GREATER BALTIMORE MEDICAL CENTER
Institutional Review Board
Standard Operating Policies and Procedures (SOP)

Name of SOP: Investigator Qualifications, Responsibilities and Training Requirements
Section Number: 4.5
Effective Date: March 2, 2016
Last Revision:
Replaced SOP Revised On:

Principal investigators are obligated to design and conduct human subjects research in accordance with the ethical principles of the Belmont Report, federal regulations, state and local laws, and GBMC institutional policies, including those policies specific to the IRB. Principal investigators should not undertake responsibility for human subjects research unless they understand these requirements and are willing to uphold them.

An IRB approved principal investigator can be any of the following:

- employees of GBMC and its affiliates
- physicians who are a member of GBMC's medical staff
- residents or fellows affiliated with GBMC
- non-affiliated individuals who have a designated GBMC liaison

Principal investigators shall have the appropriate education, training, and experience to assume full responsibility for the conduct of their human subjects research. Although the principal investigator may delegate study-related tasks to appropriately qualified and trained study personnel, the principal investigator shall maintain oversight of and retain ultimate responsibility for the conduct of those who perform delegated functions.

Principal investigators are responsible for but are not limited to:

- Designing and conducting research in a manner that minimizes risk and maximizes benefit, using sound research design and generally accepted scientific and/or scholarly standards.
- Ensuring that adequate resources and facilities are available to carry out the proposed research project.
- Submitting and obtaining IRB approval prior to the initiation of any research-related activities.
- Ensuring that all members of the research staff, and all others directly involved in the conduct of the research project, are qualified by education, training, and experience to perform their research responsibilities.
- Recruiting subjects in a fair and equitable manner, weighing the potential benefits of the research to the participants against their vulnerability and the risks to them.

- Not enrolling subjects prior to IRB approval of the research project or after expiration of IRB approval.
- Ensuring that legally effective and approved informed consent has been obtained, using an adequate and appropriate consent process, and ensuring the consent process is documented appropriately unless the IRB has granted a waiver of informed consent or documentation of informed consent.
- Ensuring that the informed consent process is led only by individuals who have appropriate training and knowledge of the research, including any investigational product involved, in order to discuss the risks and benefits of the research with prospective subjects.
- Conducting the research project in strict accordance with the current IRB-approved research protocol except where a change may be necessary to eliminate an apparent immediate hazard to a given human research subject.
- Reporting promptly to the IRB proposed changes in the research.
- Implementing no changes in the approved protocol, informed consent or other IRB approved research related documents without prior IRB approval, except in an emergency when it is necessary to safeguard the well-being or human subjects.
- Obtaining continuing review and approval of ongoing research at the interval determined by the IRB (at least annually) to avoid expiration of IRB approval and cessation of all research activities.
- Promptly reporting to the IRB any serious & unexpected adverse events, unanticipated problems involving risks to subjects and/or others, or any changes made to eliminate apparent immediate hazards to subjects.
- Reporting promptly to the IRB any deviations from the currently approved research protocol.
- Complying with all IRB policies, decisions, conditions, and requirements.

As mentioned above, principal investigators are responsible for ensuring that all members of the research staff, and all others directly involved in the conduct of the research, are qualified by education, training, and experience to perform their research responsibilities. This includes human subjects research training.

Federal regulations for the protection of human subjects do not require investigators and research staff to obtain training in the protection of human subjects in research. However, the OHRP strongly recommends that an institution holding an OHRP-approved Federalwide Assurance (FWA) and their designated IRB establish training oversight mechanisms appropriate to the nature and volume of their research.

In response to this federal recommendation, the IRB has made it policy that all principal investigators, co-investigators and designated research project coordinators receive and maintain certification in human subjects research and comply with the following by:

1. Including evidence of human subjects research training in all new project submission packages (exempt studies excluded).

2. Including evidence of human subjects research training in all continuing review submission packages.
3. Including evidence of human subjects research training in all amendment submission packages requesting a study team change and/or addition involving the principal investigator, co-investigator or project coordinator.
4. The evidence of human subjects research training submitted shall be current with a completion date within the past three years.
5. The evidence of human subjects research training shall consist of the appropriate GBMC IRB approved training course(s) or documented equivalent training obtained elsewhere.

Submission packages that do not contain the above-mentioned, required evidence of human subjects research training shall not be processed until such evidence is included.

The IRB has approved three training courses in human subjects research. These courses are made available on the Collaborative Institutional Training Initiative's (CITI) on-line training website. The web address and instructions for accessing the training courses is available on the GBMC IRB webpage.

The IRB approved training courses and modules are as follows:

Basic Course in Biomedical Research
Belmont Report and CITI Course Introduction
History and Ethics of Human Subjects Research
Basic Institutional Review Board (IRB) Regulations and Review Process
Informed Consent
Research and HIPAA Privacy Protections
Populations in Research Requiring Additional Considerations and/or Protections
Genetic Research in Human Populations
FDA-Regulated Research
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
Conflicts of Interest in Research Involving Human Subjects

Elective Modules
Records-Based Research
Social and Behavioral Research (SBR) for Biomedical Researchers
Vulnerable Subjects—Research Involving Children
Vulnerable Subjects—Research Involving Pregnant Women, Human Fetuses, and Neonates
Research with Older Adults
Stem Cell Research Oversight (Part 1)
Stem Cell Research Oversight (Part 2)
Avoiding Group Harms—U.S. Research Perspectives

All ten of the "Basic Course in Biomedical Research" modules plus two "Elective Modules" must be completed with a score of at least 80% on all quizzes to pass the entire course.

Investigators who limit their activities to records-based research may limit their human subjects research training to the following course and modules:

Basic Course in Records-Based Research
All modules must be completed with a score of at least 80% on all quizzes to pass the entire course.
Belmont Report and CITI Course Introduction
History and Ethics of Human Subjects Research
Basic Institutional Review Board (IRB) Registration and Review Process
Records-Based Research
Research and HIPAA Privacy Protections

Investigators who limit their research activities to the use of surveys and/or questionnaires may limit their human subjects research training to the following course and modules:

Basic Course in Survey/Questionnaire Research
All modules must be completed with a score of at least 80% on all quizzes to pass the entire course.
Belmont Report and CITI Course Introduction
History and Ethics of Human Subjects Research
Basic Institutional Review Board (IRB) Registration and Review Process
Social and Behavioral Research (SBR) for Biomedical Researchers
Informed Consent
Research and HIPAA Privacy Protections

The following modules are available for general interest and do not count toward the completion of the above-mentioned required courses:

Supplemental Modules
Consent and Subject Recruitment Challenges: Remuneration
Cultural Competence in Research
Gender and Sexuality Diversity (GSD) in Human Research
Humanitarian Use Devices (HUDs)
International Studies
Phase 1 Research: Understanding Phase 1 Research
Phase 1 Research: Protecting Phase 1 Subjects
Research and Decisionally Impaired Subjects
Research Involving Subjects at the End of Life
Research with Critically Ill Subjects
Research with Persons who are Socially and Economically Disadvantaged
Students in Research
Vulnerable Subjects—Research Involving Workers/Employees

The IRB will accept evidence of comparable human subjects research training from an outside source provided the completion date is within the current three years; however, the IRB prefers that the above-mentioned GBMC IRB approved course(s) and modules be taken.

The IRB can, at its discretion, require an investigator or other research staff member to take any combination of the above-mentioned courses and/or individual modules regardless of the human subjects research training evidence provided.