IRB Submission and Review Process

Definitions

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through

(a) Intervention or interaction with the individual, or
(b) Identifiable private information

Process

1. If your project qualifies as human subjects research, you must complete the Human Subjects Research Approval, including all the relevant required attachments and submit it to the IRB Administrator (Montebello Complex, D-302). A typical submission includes: an application, a consent form, a protocol, and additional supporting documents (e.g., questionnaires, advertisements, brochures, interview guides, etc.), signed by the researcher and advisor, if applicable.

2. You are strongly encouraged to provide certification that you have completed the training to conduct human subjects research (CITI - Collaborative Institutional Training Initiative or a comparable course). This is a requirement for all federally sponsored research.

3. Your application will be reviewed to determine if it is complete. Incomplete applications will be returned to the investigator for completion. Completed applications will be evaluated to determine if they fall within one or more of the specified categories of Exempt research, Expedited Review or Full Review, per federal regulations (45 CFR 46.101).

4. The IRB meets once a month for protocols review on scheduled dates. Please contact the IRB office for IRB meeting dates. Approved protocols will be valid for one year. All protocol approvals must be renewed on an annual basis, if needed.

5. Work on a project cannot extend beyond the date approved by the IRB. If it is necessary for work to extend beyond this date, a completed Renewal Request Form must be submitted.

6. Work on a project cannot be modified from the approved protocol. If any changes are to be made, a full description of the modification must be submitted to the IRB Administrator for review.

7. No research can be conducted until the investigator has received confirmation from the IRB Chairperson that the application is approved, or in the case of renewals and modifications, until they also are approved.

Please contact the IRB Administrator at 443-885-3447 if you have questions about the process.

*Note - Please submit forms at least one month prior to the projected start of research. The IRB office is committed to moving applications through the process as expeditiously as possible, while adhering to high standards of human subjects protection consistent with federal regulations 45 CFR 46 and institutional policies.