IRRB Regulations and Application Process

The Federal Policy for Protection of Human Research Subjects (also known as "The Common Rule") codifies the processes for IRRB review and approval of research with human subjects. The IRRB also has a key oversight role, including the review and approval of animal use activities, and inspection of animal facilities.

All protocol (with a few exceptions listed) will require the following forms for a complete submission:

1. **Institutional Application Form**.
   Standard form to be used (see attached linked)
   See Below for Study application type.
   a. Make sure all sections are filled in thoroughly and completely. If additional space is needed you can use an attachment.
   b. Make sure application is signed by a mentor and department chair.
   c. The section on the application that asks for a discussion of risk to participants should include; contact numbers as well as counseling service and health center contact information
   d. The primary PI is the individual responsible for the completion of the study. Mentors should be included as CoPI (co-investigator)
   e. All studies must address how information is gather, from whom, and how this information will be stored and used while maintaining confidentiality.
2. **Informed Consent**
   a. All studies using humans for collection of data must use the standardized for linked below.
   b. If there is a conflict of interest in the study, all participant must submit a conflict of interest disclaimer. (contact IRB director for correct forms).
   c. No unspecified future research may occur without additional consent.
   d. Information or bio specimens **will not** be used for future research
   e. "Key information" must be presented first with sufficient detail for subjects understanding of reasons to participate – a revised consent template is provided in the link below.
   f. For clinical trials supported by federal funding, one IRB-approved consent form used to enroll participants must be posted on publicly available website.

3. **Study Overview**
   a. All studies should address, in sufficient detail, the purpose of the study and what collected confidential materials will be needed.

4. **All surveys** to be distributed with complete list of questions to be ask.
   a. All questions and demographics must be designed to assure that subject cannot be identified though information overview.

b. No Survey should ask for identifying personal information (this is strongly suggested for all studies). Exemptions will require full board review and approval.

Application Types

Exempt IRB Review: Very few meet this criteria

To qualify for review at the exempt level, the research must not be greater than minimal risk and must fall into one or more of the exemption categories (see regulation in link). Minimal risk is defined by the federal regulations (45 CFR 46) as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

****Expedited IRB Review: Most Campus Studies**

Resent rule changes on expedited review categories remain unchanged. However, the requirements of expedited research have been updated: Expedited categories of IRB review will be annually evaluated by the HHS Office for Human Research Protections.

Single IRB Review

Single IRB review will be required for all federally funded, cooperative research studies effective January 2020 (NIH already requires single IRB review). Reviewing IRB must be identified by funding department or agency or proposed by the lead institution.

Continuing Review

(All studies are approved for one academic year only (Aug-May), resubmission is required to continue past expiration dates on approval letters.

Yearly Continuing Reviews are no longer required under federal mandate for:

a. Research approved by expedited review
b. Exempt research requiring limited IRB review
c. Research interventions completed and only involving:
    a. Data analysis, including identifiable private information or identifiable bio-specimens
    b. Accessing follow-up clinical data from clinical care procedures

Expedited review studies will be every two (2) years.

Exempt reviews will be every five (5) years.