**Procedure for IRB Policy I:**

**GUST Education Training Requirements for the Protection of Human Participants.** Investigators affiliated with the GUST are required to take the GUST's education training if they are listed on an IRB application and if they are:

- responsible for the research design and conduct of a human participant study;
- involved in research related to an intervention or interaction with human participants, including, but not limited to:
    - ✓ enrolling participants;
    - ✓ obtaining informed consent;
    - ✓ performing invasive or non-invasive procedures on or with human participants;
    - ✓ collecting and analyzing identifiable private information about living individual(s); and/or
    - ✓ accessing identifiable private information about a living individual or identifiable biological specimens for research-related activities.
- the assigned faculty advisor for student research involving human participants; or an individual who has transferred to the GUST.
- someone who has access to the link for Online Education Training at GUST.

**Procedure for IRB Policy II**

**GUST Student Class Assignments/Projects.**

Course instructors sometimes conduct activities that involve "human participants" but do not meet the definition of "research". Those who do engage in this practice, and their students, must be aware of and understand their responsibilities in a class assignment/project involving "human participants". Course instructors are ultimately responsible for assuring that human participants' rights and welfare are not violated and for students' ethical behavior in conducting an assignment/project. Students must take personal responsibility and be accountable for their actions as well. The course instructor must personally evaluate each class assignment/project and provide supervision and guidance during its execution.

Course instructors should ensure the following when evaluating a class assignment/project and advising a student on the conduct of the activities:

- The purpose of the proposed project and procedures are practicable and have merit;
- The human subjects recruitment process does not unfairly target a particular population without proper and pre-approved justification;
- "Human participants", including those with diminished autonomy (e.g., children, people with limited ability to make decisions), will be treated with respect;
- The privacy of the "human participant" and confidentiality of any data that they provide will be protected;
- The potential risks to individuals will be minimized; and
- The data collected from "human participants" do not contain identifiable private information not required to complete a class assignment/project.

The RDO strongly prefers that class projects/assignments carried out by students which may place individuals at more than minimal risk* and involve a vulnerable population ***NOT*** be conducted. However, if a class assignment/project unavoidably involves more than minimal risk and a vulnerable population, and the course instructor supports the assignment/project, the course instructor **MUST contact the RDO for advice and guidance before the initiation of the assignment/project**. In such rare instances, the class assignment/project may require review and approval by the IRB. Examples of vulnerable populations include children or adolescents, pregnant women, prisoners, people who are mentally disabled or those with impaired decision-making capacity, or human in vitro fertilization. If a class assignment/project must be reviewed by the IRB, the principal investigator listed on the IRB application must be the student's research advisor or course instructor. The student may be listed as a co-investigator.

**Procedure for IRB Policy III**

**GUST Faculty Human Research Protection.**

GUST faculty researchers who conduct research activities involving human participants must adhere to the following process:

- Fill out an IRB Research Form and submit it electronically to rdo@gust.edu.kw. See below:
  - ✓ This must be done if the research meets the definition for involving both research and human participants.
  - ✓ While studies may not meet the definition of "research" and/or involve a "human participant", investigators may not make an independent determination of the need/lack of need for IRB approval. Such determinations may only be made by qualified staff from the Office for Research Protections or Human Subjects Protection Office.
  - ✓ Certain types of research may be exempt from IRB approval. However, GUST investigators may not determine independently whether research involving human participants is exempt. Such determinations may only be made by a designated IRB member or qualified staff from the RDO's IRB.

- Initial review and approval by the IRB occurs at a convened meeting; investigators conducting research may not initiate their study prior to review and approval by the IRB. In the event that the IRB does not approve the research and/or requires further information, the researcher must do the following:
  - ✓ make all modifications to the research protocol and then seek another review and approval by the IRB prior to conducting his/her study;
  - ✓ report to the IRB problems that require prompt reporting;
  - ✓ maintain IRB approval until data collection and analysis are complete and all research activity has ceased;
  - ✓ submit progress reports at intervals stipulated by the IRB (including a final report upon completion of data collection and analysis).

- Research studies are sometimes conducted at other institutions. On these occasions, the RDO must receive a copy of approved procedures. The IRB will interact with other institutions to ensure that IRB policies and procedures are being followed by GUST researchers and students engaged in research at other institutions, or when personnel or students from other institutions perform research at GUST facilities.

**Procedure for IRB Policy IV**

**GUST Exempt Review Process and Determination.**

Applications for exemption determination must be submitted through an online eSubmission application system called the IRB-Review/Approval System (IRB-RAS), which can be accessed on the web at: **XXXXX.** Exemption determination applications are typically reviewed within seven (7) business days from date of receipt of a complete application. Review and process time may increase if (a) an application is incomplete; and/or (b) an application is unclear or lacks all information (e.g., complete application, grant application, data collection instruments, etc.) needed to make an informed decision about a study's exemption from mandated human subjects procedures.

Once human participant research is determined to be exempt, the IRB Committee will send an Exemption Determination notice to the Principal Investigator. The exemption is valid throughout the lifetime of a project unless a change(s) is made that requires additional review—again, determination of the need for additional review may be made by IRB staff only. Modification requests are submitted only under limited circumstances as described here; Continuing Progress Report forms do not need to be submitted. After five years, if the research project is still active or if the IRB has not been notified that the study is complete, the IRB will contact the Principal Investigator to request a status update on the project. If no response is received, the IRB will close the research file.

The researchers must notify the IRB at irb@gust.edu.kw, referencing the application ID number, when a research study is closed/completed. A research study should be regarded as closed when:

- It no longer meets the definition of "human subject/participant" (e.g., data have been de-identified and the researcher cannot personally identify any data; or
- Data collection and analysis are complete; or
- The researcher is no longer a GUST employee and an alternate GUST researcher has not been designated as the Principal Investigator.
- The IRB has the authority to audit research determined to be exempt. Reviews may occur before, during, and/or after the initiation of research study procedures. Studies may be selected randomly or volunteered by Principal Investigator(s) for routine reviews; if there are concerns, directed/for cause reviews may be conducted.

**Procedure for IRB Policy V**

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

The reading level of informed consent documents should be appropriate to the typical educational background of the research population. These documents should contain short sentences and everyday language.

Parental consent is one half of the consent process in the recruitment of children as human research participants. The child's assent must also be obtained. The means followed to obtain this assent must be appropriate for the age ranges and levels of mental development found within the proposed participant pool. The National Commission for the Protection of Human Subjects of Biomedical and Social Science Research expects assent to be requested from children aged 6 years or older. For children aged 6–18, the appropriate method for obtaining assent will vary. The following guidelines may be followed:

- Ages 6–7: A simple oral description of the child's involvement is given to the participant and verbal assent is requested. This is documented via a witness signature on the informed consent form.
- Ages 8–13: A more complete oral description of the research (in layman's terminology) is given to the participant. Verbal assent is requested. This is documented via a witness signature on the informed consent form.
- Above age 13: Written assent should be requested from both parent and child, using age- and background-appropriate documents.
- Although age is used as the primary criterion in determining an appropriate means of obtaining assent, factors such as literacy and mental development must also be considered. Flexibility should be followed in obtaining children's assent. Since one method may not be appropriate for all potential participants, investigators should be prepared to use different approaches with different participants. The primary goal is to ensure that the participant understands the explanation presented. The need for a witness to document verbal assent procedures depends upon the complexity of the research and risks to the participant.
- A parent or guardian may not be the witness for a child's verbal assent document.

The IRB is the sole body authorized to assess potential risks and benefits in each research proposal, and provisions for permission and assent, to determine if an activity satisfies the conditions for research involving children.