

Investigator Responsibilities Protection of Human Research Subjects Bloomsburg University of Pennsylvania

The BUIRB (Bloomsburg University 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)

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html> and the Common Rule

<http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html> are met. Bloomsburg University of Pennsylvania's 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 in accordance with 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>. Some of the responsibilities investigators have when conducting research involving human subjects are listed below:

1. **Conducting the Research:** You are responsible for making sure that 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-investigators and research staff (inclusive of 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. All recruitment materials for any form of media must be approved by the IRB prior to their use and the IRB approval number must appear on all materials related to the study. If you need to recruit more subjects than was noted in your proposal, you must submit an amendment to protocol form 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 for ensuring that no human subjects are involved in research prior to obtaining their consent. Consent forms should include both printed name and signature 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**. Prior to the date on which the IRB approval expires, you will receive several messages reminding you to submit a Renewal of Continuing Research Form. www.bloomu.edu/irb-manager
Although the IRB sends reminders, **it is ultimately your responsibility to submit the continuing review form in a timely fashion to ensure a lapse in IRB approval does not occur**. If IRB approval of your research 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 the amendment to protocol form 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 apparent immediate hazards to subjects and the IRB should be immediately informed of this necessity. This Amendment to Protocol form may be found on the IRB website www.bloomu.edu/irb-manager
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 instances of 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 the Adverse/Unanticipated Problem Form available on the IRB website. www.bloomu.edu/irb-manager
8. **Research Record Keeping:** You must keep the following research related records, at a minimum, 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 of that report to the IRB. You may submit the report at the time of continuing IRB review.

10. **Final Reports:** When you have completed (no further subject enrollment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Study Closure Form to the IRB which can be found on the IRB website.

www.bloomu.edu/irb-manager

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 or need assistance, please contact the IRB at BU-IRB @bloomu.edu or call (570) 389-4367.