Exempt Human Subject Research Procedures

I. Introduction

These procedures supplement the Protections of Human Subjects in Research Policy (the "Policy").

II. Definitions

All terms used in these procedures have the same meaning set forth in the Policy, unless otherwise defined in these procedures.

Benign Behavioral Interventions. Brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

III. Exempt Research

A. Determination.

1. While all Human Subjects Research being conducted under the auspices of Texas Christian University ("TCU") must be submitted to the IRB for review prior to TCU Engagement, Exempt Research is submitted to the IRB for review and determination of exempt status only. Exempt Research is not "approved" by the IRB. The determination of Exempt Research is made by a member of the TCU IRB or the Director of Research Compliance and Training. There is no requirement for continuing review unless explicitly stated by the IRB with a written justification.

Although Exempt Research is not covered by the Common Rule, this research is not exempt from ethical considerations, such as honoring the principles described in the Belmont Report. The IRB will determine whether to require additional protections for subjects in keeping with ethical principles (e.g., requiring disclosure/consent, etc.).

B. Limitations on Exemptions.

1. Children: The exemption set forth in III(C)(2) below, Research involving the use of educational tests, survey or interview procedures or observations of public behavior, may be applied to Research involving children only for educational tests, and observations of public behavior when the investigator does not participate in the activities being observed. Otherwise, this exemption does NOT apply.

2. Prisoners: Exemptions do NOT apply to Human Subjects Research involving prisoners, except for such Research aimed at involving a broader subject populations that only incidentally includes prisoners. Otherwise, IRB review is required**.**

C. Categories of Exempt Research

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, that are not likely to adversely impact students' opportunity to learn the required educational content or the assessment of educators who provide instruction, such as:

(a) Research on regular and special education instructional strategies, or

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

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording if at least one of the following criteria is met:

   (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; or

   (b) Any disclosure of the Human Subjects' responses outside the Research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational achievement or reputation; or

   (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

3. Research involving Benign Behavioral Interventions in conjunction with the collection of information from an **adult** subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

   (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects;

   (b) Any disclosure of the Human Subjects' responses outside the Research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

   (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

   (d) Provided all such criteria are met, examples of Benign Behavioral Interventions include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

   (e) If the Research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and are designed to study, evaluate, improve, or

otherwise examine public benefit or service programs, including 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.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

5. Taste and food quality evaluation and consumer acceptance studies, if:
   (a) Wholesome foods without additives are consumed; or
   (b) A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6. Secondary Research for which consent is not required. Secondary Research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

   (a) The identifiable private information or identifiable biospecimens are publicly available;
   (b) Information, which may include information about biospecimens, is De-identified before recorded, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
   (c) The Research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under the Health Insurance Portability and Accountability Act of 1996 and implementing regulations 45 CFR parts 160 and 164, subparts A and E ("HIPAA Privacy Rule"), for the purposes of ''health care operations'', ''research'' or ''public health activities and purposes'' as described the HIPAA Privacy Rule; or
   (d) The Research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the Research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the Research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

7. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary Research use, when broad consent is required.

8. Research involving the use of identifiable private information or identifiable biospecimens for secondary Research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary Research use of the identifiable private information or identifiable biospecimens was properly obtained; (ii) Documentation of informed consent or waiver of documentation of consent was properly obtained; (iii) An IRB conducts a limited IRB review and makes the necessary determinations; and (iv) The investigator does not include returning individual Research results to subjects as part of the study plan.

D. FDA Exemptions. The following categories of clinical investigations are exempt from the requirements for prior IRB review and approval:

1. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article is subject to IRB review.
2. Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

E. Procedures for Exemption Determination. In order to obtain an exemption determination, investigators must submit:

1. A completed protocol application;
2. All recruitment materials (e.g., letter of invitation, recruitment script, flyer);
3. Consent form/disclosure/information sheet (when appropriate);
4. All surveys, questionnaires, instruments, etc.;
5. Letter(s) of permission from each non-TCU site of performance;
6. If sponsored/funded, one copy of the grant application(s) and/or contract; and
7. Verification of current Human Research protection training for all members of the research team, including the faculty advisor.

The IRB Chairperson or their delegate reviews all requests for exemptions and determines whether the request meets the criteria for Exempt Research. Once a determination is made, the IRB Chairperson will provide the researcher with written notice of such determination, including the rationale for the determination and the category under which it was permitted.

Although Exempt Research is exempt from most provisions of the Common Rule, this Research still must comply with the ethical guidelines of the Belmont Report, applicable law, and TCU policies and procedures. The IRB may require additional protections for subjects in keeping with the guidelines of the Belmont Report.

The exempt application, review form, and determination letter are recorded and maintained in the same manner and for the same length of time as other IRB review documentation.

F. Continuing Review. Exempt determinations do not have a termination date. After a determination is made, the reviewer will file the study in the archives. Investigators must report any proposed modification to the research during the course of the exempt study for a determination of whether or not the modified activity still qualifies for exemption. Investigators

must notify the IRB office when an exempt research project is complete so that the organization can maintain an accurate database of active research.

IV. Related Research Policies and Procedures

Research Integrity Policy
Research Integrity Procedures
Protection of Human Subjects in Research Policy
Human Subjects Research Procedures
Human Subjects Research Oversight and Monitoring Policy
Human Subjects Research Oversight and Monitoring Procedures
Review of Human Subjects Procedures

V. Effective Date

Effective Date: January 21, 2019