IRB at CU

Review Guidelines

Abstract

A brief summary of 3 categories of reviews as defined by OHRP, US Department of Health and Human Services is provided. Most research involving human subjects operate under the OHRP Common Rule 45 CFR Part 46, Subpart A, or the Food and Drug Administration's (FDA) human subject protection regulations (21 CFR Parts 50 and 56). These human subject regulations, include protections to help insure the privacy of subjects and the confidentiality of information. The Privacy Rule builds upon these existing Federal protections.

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Three Categories of IRB Review Process

Depending on the risk and subject demographic, a research/proposal will fall into one of three categories: exempt, expedited, or full committee review. The IRB Chair, in consultation with committee members if necessary, will determine the correct level of review.

Exempt Review

A research activity may be declared exempt if it is considered low-risk and the only involvement of human subjects falls into the 6 categories outlined in **45 CFR 46.101(b)**. Briefly these categories are:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices**.**
2. Research using anonymous or no-risk tests, surveys, interviews, or observations.
3. Most research involving public officials.
4. Research involving the collection or study of existing data if it is publically available or if subjects cannot be identified.
5. Research examining public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies.

Although subject consent is always needed, signed consent forms are typically not recommended if they are the only identifying variable in an otherwise anonymous project. Approval for exempt projects is good for 5 years, unless the researchers decide to change the protocol. If qualified, "Exempt" category needs to be reviewed by only one IRB member, sometimes in consultation with others. Most exempt level reviews are completed within two weeks after being received by the IRB chair.

Expedited Review

There are 7 categories of research listed in **45 CFR 46.110.,** that may be reviewed as expedited. In general, research may qualify for expedited review if it present no more than minimal risk to human subject, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate informed consent procedures. For example, one of the 7 categories eligible for an expedited review is the collection of physical data through non-invasive procedures, including: Height and weight; ECG, MRI, Ultrasound; Moderate exercise

Other categories describes the use of:

- Blood
- Other bodily fluids
- Clinical studies of drugs and medical devices
- behavioral/characteristic studies
- Collection of data from any form of digital recordings
- Research involving materials collected for non-research purposes

If qualified, "Expedited" review is done by the IRB chair and one or more experienced reviewers. Most expedited reviews are completed within approximately three weeks after being received by the IRB chair. Authorized review procedures are outlined in **45 CFR 46.110., and 21 CFR 56.110.**

Full Committee Review

A full review is required for research that is not eligible for either exempt or expedited review. Briefly, a research that involves more than minimal risk, or involves protected populations such as children, prisoners, or disabled individuals, must undergo a full board review. A full board review may require longer time to complete the review process.

The following categories of research require full IRB approval:

1. Projects for which the level of risk is determined by the IRB Chair to be greater than minimal.

2. Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
3. Projects that involve sensitive or protected populations (such as children or cognitively disabled individuals).
4. Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

- Applications requiring a full board review should be received by the IRB at least 3 weeks before a meeting.

- Tentatively IRB will meet every 4th Thursday of the Month

- For application materials and instructions are available at the following link for SPO:

http://www.claflin.edu/academics-research/faculty-research/sponsored-programs/research-compliance