1. PURPOSE
1.1 This policy establishes the Principal Investigator’s responsibilities for conducting human participants research.

2. POLICY
2.1. The Principal Investigator may not initiate any research involving human subjects without prior IRB review and approval or exemption.
2.2. Principal Investigators are ultimately responsible for the conduct of Human Subjects Research studies and for the rights and welfare of human subjects participating in them.
2.3. Principal Investigators and their study teams are responsible for being knowledgeable about and complying with federal, state, and local laws and regulations, GW policies, and the determinations of the GW IRBs.
2.4. Principal Investigators are responsible for being knowledgeable regarding ethical standards and practices in research.
2.5. Principal Investigators are responsible for appointing study team members and for submission of updates on study team members as changes in the team are made (such changes encompass both additions to the team and removal of team members).
2.6. Principal Investigators are responsible for properly training research staff in activities and procedures required for the conduct of HSR, including ensuring all research staff have completed the GW required CITIprogram.org training every two years.
2.7. When the research involves entities within GW that are not under the control of the Principal Investigator, the Principal Investigator ensures appropriate communication, education, and training of those staff.
2.8. Congruence with funding proposals:
   2.8.1. It is the responsibility of the Principal Investigator to assure that the research application is consistent with the proposal for funding for extramural or intramural support.
   2.8.2. The Principal Investigator should act as a liaison between the IRB and the research sponsor (e.g., notification of IRB review and approval).
2.9. The Principal Investigator is responsible for ensuring participant privacy.
2.10. The Principal Investigator is responsible for ensuring the conditions for maintaining confidentiality.
2.11. The Principal Investigator must ensure that there are additional protections for research involving vulnerable populations as required.
2.12. It is the responsibility of the Principal Investigator to obtain IRB approval for proposed changes to the research activities (i.e., modifications) prior to implementing them, except in cases where it is necessary to avert immediate, apparent hazard to the participants.

2.13. Principal Investigators must follow all requirements for continuing review.

2.14. Principal Investigators are responsible for submitting a study closure report to the IRB within 30 days of completion or termination of all research activities, even if the current approval period has expired.

2.15. Principal Investigators are responsible for signing all transactions submitted to the IRB, reaffirming that they are ultimately responsible for the conduct of the research.

2.16. Principal Investigators are responsible for maintaining study records:

2.16.1. Study records must be maintained for a minimum of three years after the completion of the research.

2.16.2. If the study involves a pediatric population, study records must be maintained until all participants are 18 years of age, or for three years, whichever is longer.

2.16.3. Studies that involve Protected Health Information must be maintained for a minimum of six years after the completion of the research.

2.16.4. The Principal Investigator must follow any additional requirements for record retention of the Principal Investigator’s funding source.

2.16.5. It is the Principal Investigator’s responsibility to have a clear understanding of the retention requirements of a sponsor or the Food and Drug Administration (FDA).

2.16.5.1. Principal Investigators must ensure that research records are accessible for inspection and copying by authorized representatives of the IRB, Federal regulatory agency representatives, and the department or agency supporting the research.

2.17. Principal Investigators must permit monitoring and auditing by the sponsor, the Office of Human Research, and inspection by the appropriate regulatory authority(ies).

2.18. In the event the Principal Investigator moves to another location and leaves GW, the GW IRB must be notified. The Principal Investigator may either have another GW investigator assume Principal Investigator responsibilities through the submission of a modification to the IRB, close each of his or her research studies with the IRB, or transfer the research studies to the new location. The Principal Investigator must also notify in writing to the GW IRB the plan for either destroying the data or transferring the data to another Principal Investigator. The original research study documents are the property of the GW and must remain at GW.

2.19. For protocols involving investigational product(s), the Principal Investigator should be thoroughly familiar with the appropriate use of the investigational
product(s). Principal Investigators are responsible for providing the Investigational New Drug (IND) or Investigational Device Exemption (IDE) from the FDA in accordance with Federal regulations regarding the use of Investigational Articles.

2.19.1. Principal Investigator holding an IND/IDE is considered a sponsor-investigator and assumes additional regulatory responsibilities.

2.20. Principal Investigators are responsible for obtaining review and approval from other university committees and institutions as required prior to the initiation of the research.

2.21. Principal Investigators are responsible for following the requirements for:

2.21.1. Creating a research protocol for greater than minimal risk studies if a sponsor or multi-center group has not provided one;
2.21.2. Providing appropriate oversight of the research;
2.21.3. Ensuring appropriate qualifications and knowledge of study personnel and research staff;
2.21.4. Ensuring Conflicts of Interest (COI) are adequately disclosed and managed;
2.21.5. Participant Recruitment;
2.21.6. Prospectively obtaining legally effective informed consent;
2.21.7. Responding to participant complaints or requests for information;
2.21.8. Minimizing risk, monitoring participants, and reporting for greater than minimal risk research;
2.21.9. Reporting unanticipated problems, adverse events, deviations, violations, exceptions, and all other promptly reportable information per the policy Prompt Reporting Requirements (HRP-801);
2.21.10. A plan for monitoring data;
2.21.11. Registering with ClinicalTrials.gov, if applicable;