Key Changes in the Revised Common Rule

New Definitions

Human Subject

A human subject is defined as 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

(Under the old definition, a human subject was defined as a living individual about whom an investigator obtains one or both of the following: 1) Data through intervention or interaction with the individual, or 2) Identifiable private information about the individual)

Intervention

Interventions are defined as both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject's environment that are performed for research purposes

(Under the old definition, interventions were defined as physical procedures by which data are gathered and manipulations of the subject or the subject's environment are performed for research purposes.)

Vulnerable Subject

The definition of vulnerable subjects has changed. The "handicapped" and "pregnant women" have been removed from the vulnerable populations list. Also, instead of the term "mentally disabled" to describe a vulnerable group, the language has been changed to a more accurate and appropriate category description of "individuals with impaired decision-making capacity.

Persons vulnerable to coercion or undue influence are now defined as:

- Children,
- Prisoners *
- Individuals with impaired decision-making capacity
- Economically disadvantaged
- Educationally disadvantaged

List of Activities Deemed Not to Be Research:

Scholarly and journalistic activities, including the collection and use of information, that focus directly on the specific individual about whom the information is collected.

Examples include but are not limited to:

- Oral History
- Journalism
- Biography
- Literary Criticism
- Legal Research
- Historical Scholarship

OHRP has provided further guidance on how and why some related activities will continue to require IRB review:

“Although activities described in [this] category may sometimes be performed in such academic fields as anthropology or sociology, a significant portion of the activities that are characteristic of these fields fall outside of [this] category and therefore remain within the scope of [the regulations]. Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand the beliefs, customs, and practices, not only of those individuals, but also of the community or group to which they belong, would not meet [this] category. The purpose and design of such studies or activities is to reveal something about the community or group – that is, to develop generalizable knowledge. Because the purpose of such studies or activities is not to limit the inquiry to knowledge about the particular individuals being observed, the protections provided by the requirements of [the regulations], such as the requirement to minimize any harm to the specific individuals from which the information was collected, are appropriate. Such activities would continue to fall within the scope of the definition of "research" under the 2018 Requirements.”

Informed Consent

A separate, detailed document describing the changes to the elements of informed consent and procedures related to waiver and documentation of consent may be found under the Manual and Forms banner. Please refer to that document as you prepare your informed consent.

Continuing Review of Expedited Research

Continuing review of expedited research is no longer required. If a reviewer deems it necessary, the reason must be document. In place of continuing review, the Human Protections administrator will send an email notification annually asking the investigator to close protocols if research is completed, and remind them to submit modification requests for any changes.

Continuing Review of Full Committee Research

Continuing review is no longer necessary for research reviewed at a convened meeting, for which interventions and/or data collection have been completed and only involves analyzing data, including analyzing identifiable private information or biospecimens and/or accessing follow-up clinical data from clinical care procedures.

Note Regarding the Revised Common Rule and Research Approved Prior to January 21, 2019

Research approved prior to January 21, 2019, may continue to be reviewed based on the current/old rule or may be switched to the revised rule. Switching to the new rules will be done on a case-by-case basis at time of continuing review, as continuing review is required for protocols under the old Common Rule.