule

Exception: when the law prohibits it, e.g., research on tribal lands, where central IRB review is typically prohibited.

Resources

- OHRP Revised common rule Q & A's
- OHRP Revised Common Rule Video
- CITI Program Final Rule Resources
- PRIM&Rs- Focus on the revised Common Rule- Resources & Tools
- NIH Notice of Revised NIH Definition of "Clinical Trial"
- NIH Clinical Trial Requirements for Grants and Contracts