Guideline (1): General Requirements for Informed Consent.

Except as provided elsewhere in this policy, no investigator may involve a human being in research covered by this policy without the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator may seek consent only when the prospective subject or his/her representative has sufficient opportunity to consider participation, and in a manner that minimizes the possibility of coercion or undue influence. Information given to the subject or his/her representative will be in language and rendered in a manner understandable to the subject or the representative. No informed consent, whether oral or written, may include exculpatory language that waives or appears to waive the subject's legal rights or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence.

a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, the following information shall be provided to each subject during the consent process:

- A statement that the study involves research, an explanation of study purposes and expected duration of the subject's participation, a description of procedures to be followed, and identification of any experimental procedures;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A description of the extent to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation of any compensation and an explanation of any available medical treatments if injury occurs and, if so, their nature and/or how to obtain further information;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and in the event of a research-related injury; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the right to discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

b) Additional elements of informed consent. When appropriate, one or more of the following elements should be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation;
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

c) The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent described above, or waive the requirement to obtain informed consent if:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - Public benefit or service programs;
  - Procedures for obtaining benefits or services under those programs;
  - Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration.

d) An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent if:

- The research involves only minimal risk to subjects;
- The waiver or alteration will not adversely affect subjects' rights and welfare;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

e) These informed consent requirements are not intended to preempt any applicable laws that require disclosure of additional information to ensure the legality of informed consent.

Guideline (2): Documentation of Informed Consent.

The following documentation must be provided to the IRB:

1) Except as provided in paragraph (c) of this section, informed consent will be documented via a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form and a copy retained in the study's records.

2) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

   - A written consent document that embodies the required elements of informed consent. The consent may be read to the subject or the subject's legally authorized representative, but must be read before it is signed; or
   - A short form written consent document containing the required elements of informed consent that is presented orally to the subject or the subject's legally authorized representative. Those who elect this method must ensure that a witness is present for the oral presentation. The IRB will approve a written summary of what is to be said to the subject or the representative. Only the short form itself will be signed by the subject or the representative. The witness will sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. Copies of each signed document shall be kept in project files.

3) An IRB may waive the requirement for a signed consent form for some or all subjects if:

   - The only record linking the subject and the research is the consent document and the principal risk is potential harm from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking his/her with the research—the subject's wishes will govern; or
   - The research presents minimal risk of harm to subjects and involves no procedures necessitating written consent
   - If the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Guideline (3): Requirements for Permission by Parents or Guardians and for Assent by Children (or Subjects).

The following requirements must be provided to IRB office:

- In addition to determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions have been made to solicit child participants' assent when it ascertains that the children are capable of providing assent. In making this determination, the IRB will take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children who may be involved in research under a particular protocol, or for each child, as deemed appropriate by the IRB. If the IRB determines that some or all of the children have sufficiently limited capacity to understand assent/consent and will benefit from the procedure involved in the research, children's assent may not be a necessary condition for proceeding with the research. If the IRB determines that subjects are capable of assent, the assent requirement may still be waived in accord with IRB Policy V and if procedures for this policy are met.
- In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by IRB Policy V, that adequate provisions have been made to solicit permission from each child's parents or guardian. If parental permission is needed, the IRB may determine that obtaining permission from one parent is sufficient under IRB Policy V. Where research is covered by IRB Policies (II, III, & IV) and parental permission must be obtained, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- In addition to the waiver provisions in IRB Policy V, the IRB may waive requirements in subpart A of this part and paragraph (b) of this section if it determines parental or guardian permission is not a reasonable requirement to protect subjects in a participant population (e.g., neglected or abused children), provided that an appropriate protective mechanism is substituted, and that the waiver is not inconsistent with existing laws. The choice of an appropriate mechanism depends on the nature and purpose of activities described in the protocol, risk and anticipated benefit to research subjects, and their age, maturity, status, and condition.
- Permission by parents or guardians will be documented in accordance with and to the extent required by IRB Policy V.

- When the IRB determines that assent is required, it shall also determine whether and the manner in which assent must be documented.

Guideline (4): Online Education Training for Researchers in GUST.

GUST requires all researcher(s) who conduct(s) new and ongoing research projects and/or activities to have received training in the protection of human research participants—that is, anyone involved in the conduct or oversight of human participant research must receive human subjects protection education before proceeding with work on a research project. GUST's human research protection training may be accessed at: www.gust.edu.kw/rdo. Clicking on this link, an individual user goes to the CITI website and chooses GUST as an affiliation institution. Human subjects education training is provided through CITI. Upon completing their human subjects training, GUST investigators are instructed to print a copy of the completed report, which is sent to the applicant's email address. A notification email is submitted to the RDO for filing and status updates.

Guideline (5): IRB Review of Research.

This guideline provides actions that must be taken by the IRB office before the conduct of research:

- The IRB shall review and have authority to approve, require modifications to (to secure approval), or reject all research activities covered by this policy.

- The IRB shall require that information given to subjects as part of the informed consent process is in accordance with IRB Policy V. The IRB may require that information, in addition to that specifically mentioned in IRB Policies (II, III, and IV), be given to the subjects when in its judgment this information may meaningfully add to subjects' rights and welfare.

- The IRB shall require documentation of informed consent or may waive documentation in accordance with University policy.

- The IRB shall notify Principal Researchers and the VPAA in writing of a decision to approve or not approve a proposed research activity, or require modifications that must be completed to secure IRB approval of a research activity. If the IRB decides not to approve a research activity, it shall state in its written notification the reasons for its decision and offer the PI an opportunity to respond in person or in writing.

- The IRB shall conduct continuing reviews of research covered by IRB policies at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and research.

Guideline (6): Criteria for IRB Approval of Research.

The following criteria must be met to obtain approval of research:

- To obtain approval, all of the following requirements should be satisfied:
  - Risks to subjects are minimized:
    - by using procedures consistent with sound research design and that do not unnecessarily expose subjects to risk, and
    - whenever appropriate, by using procedures already being performed on subjects for research purposes.
  - Risks are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result from the study. In evaluating risks and benefits, the IRB should consider only those possible from the research (as opposed to those stemming from therapies received by subjects even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in research (e.g., possible effects on public policy) as among those research risks that fall within the purview of its responsibility.
  - Selection of subjects occurs in an equitable manner. As it makes this assessment the IRB should include the purposes of and settings of the research study, and be particularly cognizant of special problems in involving vulnerable populations in research (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).
  - Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by §46.116.
  - Informed consent will be appropriately documented in accordance with and to the extent required.
  - When appropriate, the research plan will make adequate provision for data monitoring to ensure subjects' safety.
  - When appropriate, adequate provisions will be made to protect subjects' privacy and to maintain data confidentiality.
- If any of the potential population groups may be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards will be included in the study to protect their rights and welfare.

Guideline (7): Suspension or Termination of IRB Approval of Research.

The IRB may suspend or terminate approval of research not being conducted in accordance with its requirements or that has been associated with unexpected serious harm to subjects. Notice of suspension or termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

Guideline (8): IRB Registration Information and Procedures.

IRB Registration

The IRB designated by the Research and Development Office (RDO) is registered with the RDO.

Information for IRB Registration

The following information was submitted by the RDO when registering the IRB:

- The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB; and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official at the University (GUST) responsible for overseeing its activities.
- The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.
- The name, if any, assigned to the IRB by the University, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.
- The name, phone number, and electronic mail address of the IRB chairperson. (i)The approximate numbers of:
    - all active protocols; and
    - active protocols conducted or supported by the RDO

  (ii) An "active protocol"' is any protocol for which the IRB conducted an initial or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months.
- The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

IRB Registration and Date of Effect

- An IRB must be registered before being designated under an assurance approved for University research use by the RDO.
- IRB registration becomes effective when reviewed and accepted by the RDO.
- The registration is effective for three (3) years.

Renewal/Updating of IRB Registration

- The IRB must renew its registration every three years.
- The registration information for an IRB must be updated within 90 days of a change in information regarding the contact person providing IRB registration information or of the IRB chairperson. The updated registration information must be submitted to the RDO.

- Any renewal or update submitted to, and accepted by, the RDO begins a new 3-year effective period.
- The University's decision to disband a registered IRB must report this decision to the RDO within 30 days of the permanent cessation of IRB review.

Guideline (9): Cooperative Research. Policy Definition:

Cooperative research projects are those projects that involve more than one institution. Each institution involved in cooperative research projects is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. Subject to approval of a department or agency head, a participating institution may enter into a joint review arrangement, rely upon a review conducted by another institution's qualified IRB, or make similar arrangements in order to avoid duplication of effort.

Guideline (10): Research Undertaken That Does Not Involve Human Subjects.

Research that was originally undertaken without human subjects but consequently found to require their involvement must be reviewed and approved by an IRB, as provided in this policy, a certification submitted, and final approval given to the proposed change before the human subjects portion of the study may be started.

Exempt Review Categories:-

A research/ project is identified as **exempt** if the project:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(i) research on regular and special education instructional strategies, or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures or observation of public behavior, UNLESS: (below point (a) and (b) will not be exempted)**

(a) information obtained is recorded in such a manner that human subjects can be identified, directly or linked to the subjects; **and**

(b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2 a & b) **IF the human subjects are elected or appointed public officials or candidates for public office.**

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(a) Public benefit or service programs;

(b) procedures for obtaining benefits or services under those programs;

(c) possible changes in or alternatives to those programs or procedures; or

(d) possible changes in methods or levels of payment for benefits or services under those programs.

Guideline (12): IRB Committee Initial Review of Research

This guideline (12) provides information on the initial review process of research submitted to IRB committee(s) in each of the college. Information as required by GUST Research and Development Office (RDO) is detailed as below.

- The full protocol, application, or a protocol summary containing the relevant information to determine whether the proposed research fulfills the criteria for approval.
- Proposed consent document.
- Recruitment of materials (i.e. scientific research).

Guideline (13): IRB Committee Continuing Review of Research

This guideline (13) provides information on the continuing review process of research submitted to IRB committee(s) in each of the college. Information as required by GUST Research and Development Office (RDO) is detailed as below. All members of IRB Committee must be provided with and review:

a) The full protocol, application, or a protocol summary containing the relevant information necessary to determine whether the proposed research continues to fulfill the criteria for approval.

b) The current consent document is still accurate and complete.

c) Any newly proposed consent document.

d) A status report on the progress of the research.

e) For continuing review of research by a convened IRB, each IRB member reviews the complete protocol including any protocol modifications previously approved by the IRB committee.

f) The protocols that need verification from sources other than the researchers that no material changes had occurred since previous IRB review.

g) Significant new findings that arise from the review process and that may relate to participants' willingness to continue participation will be provided to participants.

h) Provides a status report on the progress of the research including:

- The number of participants collected.

- A summary of revisions includes the following:
    - Adverse events and/or outcomes experienced by participants involved in research.
    - Unexpected problems involving risks to participants or others involved in the research.
    - Participant withdrawals during research.
    - The reasons for withdrawals during research.
    - Complaints about the research (i.e. topic, nature, methodology, publications, and …etc).
    - Amendments or modifications occurred in research since the last IRB initial review.
    - Any relevant literature added in research.
    - Any interim findings during research since the last IRB initial review.

NOTE: *When the IRB committee does not approve or approves with modifications, it provides the researcher with a statement of the reasons for its decision and gives the researcher an opportunity to respond in person or in writing to be submitted via e-IRB Submission System* (https://irb.gust.edu.kw/).

Guideline (14): IRB Committee Review of Modifications

This guideline (14) provides information on the review of modifications in research submitted to IRB committee(s) in each of the college. Information as required by GUST Research and Development Office (RDO) is detailed as below. All members of IRB Committee must receive and review all modified documents of research including:

a) Using the criteria to approve modifications to previously approved research when the modifications affect one or more criteria.

b) Determining any significant new findings arise from the previous review process and that might relate to participants' willingness to continue participation are provided to participants involved in research.

c) Stating the changes in approved research that are initiated without IRB approval to eliminate apparent immediate hazards to the participant must be:

- Report to the IRB committee the proposed changes in a research study.
- Reviewed by the IRB to determine whether each change was consistent with ensuring the participants' continued welfare.
- Report to the IRB the premature completion of a study.

NOTE: *Proposed changes in approved research during the period for which IRB approval has already been given cannot be initiated without IRB approval.*

Guideline (15): Constitution of IRB Committee

This guideline (15) provides information on the constitution of each IRB committee. Information as required by the Research and Development Office (RDO) in GUST is described below.

- Each IRB committee must have at least five members with different backgrounds.
- Each IRB committee must have male and female members.
- Each IRB committee must represent different professions.
- Each IRB' committee must have at least one member in scientific areas.
- Each IRB committee must have at least one member in nonscientific areas.
- Each IRB committee must have at least one member who is not affiliated with the GUST and not part of the family affiliated with GUST.
- Each IRB committee must have at least one member as ex-officio and should not be involved in the review process.

Guideline (16): IRB Committee(s) Member(s) with Conflict of Interests

This guideline (16) provides information on the IRB committee member(s) with a conflict of interests. Information as required by GUST Research and Development Office (RDO) is detailed below.

- Is excluded from discussion except to provide information requested by the IRB Committee in each college.
- Is excluded from voting.
- Leave(s) the meeting room for discussion and voting.
- Is not counted towards quorum.
- Provide(s) information to the IRB Committee in case of consultations (i.e., information provided by the consultant, co-researcher, language editor, analyst, research assistants, and …etc).