

## **IRB Policy I:**

### **GUST Education Training Requirements for the Protection of Human Participants.**

**Policy Definition.** All investigators who engage in the design, conduct, or reporting of human participant research (including exemption-level human participant research) must be trained in the protection of human participants. At a minimum, all individuals must complete an online education training course. Additional training requirements may be needed depending on the nature of the research being conducted or type of education required.

## **IRB Policy II:**

### **GUST Student Class Assignments/Projects.**

**Policy Definition.** Any activities required in a course of study as student class assignments and/or projects involving human participants may or may not meet the definition of research. It is the policy of the IRB not to review class assignments/projects unless they meet the definition of “human participant research.” The purpose of this policy is to provide: (1) information for students and their course instructors in determining when application to the RDO's IRB is required through understanding of the definition of “research” and “human participant” and (2) information on the responsibilities of the student(s) and course instructor(s) in the conduct of activities when IRB or RDO review is not required.

IRB review and approval or an RDO exemption determination is required only when activities meet the definition of both “research” and “human participant”. Student class assignments/projects that meet the definition of both “research” and “human participant” must be submitted to the RDO’s IRB for review and approval.

Generally, student class assignments/projects are not intended or likely to lead to generalizable results and would not meet the definition of “research” as defined in GUST’s research policy. True student class assignments/projects are typically conducted within the realm of assignments/projects for a class setting and do not extend beyond the classroom via dissemination.

Dissemination of findings to a scientific audience is a sufficient, but not the exclusive, criterion for meeting the definition of research. Dissemination includes, but is not limited to the following:

- Undergraduate honor's theses;
- Master's theses;
- Research exhibitions;
- Presentation at a scientific meeting or conference;
- Submission to or publication, paper or electronic, in a professional journal; and internet postings.
- If the results of a student’s class assignment/project will be published, presented, or otherwise disseminated beyond the GUST community, the student’s class assignments/projects must be reviewed and approved by the RDO’s IRB prior to involving human participants.

## **IRB Policy III**

### **GUST Faculty Human Research Protection.**

#### **Policy Definition.**

GUST's human research protection policy is founded on and guided by ethical principles, national and international laws, and institutional standards, policies, and procedures. Those that guide ethical principles may be found in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>). Compliance ensure the protection of human participants as mandated by applicable laws, regulations, and standards of local and national government agencies, in Kuwait and worldwide. GUST's policy regarding human research protection has been developed to meet high institutional standards and follows ethical principles and regulations. This policy applies to all research, not only that research receiving national funding.

## **IRB Policy IV**

### **GUST Exempt Review Process and Determination.**

**Policy Definition.** The GUST IRB mandates that all research projects and/or activities involving human participants be reviewed and approved by the IRB, unless an exemption is granted by the IRB within the RDO, according to standards/criteria for exemption established in IRB policy governing the use of human participants in research. This policy has been developed in order to provide: (1) information to researchers about those human research activities that may be considered exempt from IRB review and approval; (2) researchers' ethical responsibilities with regard to the involvement of human participants in research, since IRB oversight is not required; (3) the application process for research that is exempt; and (4) information about changes made to research that may require IRB review. Research activities must meet specific criteria in order to be exempt from initial and continuing IRB review. Exemption determinations are made by a committee within the IRB. All Principal Investigator(s) is/are responsible for ensuring the protection of human participants in research activities, and for performing research in a manner that has integrity and occurs within accepted ethical standards. In addition, the researcher(s) performing exempt research may be required to make provisions to obtain informed consent, protect confidentiality, minimize risks, and discuss problems or complaints with the RDO's IRB committee. Further, Principal Investigators are expected to see that they and all individuals working on their research projects have successfully completed IRB training, which can be accessed at: XXXXX. Exemption determinations are made by IRB staff not affiliated with research activities. Researchers may not make exemption determinations on their own.

## **IRB Policy V**

### **GUST Parental and Student/Child Consent.**

**Policy Definition.** Research that focuses on sensitive issues and the participation of children is becoming more common. Kuwait national law defines “children” as persons not yet of legal age to agree to research-related treatments or procedures under the applicable law of the jurisdiction in which the research is to be conducted. Under Kuwait law, persons under the age of eighteen (18) are generally regarded as “children, with the exception noted below. Permission to involve a child in a research study must be granted by the child’s parent(s) or guardian(s) prior to that child’s participation in research. The only exception is when a person under the age of 18 does not meet the national definition of “child” and thus may provide legally effective consent to participate in research.