1. PURPOSE
   1. This policy defines when Classroom Research projects require review and approval from the George Washington University Institutional Review Board (GW IRB).
   2. This policy defines the responsibilities of GW-affiliated individuals who are overseeing or conducting classroom activities that do not require submissions to GW IRB.
2. GUIDANCE
   1. Research conducted by students, graduate or undergraduate, as a part of classroom assignments does not usually fall under the federal regulation of research because it is not intended to or likely to lead to generalizable results. Rather, the activities are designed to facilitate learning of concepts and the opportunity to practice various procedures, including research methods (interviewing, observation and survey techniques, as well as data analysis). In such cases, the classroom project does not require GW IRB submission and approval.
   2. A classroom project is defined as a project which:
      1. is a normal part of the student’s coursework;
      2. is supervised by the course instructor;
      3. its primary purpose is education and the development of the student’s research skills;
      4. does not present more than minimal risk to participants or to the student investigator;
      5. does not involve collection of sensitive information, including but not limited to the following:
         1. sexual orientation, attitudes, preferences or practices;
         2. sexual assault or abuse, domestic violence, or harassment;
         3. practices of contraception, previous abortion and/or pregnancy;
         4. use of alcohol, drugs or other addictive products;
         5. traumatic experiences;
         6. illegal activities, involvement in criminal behavior, immigration status, if undocumented,
         7. opinions about supervisors or other employees or students
         8. individual’s psychological well-being or mental health;
         9. genetic information;
         10. health information or other information that would normally be recorded in a patient’s medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
         11. other information that if released could reasonably damage an individual’s financial standing, employability, or reputation within the community.
      6. does not include any persons as research subjects who are classified as part of a vulnerable populations according to Federal regulations, including: minors (under eighteen years of age), fetuses or products of labor and delivery; pregnant women (in studies that may influence maternal health); prisoners; individuals with a diminished capacity to give informed consent.
      7. will not result in publications, presentations outside the classroom, or any other form of public dissemination.
   3. The intent to publish or otherwise disseminate the results of the activity outside the classroom is one factor that is considered when determining whether the activity is regulated as research and needs IRB review. When class projects or activities are intended to collect information systematically with the intent to develop or contribute to generalizable knowledge, the project or activity meets the definition of research and will fall under the jurisdiction of the IRB.
   4. Even if the intent is to not produce generalizable knowledge, if a special population or sensitive topic area is part of the project, the student’s project DOES require GW IRB approval.
   5. IRB approval cannot be granted retroactively. If there is any likelihood that the results of the classroom project might later be used for research that does lend to generalizable knowledge (for example, a presentation to a group other than the class), IRB approval must be sought prior to conducting the research.
   6. It is the responsibility of the course instructor to determine whether an assigned project involving human participants can be classified as a classroom project.
   7. Both the course instructor of a classroom project and the student have an obligation to uphold ethical principles and to do their best to minimize any harm to other students or individuals.
      1. Instructors and students should work together to review the proposed project and discuss protections for privacy and confidentiality
      2. Students should take the CITI on-line training (www.citiprogram.org) on human subject protection before collecting information from others
      3. Students who wish to conduct research at an organization or institution outside of GW must obtain a letter of permission from the external organization or institution and include it with their IRB application
      4. Whenever possible, data collection should be anonymous so that data are not linked to individuals’ identities.
      5. If the collection of identifiable information is necessary, the information identifying individuals should be kept separately from the information collected from those individuals.
      6. Students must participants to provide a verbal consent to participate and present them with a document that contains the following information:
         1. student identification as a GW student who is performing the activity to fulfill a course requirement and identification of the course name
         2. name and contact information for the course instructor or supervising faculty member to contact for questions
         3. list of persons who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/agency/organization).
         4. statement that participation is voluntary, that they do not have to participate in the study if they don’t want to, and that they can stop participating at any time.
   8. This policy does not apply to independent student-initiated research projects conducted by undergraduate or graduate students, such as theses, honors projects, and independent study projects. Independent student research projects must be submitted to the GW IRB for review and approval. The application to the IRB for these student research projects must include overall responsibility by a faculty member who will be named as the Principal Investigator of the project.
3. ****Reference(s)****
   1. 45 CFR Part 46.