PROVIDENCE COLLEGE

New IRB Common Rule -Updates relevant to PC Investigators

KEY CHANGES

Informed Consent

There are new changes to the structure and content of informed consent documents. Consent forms must begin with a concise summary of "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to join the research. This section must be organized in a way that facilitates understanding. These 5 key elements must be addresses clearly in accessible language.

Modified from www.citiprogram.com

- For exempt research that involves “benign behavioral intervention” the consent should include that the full purpose of the study cannot be revealed ahead of time, but the purpose will be revealed upon debriefing.

Exempt Research

The Revised Common Rule broadens the types of research that qualify for exemption and offers new categories of exemptions. Projects in the exempt category do not require continuing review by the IRB (i.e., they do not expire).

The significant revisions include the following:

1. Research involving educational methods remain exempt, **but only if the research is not likely to adversely affect classroom instruction time or student performance**.

2. Educational testing remains exempt as long as (a) any recorded information is completely de-identified; (b) any disclosures of information would not place the subjects at risk of criminal or civil liability or financial or reputational harm; or (c) the recorded information cannot be de-identified and the procedures have been reviewed by an IRB.

3. Research that involves **benign behavioral interventions with adults** is now exempt **but only** if

(a) recorded information is completely de-identified,
(b) disclosures of information would not place the subjects at risk of criminal or civil liability or financial or reputational harm, or
(c) the recorded information cannot be de-identified **and** the procedures have been reviewed by an IRB.

- As stated above, for a project to be considered exempt with benign behavior intervention, participants must be aware that the full purpose of the study cannot be revealed until they complete the study.

What is a benign behavioral intervention?

"Benign behavioral intervention" involves any behavioral (not biomedical) interventions used while collecting data on adult participants through oral or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met. Benign behavioral interventions should be brief in duration, harmless, unlikely to have a significant adverse lasting affect on the participants, and the investigator has no reason to think the subjects will find the interventions offensive, embarrassing, painful, or physically invasive.

Some examples of benign behavioral interventions: having the subjects play an online game; solve puzzles under various noise conditions; comparing test performance of test takers in quiet or noisy surroundings; or deciding how to allocate a nominal amount of received cash between themselves and someone else.

These studies have "limited IRB review" and are approved via an expedited approach (meaning at least two IRB members review the application to ensure it falls in the exempt category).

Continuing Review

The Revised Common Rule removes the requirement for continuing review for minimal risk research and for full-board research that is in long-term follow-up or data analysis only.

New minimal risk research will not automatically undergo continuing review by the IRB. The IRB may require continuing review for special circumstances such as studies involving conflict of interest, IRB reliance, or prior compliance concerns.

Even when continuing review is not required, investigators remain responsible for updating the IRB about adverse events and other unanticipated problems,

seeking IRB approval for changes to personnel, protocol amendments, recruitment materials, etc., and informing the IRB when the research is complete.

Single IRB Review. Single IRB review for studies conducted or supported by federal agencies will be required starting in January 2020. This means that studies in multiple sites must select a single IRB to conduct a review.

New Definition of Vulnerable Populations

The category of vulnerable subjects of whom the IRB should be cognizant is amended to include children, prisoners, and individuals with impaired decision-making capacity or economically or educationally disadvantaged persons. **Pregnant women are now excluded.**

Definition of Research

The original definition of research HAS NOT changed. Thus, research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

However, the New Common Rule has expanded a list of activities that DO NOT REQUIRE IRB REVIEW (i.e., not deemed research), including :**certain scholarly and journalistic activities, including oral histories**, certain public health surveillance activities, collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes, and certain authorized operational activities for national security purposes.

NOTE: Please remember, projects that are not designed to contribute to generalizable knowledge (e.g., program assessment, student projects completed for educational purposes, and projects that will not be shared with individuals beyond Providence College) **DO NOT** require IRB review. If you aren't sure whether the common rule applies, contact irb@providence.edu and we can let you know.