Investigator Responsibilities
Protection of Human Research Subjects

The Institutional Review Board reviews research to ensure that the federal regulations for protecting human research subjects outlined in the Department of Health and Human Services (DHHS) regulations (45 CFR 46) and the Common Rule are met.

Federalwide Assurance (FWA), awarded by the Office for Human Research Protections (OHRP) at DHHS, is a pledge to follow federal guidelines for protecting human research subjects following the principles of the Belmont Report.

All investigators are responsible for reading the Belmont Report to understand their responsibilities in conducting human subject research:

http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Important responsibilities investigators have when conducting research involving human subjects are:

1. **Conducting the Research:** You are responsible for ensuring the research is conducted according to the IRB-approved research protocol.

2. **Research Staff/Assistants:** You are responsible for the actions of all your co-investors and research staff (including students).

3. **Subject Enrollment:** You may not recruit or enroll subjects prior to the IRB approval date or after the expiration date of IRB approval. The IRB must approve all recruitment materials for any form of media before their use, and the IRB approval number must appear on all materials related to the study. If you need to recruit more subjects than noted in your proposal, you must submit a protocol amendment to the IRB for approval.

4. **Informed Consent:** You are responsible for obtaining and documenting effective informed consent using **only** the IRB-approved consent documents and ensuring that no human subjects are involved in research before obtaining their consent. Consent forms should include both printed names and signatures of research subjects. Keep originals in your secured research files for at least three years following the conclusion of your research.

5. **Continuing Review:** The IRB must review and approve all IRB-approved research protocols at intervals appropriate to the degree of risk, but not less than once per year. **There is no grace period.** Before the date on which the IRB approval expires, you will receive several messages reminding you to submit a Renewal of Continuing Research Form. Although the IRB sends reminders, **it is ultimately your responsibility to submit the continuing review form promptly to ensure no lapse in IRB approval occurs.** If IRB approval lapses, you must stop new subject enrollment and contact the IRB immediately.

6. **Amendments and Changes to Protocol:** If you wish to amend or change any aspect of your research (such as design, interventions or procedures, number of subjects, subject population, consent document, instruments, surveys, or recruiting material), you must submit a protocol amendment for review by the IRB. **You may not initiate any amendments or changes to your research without first obtaining written IRB review and approval.** The only exception is when it is necessary to eliminate sudden and unexpected hazards to subjects, and the IRB should be informed immediately.

7. **Adverse or Unanticipated Events:** Any serious adverse events, subject complaints, and all unanticipated problems that involve risks to subjects or others, as well as any research-related injuries, occurring at any research site, must be reported to the IRB within **five (5) days** of discovery of the incident. You must also report any serious or continuing problems or non-compliance with the IRB's requirements for protecting human research subjects. All reportable events should be submitted to the IRB using an unanticipated problem form.

8. **Research Record Keeping:** You must keep the following research-related records in a secure location for a minimum of six years: the IRB-approved research protocol and all amendments; all consent documents; recruiting materials; continuing review reports; adverse and/or unanticipated events; and all correspondence to and from the IRB.

9. **Reports to Sponsors:** When you submit the required annual report to your sponsor, you must provide a copy to the IRB. You may submit the report at the time of continuing IRB review.

10. **Final Reports:** When you have completed or stopped work on your research, you must submit a study closure form to the IRB.

11. **On-Site Evaluations or Audits:** If you are notified that your research will be reviewed or audited by the sponsor, any other external agency, or any internal group, you must inform the IRB immediately of the impending audit or evaluation.

    If you have questions, please contact the IRB at CU-IRB@commonwealthu.edu.