The U.S. Department of Health and Human Services and Office for Human Subjects Protections Final Revisions to the Common Rule went into effect on **January 19, 2019.**

Major Areas of Change

- New and Revised Definitions
- New and Revised Exemption Categories
- Elimination of Continuing Review (Expedited Classification)
- Revised Informed Consent Requirements
- Guidance on Application to Clinical Data Registries
- Single IRB - Cooperative Research Studies

Important Definitions

1. Humans Subjects means a living individual about whom an investigator (professional or student) conducting research:
    a. Obtains **information or biospecimens** though intervention or interaction with the individual, and **uses studies or analyzes the information or biospecimens** OR
    b. Obtains, **uses, studies, analyzes or generates** identifiable private information **or identifiable biospecimens**
2. Activities deemed **not to be research** include the following four activates
    a. Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship) including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
    b. Public health surveillance activities
    c. Collection and analysis of information, biospecimens, or records for criminal justice or criminal investigative purposes; and
    d. Certain activities in support of intelligence, homeland, security, defense, or other national security missions
3. Intervention includes both physical procedures by which **information or biospecimens** are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
4. Interaction includes communication or interpersonal contact between investigator and subject
5. Clinical Trial - The final rule added the definition of "clinical trial," which was not defined in the previous version of the Common Rule. A clinical trial is "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."
6. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information **that** has been provided for specific purposes by an individual and **that** the individual can reasonably expect will not be made public (e.g., a medical record).
7. Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information

Exempt Studies

New categories for exemption have been created and some of the existing categories have been modified or clarified. You can find the full list of the exempt categories at the Office for Human Research Protection.

As a reminder exempt classification is still a category of review. Even if you believe you protocol submission falls into this category you must submit to the IRB for review. The University of Memphis Human Subjects Protection Policy states that the IRB is to review all research involving human subjects

Continuing Review (Renewal)

Unless the IRB determines otherwise, continuing review will not be required in the following circumstances:

- Studies approved through an exempt review
- Studies approved through an expedited review

A system-generated annual notice will be sent to investigators as a reminder that modifications, reportable events, and completion reports still need to be submitted to the IRB for review. [§46.109(f)(1)]

Consent Process and Forms

Informed consent must begin with a "concise and focused presentation of the key information" that would assist subjects in deciding whether they want to want to participate in the research. It needs to be organized and presented in a way that facilitates comprehension. [§46.116(a)].

Broad consent (e.g. prospective consent to unspecified future research) may be obtained in lieu of informed consent for secondary research use, storage, and maintenance of identifiable private information and identifiable biospecimens. Recommendations for a Broad Consent Template

For research involving collection of identifiable private information or identifiable biospecimens, subjects should be provided with:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens; and, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent, where applicable; OR
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

New Elements of Informed Consent

- Statement that biospecimens may be used for commercial profit (when applicable), and whether or not the subject will share in that profit;
- Statement regarding whether clinically relevant research results will be returned to subjects, and under what conditions; and
- Statement specifically for research involving biospecimens about whether the research will or might include whole genome sequencing.

These new elements will be expected in consent forms approved after January 19, 2019.

Waiver of Informed Consent

An additional criterion has been added that requires investigators to justify the use of identifiable private information or identifiable biospecimens. A waiver of informed consent is no longer necessary for screening or recruitment procedures as long as the IRB approves the procedures as a part of the protocol. [§46.116(g)]

Single IRB for Federally Funded Studies

- A single IRB must approve cooperative studies for research (projects that involve more than one institution) conducted in the United States, except where:
    - More than a single IRB review is required by law (including tribal law); or
    - Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate.
- The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of such Federal department or agency
- Documentation specifying the responsibilities of each entity, when research takes place at an institution in which IRB oversight is outsourced
- Common Rule agencies and departments will be given authority to enforce compliance against IRBs that are not operated by a Federal Wide Assurance (FWA)-holding institution
- Common Rule effective date is January 19, 2020. The NIH Single IRB (sIRB) requirement was effective as of January 25, 2018.

How Does This Affect Me as a Researcher?

Pending applications for new studies after January 19, 2019 will be reviewed under the new regulations. Researchers may need to work with IRB administrator to address any adjustments to protocol materials to achieve compliance with the revised regulations. If you have question or concerns about the new change or would like to schedule an educational training session contact us at IRB@memphis.edu

Where Can I Learn More?

- The Office for Human Research Protections (OHRP), a division of HHS, is the lead agency who published the final rule. This site provides a news release and commentary on the revised common rule.
- The published version of the changes to the Common Rule in the Federal Register.
- Public Responsibility in Medicine & Research (PRIM&R) provides many helpful resources on their website. Also see PRIM&R's Primer on the Revised Common Rule Q&A
- Collaborative Institutional Training Initiative (CITI) Program offers a wealth of resources on its website