Tarrant County College District

Institutional Review Board Charter

Office of Institutional Research, Planning and Effectiveness

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November 2013

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Institutional Review Board
Charter*

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*With appreciation to Sinclair Community College for permission to adapt its IRB model to suit TCCD.

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INTRODUCTION

The Tarrant County College District (TCCD) encourages and supports the scholarly endeavors of District students, faculty and staff. Pursuit of scholarly work and research often involves the use of human subjects for data collection and analysis. TCCD defines research as *the systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.* TCCD's Institutional Review Board (IRB) reviews human subjects research proposals to ensure that: (a) the rights and welfare of human subjects used in research studies by District personnel are protected, (b) risks have been considered and minimized, (c) the potential for benefit has been identified and maximized, (d) all human subjects volunteer to participate in research only after being provided legally effective informed consent and (e) any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit subject participation or begin data collection until they have obtained clearance by the TCCD IRB.

Some research projects involving human subjects are exempt from IRB approval requirements. The types of research generally exempt from IRB approval requirements include normal educational practices, such as: (a) work undertaken as a part of a course, (b) educational tests when the subjects are not identified and (c) surveys or interviews in which the subjects volunteer and are not personally identified.

The IRB for human subjects research at TCCD has responsibility to oversee procedures for carrying out the District's commitment to protect human subjects in research. The TCCD IRB can: (a) review, (b) approve, (c) disapprove or (d) require modifications to submitted research proposals that involve human subjects. The District's IRB does not evaluate the merits of research design or review proposals for contribution to scholarly literature. The sole role of the TCCD IRB is to review research proposals for standards of compliance in regards to participant risk, informed consent and confidentiality.

I. INSTITUTIONAL AUTHORITY.

This Charter establishes and empowers the TCCD IRB for the protection of human subjects. Currently TCCD has one Committee registered with the federal Office for Human Research Protections (OHRP) as its Institutional Review Board (IRB 00009412). This committee is hereinafter referred to as the "IRB." According to the terms of the Federal-Wide Assurance (FWA), TCCD adopts the following reporting procedure:

Principal Investigator(s) and TCCD employees are required to report to the Chair of the IRB Committee any of the following upon knowledge of the following:

(a) unanticipated problems involving risks to subjects or others and
(b) serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the: (a) TCCD IRB, (b) TCCD Chancellor, (c) head of any department or agency conducting or supporting said research, (d) any applicable regulatory body and (e) the OHRP.

II. PURPOSE.

The primary purpose of the IRB is to protect the welfare of human subjects used in research.

III. BASIC PRINCIPLES.

A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** (The Belmont Report) and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

B. The following principles apply to all research, including student projects, involving human subjects at TCCD to ensure that **adequate safeguards** are provided:

1. Subjects' legal rights will be respected; their rights to privacy, dignity and comfort will be considered in approving proposed research.

2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

3. Adequate provision(s) must be made for all facilities, procedures and professional attention necessary for the protection of the individual as a research subject.

4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation, unless scientifically justified.
5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.

6. Participation of a human subject in research must be voluntary, and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate and presented in lay language appropriate to the subject population.

7. All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted review ***prior*** to their initiation or ***prior*** to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out at least once a year.

C. In making the decision to conduct an IRB review of submitted proposals, the IRB's first priority is to focus on factors **promoting TCCD's mission**. Any submitted proposal must meet the minimum standard of having the likelihood of providing knowledge that contributes to the long-term success of TCCD's faculty, staff and students. In reaching its conclusions concerning the granting of an IRB review, the IRB will take into consideration the following factors:

1. Has the researcher made a strong and compelling case that the research will provide insight into learning and student success factors, and is the research aligned with TCCD's mission?

2. Has the proposal clearly articulated how findings will be communicated to the TCCD community?

3. Have all costs which will be incurred by the TCCD community been fully considered? Do the benefits: (a) outweigh the costs and (b) have provisions been made to reimburse TCCD for any unusual data collection expenses?

4. Has the research been determined to be in compliance with Family Educational Rights and Privacy Act (FERPA) requirements?

5. In the opinion of the IRB, is the research design sufficiently rigorous to lead to meaningful insights?

6. Has the researcher: (a) identified a TCCD full-time faculty or staff member who is willing to serve as the **internal sponsor** for the research, (b) obtained written acceptance of said sponsorship and (c) identified the value of the research findings to his/her area of responsibility

7. In the opinion of the IRB, have the individuals making up the research sample been overly burdened with requests to serve as research subjects?

IV. THE AUTHORITY OF THE IRB.

A. TCCD holds a FWA through OHRP. As part of this Assurance, TCCD agrees to consider ***all*** research involving the use of humans as research participants as being subject to federal regulations, regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by TCCD (unless the research is conducted at another institution with which TCCD has an *IRB Authorization Agreement* as specified in TCCD's FWA); or

2. The research is conducted by or under the direction of a TCCD employee or agent (unless the research is conducted at another institution with which TCCD has an *IRB Authorization Agreement* as specified in TCCD's FWA); or

3. The research is conducted by or under the direction of any TCCD employee or agent using any TCCD property or facility; or

4. The research involves the use of TCCD's non-public information to identify or contact human research subjects or prospective subjects.

In some instances, students may be involved in course activities such as: (a) questioning, participation in minimally physically stressing classroom exercises, (b) observing and/or (c) interacting with other individuals. **The course instructor is responsible** for determining whether such activity is classified as those kinds of activities that require IRB approval. If the instructor has any doubt concerning the classification of these activities, he/she is encouraged to complete an *Exempt Research Form* for approval and submit it along with the protocol and any accompanying: (a) consent form(s), (b) cover letter(s) and/or (c) questionnaire(s) in order to obtain the guidance of the IRB regarding these activities.

B. The IRB reviews all projects and programs involving human subjects in accordance with this Charter and applicable federal regulations.

C. The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.

D. The IRB has approval authority of human subject protocols and can disapprove, modify or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Executive Director of Institutional Research, Planning and Effectiveness (IRPE). However, the Executive Director of IRPE may not approve non-exempt research if it has not been approved by the IRB.

E. The IRB has authority to require progress reports from investigators and oversee the conduct of the study.

F. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.

G. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population.

H. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given regarding the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

V. THE IRB'S FUNCTIONAL RELATIONSHIPS.

A. The IRB functions administratively through the Office of IRPE. This structure provides for administrative coordination for the IRB with the various academic and administrative units at TCCD.

B. The IRB advises and makes recommendations to: (a) the Chancellor, (b) policy and administrative bodies and (c) any member of the TCCD community on all matters related to the use of human subjects in research.

VI. THE MEMBERSHIP OF THE IRB.

A. The IRB is composed of at least five voting members. Alternates and non-voting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting. All appointments are made by Executive Memorandum and reported to OHRP.

B. The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of District: (a) regulations, (b) relevant law, (c) ethical standards and (d) standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

C. The IRB must include both men and women, at least one member whose primary concerns are in science areas, one whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with TCCD.

D. No person shall be excluded from serving on the IRB based on: (a) race, (b) color, (c) religion, (d) sex, (e) age, (f) national origin, (g) veteran status or (h) disability.

VII. MANAGEMENT OF THE IRB.

A. The IRB Chair is the Executive Director of the Office of IRPE. The Chair has authority to sign all IRB action items.

B. The IRB Vice Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair is appointed by the Chair and has authority to sign all IRB action items in the absence of the Chair.

C. Members and alternates of the IRB shall be appointed by the IRB Chair for tenure of three (3) years. However, the term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and
the Chair.

D. All IRB members are **required to undergo formal training** at the time of their initial appointment. Training that satisfies this requirement is an online tutorial offered by OHRP. The IRB Chair's Administrative Office Assistant will maintain a log of training completion dates. IRB members must complete IRB training once every three years.

E. IRB members do not receive compensation for their service.

F. Educators Legal Liability insurance coverage for IRB members is provided through TCCD's insurance program while acting within the scope of their duties as members of the committee. Such protections are subject to the terms and conditions of the insurance policy.

G. Consultants with competence in special areas may be used when deemed appropriate.

H. Conflict of interest policy and procedure:

1. Investigators shall not be involved in the selection of IRB members.

2. Investigators will be asked whether they have a vested interest in any commercial enterprise associated with any aspect of the protocol, and, if yes, to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process. Investigators must comply with TCCD's *Board Policy Manual*, Section DBD, Employment Requirements and Restrictions, Conflict of Interest Policy.

3. Investigators and IRB members who are TCCD employees, and who apply for federal or state government grants and contracts. may be subject to completing the Texas Ethics Commission's Local Government Officer Conflicts Disclosure Statement.

4. The Office of Grants Development and Compliance will forward to the IRB any financial interest disclosures received in connection with proposals for extramural funding that involve human subjects.

VIII. PROCEDURES OF THE IRB.

A. Initial Review.

1. No or Minimal Risk:

Under the auspices of the IRB, the IRB Chair will review Exempt Protocol Summary Forms eligible for "exempt" (see below) or expedited review or, if significant risk is inherent in the study, refer the petition to the IRB for full board review.

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise.

Exempt types of research include:

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on: (1) regular and special education instructional strategies or (2) the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (1) information obtained is

recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and (2) 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.

c. 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 two of this section, if: (1) the human subjects are elected or appointed public officials or candidates for public office or (2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

d. 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.

e. Research and demonstration projects which are conducted by or subject to the approval of program or agency heads, and which are designed to study, evaluate or otherwise examine: (1) public benefit or service programs, (2) procedures for obtaining benefits or services under those programs, (3) possible changes in or alternatives to those programs or procedures or (4) possible changes in methods or levels of payment for benefits or services under those programs.

f. Taste and food quality evaluation and consumer acceptance studies: (1) if wholesome foods without additives are consumed or (2) 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the United States Department of Agriculture.

The IRB Chair, not the investigator, shall make the determination as to whether a project is or is not exempt. To obtain an exemption, investigators must complete and submit the IRB's *Exempt Research Form* citing a specific exemption category and providing justification for the exemption.

Under federal regulations certain types of research qualify for an expedited review. These activities: (1) present no more than minimal risk to human subjects and (2) involve only procedures specified in federal regulations. The activities

listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

a. Clinical studies of drugs and medical devices only when condition (1) or (2) is met.

(1) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(2) Research on medical devices for which: (a) an investigational device exemption application (21 CFR Part 812) is not required or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

b. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:

(1) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week or

(2) from other adults and children, considering the: (i) age, weight and health of the subjects, (ii) collection procedure, (iii) amount of blood to be collected and (iv) frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

c. Prospective collection of biological specimens for research purposes by noninvasive means:

Examples include: (1) hair and nail clippings in a nondisfiguring manner, (2) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction, (3) permanent teeth if routine patient care indicates a need for extraction, (4) excreta and external secretions

(including sweat), (5) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue, (6) placenta removed at delivery, (7) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, (8) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques, (9) mucosal and skin cells collected by buccal scraping or swab, skin swab or mouth washings, (10) sputum collected after saline mist nebulization.

d. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (1) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy, (2) weighing or testing sensory acuity, (3) magnetic resonance imaging, (4) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow and echocardiography, (5) moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight and health of the individual.

e. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

f. Collection of data from voice, video, digital or image recordings made for research purposes.

g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation,

human factors evaluation or quality assurance methodologies. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

h. Continuing review of research previously approved by the convened IRB as follows:

(1) where: (i) the research is permanently closed to the enrollment of new subjects, (ii) all subjects have completed all research-related interventions and (iii) the research remains active only for long-term follow-up of subjects; or

(2) where no subjects have been enrolled and no additional risks have been identified; or

(3) where the remaining research activities are limited to data analysis.

i. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories b through h do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Prospective Principal Investigators (PIs) seeking an exemption or an expedited review must submit an electronic copy of the *Exempt Research Form* or the *Expedited Review of Research Form* to the IRB Chair. Other pertinent documents for submission include the: (i) PI Cover Sheet, (b) pertinent informed consent documentation and (c) survey instrument, if applicable. Necessary IRB forms are located on the District's IRB website. Categories of research that may qualify for exemption or expedited review are also located on the District's website.

The IRB attempts to review proposals within four weeks of their receipt. Proposals submitted during the summer or during District holidays may be delayed. Because proposals may need to be revised prior to IRB approval, **researchers should allow sufficient time for the IRB to re-review proposals**. TCCD's IRB meets on an *as needed basis* and meetings can be conducted in person or via telephone conferences.

The IRB Chair may recommend a protocol to the IRB for: (a) expedited review, (b) expedited review pending recommended changes/clarifications or (c) review by the full Board. The IRB Chair cannot disapprove of a protocol but may table action pending further information/clarifications. The IRB Chair will inform the PI of its actions. Any disagreement between the PI and the IRB Chair must be resolved by the full Board.

The PI will be notified in writing of the IRB decision by the Chair. If it is determined that

one of these protocols require full IRB review, the proposal will be returned to the PI, with comments, for revision and submission to the full board. Upon receipt of the material from the PI, the IRB Chair will distribute copies to each IRB member.

2. More Than Minimal Risk:

Protocols for full Board review should be submitted a minimum of 30 days in advance. The prospective PI will submit to the IRB an electronic copy of the *Full IRB Research Form*. In the Petition, the PI(s) assures the IRB that he/she will follow the principles, procedures and guidelines established in the present document and agrees to provide the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with this policy. **The PI must be available to discuss the protocol and/or consent forms at the discretion of the IRB.**

3. Actions of the IRB:

The IRB may take one of the following four actions in regard to the proposed protocol and consent form: (a) *Approved,* (b) *Approved Subject to Restrictions,* (c) *Tabled* or (d) *Disapproved.*

a. Approved

When a protocol has been approved, the Chair completes the *IRB Cover Approval Form*, signs and dates it and distributes one copy of the form to the: (i) PI,(ii) IRB files and (iii) dean, director or faculty sponsor.

Approval of the protocol will be based on the following:

(i) The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.

(ii) Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.

(iii) Assurances of acceptable debriefing, if appropriate. It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if, in the judgment of the IRB, such information could adversely affect subsequent data collection in the same

study, the full explanation may be delayed for a reasonable period of time. There is an exception to this delay: In those cases in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.

(iv) The adequacy of facilities and other resources necessary for completion of the study and protection of subjects' rights.

(v) Anticipated benefits, if any.

(vi) The personal risk to the subject in relation to expected benefits.

(vii) The adequacy of procedures for securing informed consent from the subject.

(viii) The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort and legal rights of the subject.

(ix) The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

b. Approved Subject to Restrictions

If the protocol is approved subject to restrictions, then the Chair notifies the PI in writing, outlining the restrictions. The PI then must respond to the restrictions as indicated by the IRB. Upon receipt and approval of the responses, the restrictions are removed and the research study is then processed as an approved study and distributed as described above.

c. Tabled

Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. In this case, the PI is notified by the IRB Chair, and the additional information necessary for completion of the IRB review is requested. In the case of a tabled protocol, the PI may be invited to attend an IRB meeting to present/clarify the protocol for the Board.

d. Disapproved

If the protocol is disapproved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit his/her protocol for another review.

B. Continuing Review.

The IRB may conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. PIs will be informed of the annual review by receipt of a *Continuing Research Form*. This *Continuing Research Form* is to be completed and returned to the IRB Chair along with the informed consent document currently in use with the project being reviewed. The PI will be notified of the action taken (e.g., Approved, Approved Subject to Restrictions, etc.) in writing.

When a Continuing Review request is submitted, the IRB Chair shall consider the following: (1) changes to the research, protocol deviations and violations, since the last scheduled review, (2) adverse event reports, (3) reports of unanticipated problems involving risks to subjects and, if available, (4) data safety monitoring reports. If the protocol and/or other documents used in the project have been amended, the PI will be requested to submit a new protocol incorporating these amendments if such has not previously been submitted.

Pursuant to OHRP guidelines, the IRB approval period may be held constant from year-to-year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. However, if an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB Chair or Vice Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the protocol will be considered closed and enrollment of new subjects cannot occur nor can any data collected be used for research purposes.

C. Procedures Pertaining to Both Initial and Continuing Review.

1. The IRB shall have authority to determine which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review, particularly: (i) complex projects involving unusual levels or types of risk to subjects, (ii) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB and (iii) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

2. PIs shall be informed at the time of protocol approval (both initial and continuing) that change in approved research may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

3. PIs shall be informed at the time of protocol approval (both initial and continuing) that any serious or on-going problems are to be reported promptly to the IRB.

4. Serious or continuing noncompliance by an investigator, or any suspension or termination of activities, is to be reported promptly to the IRB Chair so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

D. Adverse Event Reporting Guidance.

1. OHRP recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged IRBs with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

2. PI(s) and any TCCD employee will report to the IRB Chair any of the following upon knowledge of such:

a. Unanticipated problems involving risks to subjects or others; and
b. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

IX. OPERATIONS OF THE IRB.

A. The IRB meets once every fall and spring semester.

B. The place and time of meeting, agenda and study material to be reviewed are distributed to IRB members at least seven (7) days prior to the meeting.

C. The IRB Chair assigns one primary reviewer and at least one secondary reviewer for each new Full Research Review. The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers, who are assigned, based on their expertise, lead the discussion of that protocol. Other IRB members review summary information only but have access to complete study documentation upon request. If external reviewers are also assigned, they must be subject to the same conflict of interest policies as IRB members.

D. Voting requirements.

1. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.

2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.

3. PIs, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).

4. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the meeting to executive session, then any visitors will be asked to leave the room until the executive session has ended.

E. Appeals.

A PI may appeal the decision of the IRB when a protocol has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc* committee of three or more faculty and/or consultants to review the protocol a second time. The *ad hoc* committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established herein and the decision of the *ad hoc* committee will be referred to the IRB. The PI will be promptly notified of actions of the *ad-hoc* committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

F. Amendments.

1. Amendments are categorized into minor changes and significant changes.

Minor modification/change - A proposed change in research-related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

Examples of **minor changes** to a research study include, but are not limited to, the following:

a. Addition or deletion of study team members,
b. Addition of procedures that do not significantly increase risk to subjects,

considering the original purpose and study design of the approved study,
c. Removal of research procedures that would thereby reduce the risk to subjects,
d. Addition of nonsensitive questions to unvalidated survey or interview procedures,
e. Addition of or revisions to recruitment materials or strategies,
f. Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

Significant modification/change - A proposed change in research-related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of **significant changes** to a study may include, but are not limited to, the following:

a. Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);
b. Addition of research procedures that involve greater than minimal risk to subjects;
c. Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability or reputation;
d. Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

2. Level of Review for Amendments.

Significant modifications will generally be reviewed at the same level of review in which the study was first reviewed, either by the screening committee or by the full IRB. However, if an amendment by the screening committee is determined to increase the level of risk beyond minimal risk, the screening committee will refer the amendment to the full IRB.

Minor modifications may be reviewed and approved using an administrative approval process. Administrative approval may be given by the IRB Co-Chair. Such approvals are then put on the agenda of the next IRB or screening committee, as appropriate, for concurrence.

3. Sponsor Agency Modifications.

Modifications can be made only to IRB-approved studies. A sponsor agency may modify the research protocol before the study has received final approval from the IRB. If this occurs, it is recommended that investigators await receipt of the IRB approval letter before making changes to the research protocol.

Sponsor agency-generated modifications (or addenda) require review and approval by the IRB or Screening Committee, as appropriate. The PI should provide all sponsor documentation and summarize how the changes affect the approved protocol, recruitment, enrollment, treatment and follow-up of participants.

G. Grievances.

The IRB shall be informed of all grievances (e.g., of a research subject against a PI) and, if requested, the IRB will act in an advisory capacity.

H. Cooperative Activities.

Cooperative activities relating to human subjects are those which involve TCCD and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

1. Both institutions have FWAs approved by OHRP,

2. Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties and

3. The appropriate section of the FWA of the deferring institution designates the
IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB Chair will verify (via the OHRP website) that the other institutions have approved FWAs.

X. RECORD REQUIREMENTS.

A. The IRB prepares and maintains adequate documentation of IRB activities, including the following:

1. Electronic copies of all research proposals: (a) reviewed, (b) approved sample consent documents and (c) continuing reports submitted by PIs.

2. Minutes of IRB meetings, showing the following:

a. Members present (any consultants/guests/others shown

separately). b. Results of discussions on debated issues and record of

IRB decisions.

c. Record of voting (showing votes for, against and abstentions).

3. Records of continuing review activities, updated consent documents and summaries of on-going project activities. Consent documents are stamped to show IRB approval and date of approval expiration.

4. Copies of all correspondence between IRB and the investigators.

5. Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.

6. Adverse reactions reports and documentation that the IRB reviews such reports.

7. Emergency use reports.

8. General project information provided to subjects (e.g., fact sheets, brochures). These documents and records shall be retained for at least three (3) years after completion of the research and the records shall be accessible for inspection and copying by authorized representatives of the: (a) Department of Health and Human Services, (b) Food and Drug Administration, (c) Department of Veterans Affairs and (d) other federal regulatory agencies, at reasonable times and in a reasonable manner.

In addition, the IRB maintains a permanent record of the list of current IRB members, written procedures for the IRB and self-assessments.

B. **All forms submitted or retained as evidence of informed consent must be preserved by the PI indefinitely.** Should the PI leave TCCD, signed consent forms are to be transferred to the IRB Chair.

XI. INFORMATION THE PI PROVIDES TO THE IRB.

A. Professional qualifications to do the research (including a description of necessary support services and facilities).

B. Appropriate TCCD review type forms.

C. Complete study protocol which includes/addresses the following:

1. Title of the study and summary of the research to be conducted,

2. Purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits),

3. Sponsor of the study,

4. Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research),

5. Justification for use of any special/vulnerable subject populations (such as children [under age 18], prisoners or handicapped, economically/educationally disadvantaged or mentally disabled persons),

6. Study design (including discussion of the appropriateness of research methods),

7. Description of procedures to be performed,

8. Provisions for managing adverse reactions,

9. Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties and vulnerable populations,

10. Procedures for documentation of informed consent, including any procedures for obtaining assent from minors ('minor' is defined in Texas as an individual under the age of 18), using legally authorized representatives, witnesses, translators and document storage,

11. Remuneration to subjects for their participation,

12. Any compensation for injured research subjects,

13. Provisions for protection of subject's privacy,

14. Extra costs to subjects for their participation in the study,

15. Inclusion/exclusion of women, minorities and/or children.

D. Investigator's brochure (when one exists),

E. The case report form (when one exists),

F. The proposed informed consent document, including translated consent documents, as necessary, considering likely subject population(s) or request for waiver of the requirement to obtain informed consent,

G. Copies of advertisements and surveys, questionnaires or other materials provided to subjects,

H. Copies of relevant grant applications (if any),

I. Requests for changes in study after initiation including changes to consent forms,

J. Reports of unexpected adverse events and unanticipated problems involving risks to subjects, including, if available, data safety monitoring reports,

K. Progress/interim reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance.

XII. PRINCIPLES OF INFORMED CONSENT.

A. When an activity does not involve therapy, diagnosis or management, and a professional/subject relationship exists, e.g., participation in a research project, the subject is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options and opinions which a reasonable person might be expected to consider before giving his/her consent. A copy of the signed consent form must be given to the person signing the form and a copy must be kept on file with the investigator or TCCD as indicated below.

B. The informed consent of subjects will be obtained by methods that are adequate and appropriate. Consent must be obtained from the subjects themselves except when the subjects are not legally capable of giving informed consent because of age, mental incapacity or inability to communicate. In the case of a minor, the IRB may accept the permission of the minor's parents (or parent) or legal guardian, along with the assent of the minor, in accordance with applicable federal regulations. In the case of other subjects not legally capable of giving informed consent, the IRB may accept the consent from a legally authorized representative (LAR). The LAR must be authorized either by a power of attorney or a court order.

C. Informed consent means ensuring that potential subjects and/or their LARs are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. The basic elements of information necessary to such consent are available for review, along with TCCD's *Informed Consent Guidelines*.

The IRB may approve a telephonic consent procedure under which the subject's LAR is sent a faxed or hand-carried version of the informed consent document, a consent interview is conducted by phone while the LAR has the document in hand, and the LAR signs and returns the signed document to the investigator by return fax (or courier) before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an investigator, coordinator, etc.) should monitor the consent process.

D. The IRB shall determine whether the consent is adequate in light of the risks to the subject and the circumstances of the research. The IRB shall also determine whether

the information to be given to the subject or to qualified third parties, verbally or in writing, is a fair explanation of the procedure, its possible benefits and its attendant hazards. Where debriefing procedures are considered as a necessary part of the research plan, the IRB will ascertain that any such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon (i.e., use lay language appropriate to the subject population).

E. If it is determined by the IRB that the research involves more than minimal risk to subjects, a compensation for injury statement will be required in the consent form. This statement should clarify who is responsible for any costs associated with any medical treatments required or any personal compensation for injuries received as a result of participation in the research.

F. Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the PI to provide subjects with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the protocol.

The IRB may also choose to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents the following:

1. The research involves no more than minimal risk to the subjects,

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects,

3. The research could not practicably be carried out without the waiver or alteration, and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

G. Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those studies in which it is proposed to mislead the subjects during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of the subjects and then setting the limits for such procedures.

XIII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS.

A. An IRB member is said to have a conflicting interest whenever that IRB member, spouse or dependent child of the member:

1. Is the PI and/or Co-PI on the protocol,

2. Has a significant financial interest in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest (see TCCD's Conflict of Interest Policy, for the definition of significant financial interest),

3. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB or

4. Has identified him or herself for any other reason as having a conflicting interest.

B. It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters for which they are assigned reviewers immediately upon receipt to determine whether they may have a conflict.

C. Typically, there are three distinct phases of an IRB's consideration of a matter: (1) discussion, (2) deliberation and (3) actions (including vote). In general, IRB member(s) who

have a real or perceived conflict of interest may remain in the meeting room, at the discretion of the IRB Chair during the discussion of the matter in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

D. Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.

APPENDIX A:

Tarrant County College District
Institutional Review Board
Federal-Wide Assurance Number
(August 8, 2013)

The District's Federal-Wide Assurance is located at:
http://www.tccd.edu/documents/About%20TCC/Institional_Review_Board/IRB_Board_Materials/IRB_Authority/IRB%20FWA%20Permission.pdf.

APPENDIX B:

Tarrant County College District
Institutional Review Board
Research Misconduct Process

According to the Office of Research Integrity of the U.S. Department of Health and Human Services and the Office of Investigations of the National Science Foundation (NSF), research misconduct means fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results:[1,2] (a) **Fabrication** is making up data or results and recording or reporting them, (b) **Falsification** is manipulating research materials, equipment, processes or changing or omitting data or results such that the research is not accurately represented in the research record and (c) **Plagiarism** is the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

In addition, intellectual property permission related to ownership of ideas, concepts and protocols must be followed. Research misconduct does not include honest error or differences of opinion.

The NSF requires a grantee to bear primary responsibility for prevention and detection of misconduct. NSF will rely on a grantee to take the following actions promptly:[3]

(a) Initiate an inquiry into any suspected or alleged misconduct;
(b) Conduct a subsequent investigation, if the inquiry finds substance;
(c) Take action necessary to ensure the integrity of research, the rights and interests of research subjects and the public and the observance of legal requirements or responsibilities and
(d) Provide appropriate safeguards for subjects of allegations as well as informants.

TCCD promotes the importance of and has procedures for referring to TCCD's General Counsel any potential incidents of research misconduct reported for resolution according to procedures identified in the Code of Federal Regulations 45 CRF 689 (for NSF) or 42 CFR Parts 50 and 93 (for the Department of Health and Human Services).

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[1] From the U.S. Department of Health and Human Services, Office of Research Integrity web site http://ori.hhs.gov/misconduct/definition_misconduct.shtml.

[2] Code of Federal Regulations 45 C.F.R.§689.1.

[3] National Science Foundation ***Proposal & Award Policies & Procedures Guide*** (NSF 07-140 June 2007) Chapter VII - Grant Administration Disputes and Misconduct.

If a grantee wishes NSF to defer independent inquiry or investigation, it should take the following actions:

I. Inform NSF immediately if an initial inquiry finds substance.
II. Keep NSF informed during such an investigation.
III. Notify NSF even before deciding to initiate an investigation or as required during an investigation:
    A. If there is reasonable indication of possible violations of civil or criminal law.
    B. If public health or safety is at risk.
    C. If NSF's resources, reputation or other interests need protecting.
    D. If Federal action may be needed to protect the interests of a subject of the investigation or of others potentially affected.
    E. If the research community or the public should be informed.
    F. If research activities should be suspended.
IV. Provide NSF with the final report from any investigation.

In order to implement federal research misconduct regulations, the TCCD Office of Grants Development and Compliance will implement the following procedures:

I. Post federal research misconduct regulations and information on the website of the Office of Grants Development and Compliance.
II. Communicate with and provide training to grant-funded PIs, Co- PIs and Senior Personnel appropriate federal policies and TCCD procedures relating to research misconduct.
III. Require grant-funded PIs, Co- PIs to certify during the proposal transmittal process that they:
    A. Have read and understand federal research misconduct regulations.
    B. Will not engage in fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results.
    C. Will report any suspected incidents of research to the Associate Vice Chancellor of Grants Development and Compliance or the TCCD General Counsel.

APPENDIX C:

Tarrant County College District
Institutional Review Board
Other IRB Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution/Organization A):

IRB Registration #: **Federal-Wide Assurance (FWA) #, if any:**

Name of Institution Relying on the Designated IRB (Institution B):

FWA #:

The Officials signing below agree that (*name of Institution B)* may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (*check one*)

( ) This agreement applies to all human subjects research covered by Institution B's FWA.

( ) This agreement is limited to the following specific protocol(s):

Name of Research Project:

Name of Principal Investigator:

Sponsor or Funding Agency:

Award Number, if any:

( ) Other (*describe*):

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B.

Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):

Date:

Print Full Name:

Institutional Title:

Signature of Signatory Official (Institution B):

Date:

Print Full Name:

Institutional Title:

Email forms and supporting documentation to: irb.irpe2@tccd.edu.

APPENDIX D:

Tarrant County College District
Institutional Review Board
Exempt Research Form

Activities Exempt from IRB Review

An exempt review doesn't require monitoring by the Institutional Review Board (IRB). Exempt categories are outlined by the Department of Health and Human Services in 45 CFR 46.101(b). The significance of an exempt review is that the research activity is not monitored by the IRB. It is important to note that while a project may be exempt from IRB regulations, the ethical principles of conducting human subject research still apply. More importantly, it is not up to the researcher to determine whether a project is exempt, as all District research must be approved by the IRB. Researchers that believe their project is exempt should submit their research proposal to the IRB, selecting exempt for their category of review. Exempt reviews are carried out by the IRB Chair or their designee. Email forms and supporting documentation to: irb.irpe2@tccd.edu.

The following exemptions do not apply when: (a) deception of subjects may be an element of the research, (b) subjects are under the age of eighteen, (c) the activity may expose the subject to discomfort or harassment beyond levels encountered in daily life or (d) fetuses, pregnant women, human in vitro fertilization, children or individuals involuntarily confined or detained in penal institutions are subjects of the activity.

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally-approved Categories of Exemption are:

I. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as research on: (a) regular and special education instructional strategies and (b) the effectiveness of, or the comparison among, instructional techniques curricula or classroom management methods.

II. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects **and** (b) any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

III. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under Category II if: (a) the human subjects are elected or appointed public officials or candidates for public office **or** (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

IV. 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.

V. 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.

VI. 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 U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempting an activity from review <u>does not</u> absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity. Questions about whether a research activity may be exempt from human subjects review can be directed to the IRB Chair.

Tarrant County College District
Institutional Review Board
Exempt Research Form*

Date:

Research Proposal Title:

Principal Investigator:

Department:

Phone: **Email address:**

Co-Investigator:

Department:

Phone: **Email address:**

Anticipated Funding Source:

Projected Duration of Research: **months**

Proposed Projected Starting Date:

Other organizations and/or agencies, if any, involved in the study:

Exempt under code (see definitions on page one – check one)

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

SUMMARY ABSTRACT: Please supply the following information below, a BRIEF description of the: (a) participants, (b) location(s) of the project, (c) procedures to be used for data collection, (d) whether data will be confidential or anonymous, (e) storage of the data and (f) who will have access to the data. Attach a copy of the Informed Consent Form, surveys and any recruitment material to be used in the project.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

(a) Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to changes being implemented.

(b) Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair.

(c) The Principal Investigator is responsible for retaining informed consent documents for a period of three years after the project.

(d) The Principal Investigator shall notify the TCCD IRB chairperson when the research proposal has been approved or modified by another institution's IRB.

(e) The Principal Investigator will provide a copy of the final research results to TCCD's IRB and complete the IRB's Research Closure Form.

Principal Investigator Signature: **Date:**

Co-Investigator Signature): **Date:**

*Please note that the IRB Chair uses the Exempt Research Checklist as a guideline when review exempt research. It would behoove researchers to align their research proposal with the checklist's criteria.

Email forms and supporting documentation to: irb.irpe2@tccd.edu.

APPENDIX E:

Tarrant County College District
Institutional Review Board
Informed Consent

Researchers must obtain the signed ***informed consent*** of participants. For those participants younger than 18 years of age, the researcher must obtain the signed informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's ***assent***, which is defined as the participant's agreement to participate in the study.

The informed consent must include the following in sequential order and in language which the participants can understand:

(a) Statement of purpose of the study.

(b) Short description of methodology and duration of participant involvement.

(c) Statement of risks/benefits to the participants.

(d) Statement of data confidentiality.

(e) Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.

(f) An offer to answer any questions the participant may have.

(g) Contact information of all Principal Investigators and for TCCD's Institutional Review Board.

(h) Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.

(i) Statement that participant is 18 years of age or older, unless parent or legal guardian has given consent.

In situations where participants will be **deceived**, items I and II are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete,** each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

Tarrant County College District
Institutional Review Board
Informed Consent and Assent Consent Form

The following informed consent suggestions are offered as guidelines. The exact language is the decision of the researcher. Keep in mind that the Institutional Review Board must determine if the participants will be giving ***informed consent*.** (Note: that in the case of children, it is ***assent***).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine . In this study, you (your child/ward) will be asked to . Your participation should take about minutes.

There are no risks to you (your child/ward).
or
The only risks to you (your child/ward) include: x, y and z.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported. Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study simply .

Please feel free to contact (names(s), title(s) of principal investigators) at (phone) or (email) if you have any questions about the study. For Institutional Review Board questions, please contact TCCD's Institutional Review Board chair at 817-515-1516.

If the participant is of age (18 years old or older), use this language:

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

Signature of Subject: **Date:**

If the participant is not of age, use this language:

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible. I understand what I must do in this study and I want to take part in the study.

Signature of Subject: **Date:**

Signature of Minor: **Date:**

APPENDIX F:

Tarrant County College District
Institutional Review Board
Expedited Review Form

An expedited review is typically carried out by the IRB Chair or their designee and involves research that doesn't involve more than minimal risk to participants. Minimal risk is defined as: *the probability and magnitude of harm or discomfort anticipated in the research are not greater than those encountered in daily life or through the performance of routine physical or psychological exams/tests.* While the IRB Chair can review and approve expedited review research, the Chair cannot disapprove research proposals without moving the research project to full review.

Research activities eligible for expedited review:

(a) Clinical studies of drugs and medical devices only when certain conditions are met (see regulations).

(b) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture.

(c) Prospective collection of biological specimens for research purposes by noninvasive means.

(d) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

(e) Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to45 CFR 46.101(b)(4)).

(f) Collection of data from voice, video, digital or image recordings made for research purposes.

(g) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(2) and (b)(3)).

Expedited review may also be used to review minor changes in previously approved research.

Tarrant County College District
Institutional Review Board
Expedited Review Form*

Date:

Research Proposal Title:

Principal Investigator:

Department:

Phone: **Email address:**

Co-Investigator:

Department:

Phone: **Email address:**

Anticipated Funding Source:

Projected Duration of Research: **months**

Proposed Projected Starting Date:

Other organizations and/or agencies, if any, involved in the study:

SUMMARY ABSTRACT: Please supply the following information below, a BRIEF description of the: (a) participants, (b) location(s) of the project, (c) procedures to be used for data collection, (d) whether data will be confidential or anonymous, (e) storage of the data and (f) who will have access to the data. Attach a copy of the Informed Consent Form, surveys and any recruitment material to be used in the project.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

(a) Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to changes being implemented.

(b) Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair.

(c) The Principal Investigator is responsible for retaining informed consent documents for a period of three years after the project.

(d) The Principal Investigator shall notify the TCCD IRB chairperson when the research proposal has been approved or modified by another institution's IRB.

(e) The Principal Investigator will provide a copy of the final research results to TCCD's IRB and complete the IRB's Research Closure Form.

Principal Investigator Signature and Date:

Co-Investigator Signature and Date (if appropriate):

**Please note that the IRB Chair uses the Expedited Research Checklist (available on the IRB website under Forms) as a guideline when review exempt research. It would behoove researchers to align their research proposal with the checklist's criteria.*

Email forms and supporting documentation to: irb.irpe2@tccd.edu.

APPENDIX G:

Tarrant County College District
Institutional Review Board
Full IRB Research Form*

Date:

Research Proposal Title:

Principal Investigator:

Department:

Phone: **Email address:**

Co-Investigator:

Department:

Phone: **Email address:**

Anticipated Funding Source:

Projected Duration of Research: **months**

Proposed Projected Starting Date:

Other organizations and/or agencies, if any, involved in the study:

Please answer the questions below and return this form with the following items, a:

(a) memo that briefly describes the intent of the project,
(b) completed copy of the Informed Consent Form Checklist,
(c) copy of the Informed Consent Form that will be provided to the participants and
(d) a brief description and copy of survey instrument (if applicable).

I. Project Information:

a. This project involves Tarrant County College District students:

Yes No

b. Human Subjects from the following populations will be involved in this study:

c. Total number of subjects to be studied:

II. Abstract Describing Project and Purpose (Include a description of research design to be used, including program activities and what measures or observations will be used in the study.)

III. Protocol (Who will be the research subjects? How will they be solicited or contacted? Include any recruitment letters or other recruitment materials with this document. How much time will be required of each subject? Describe procedures to which humans will be subjected – use additional pages if necessary.)

IV. Precautions (What steps will be taken to insure that each subject's participation is voluntary? What, if any, incentives will be offered to the subjects for their participation?)

V. Confidentiality of data (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc.)

VII. Consent (Attach a copy of all consent forms to be signed by the subjects and/or any statements to be read to the subject.)

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

(a) Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to changes being implemented.

(b) Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair.

(c) The Principal Investigator is responsible for retaining informed consent documents for a period of three years after the project.

(d) The Principal Investigator shall notify the TCCD IRB chairperson when the research proposal has been approved or modified by another institution's IRB.

(e) The Principal Investigator will provide a copy of the final research results to TCCD's IRB and complete the IRB's Research Closure Form.

Principal Investigator Signature and Date:

Co-Investigator Signature and Date (if appropriate):

**Please note that the IRB Chair uses the Full Committee Checklist (available on the IRB website under Forms) as a guideline when review exempt research. It would behoove researchers to align their research proposal with the checklist's criteria.*

Email forms and supporting documentation to: irb.irpe2@tccd.edu.

APPENDIX H:

Tarrant County College District
Institutional Review Board
Continued Research Form **IRB#:**

Date: **Campus:**

Principal Investigator Name:

Phone: **Email:**

Federal Regulations **mandate** that all human subject research receive continuing review and approval **not less than once per year.** In order to comply with this policy on research involving human subjects, sufficient information must be collected to allow the IRB to conduct a substantive and meaningful review. Therefore, in order for the District IRB to comply with this and other directives and to grant continuing approval of your protocol, the following information/documents are required: (a) a completed continuing review questionnaire, (b) copies of all informed consent documents and (c) copies of all surveys and/or questionnaires currently being used.

In addition, please respond complete the information below. If a question does not apply to your research, indicate (e.g., "Not Applicable" or "N/A").

I. Briefly summarize the study objectives and procedures: (attach additional pages if required).

II. Dates covered by this progress report:

III. Project Summary

(a) **Leadership:** Have there been any changes in leadership, responsibility or major personnel? Yes No

If Yes, fully describe the changes:

(b) **Objectives:** Have there been any changes? Yes No

If Yes, fully describe the changes:

(c) **Procedures:** Have there been any changes? Yes No

If Yes, fully describe the changes:

(d) **Informed consent documents:** Have there been any changes? Yes No

If Yes, fully describe the changes:

(e) **Research subjects:**

1. List each group, cohort, etc., if applicable, including control groups, on separate lines. If there is only one group, description would be "All."

NUMBER OF SUBJECTS (at all sites for which you are the PI)		**AGE RANGE OF SUBJECTS** (at all sites for which you are the PI)		**GENDER** (of subjects to date)	
This Period	Next Period (anticipated)	This Period	Next Period (anticipated)	% Male	% Female

2. Was the subject population representative of the population base from which subjects could be selected with respect to:

   a. Gender representation? Yes No

      If No, explain:

   b. Minority representation? Yes No

      If No, explain:

3. Have any subjects withdrawn from study since the study began? Yes No

   If No, explain:

4. Are you aware of any breach in confidentiality? (e.g., unauthorized access to records) Yes No

   If No, explain:

A. **Adverse Events**:

1. Have there been any adverse events? Yes No

   If Yes, please summarize these unexpected problems, including the number of occurrences and indicate if they required consent document changes, particularly in the risks section. If risks are affected, describe how they are minimized and reasonable in relation to expected benefits. Attach any adverse effect reports.

B. **Proposed Revisions/Amendments/Modifications:**

1. Are there revisions/amendments to the protocol, consent form(s), questionnaires, etc., that are included with this renewal? Yes No

   If Yes, provide a brief description below, and highlight the changes on the document(s) to be reviewed.

2. Will the revisions/amendments change the scope or research objectives of the protocol? Following are examples of actions considered to change the scope or research objectives: A change in the specific aims approved at the time of award (funding); a change from the previously approved use of human subjects; shifting the emphasis of the research from one disease to another. Yes No

   If Yes, provide sufficient information/documentation to allow the IRB to review and approve prior to initiation.

3. Will the revisions/amendments change risks to subjects? Yes No

   If Yes, provide sufficient information/documentation to allow the IRB to review and approve prior to initiation. In particular, describe how risks are minimized and reasonable in relation to expected benefits.

C. **Publications, Presentations, Reports:** Provide a listing of all publications, presentations and reports that have resulted from this work since the last review. If none, so state.

As **Principal Investigator**, I acknowledge that I am responsible for reporting any: (a) emergent problems or (b) proposed procedural modifications to the IRB for its review and approval. Except where necessary to eliminate apparent immediate hazards, no such modifications will be put into effect without prior IRB approval. Unless otherwise directed by the IRB Chairperson, I will renew this application with the IRB no less than annually. The research project being conducted in compliance with the IRB's understanding and recommendations and the IRB has been provided all necessary information on the research project in order for a complete review. This research project will not be put into effect until final IRB approval is received.

Signature of Principal Investigator: **Date:**

Email forms and supporting documentation to: irb.irpe2@tccd.edu.

APPENDIX I:

Tarrant County College District
Institutional Review Board
Principal Investigator Cover Sheet

Date:
Principle Investigator Name:

Principle Investigator Phone:

IRB Proposal Title:

Materials Checklist and Location:
In submitting this proposal to the Committee for the Protection of Human Subjects, I have included the following information. Where appropriate, the information can be found on the following page(s) of the proposal or supporting material:

Information	Pages(s) where the information can be found
The proposal as it will be submitted to the granting agency	
A. A review of the relevant literature.	
B. A research question or hypothesis.	
C. An experimental or research design which will answer the research question or hypothesis.	
D. The method for determining the sample size.	
E. How the data will be used to answer the research question or hypothesis.	
F. The benefits to be gained from the research.	
G. A statement of anticipated risks to the physical and mental health, comfort and privacy of experimental subjects.	
H. A description of measures that will be taken to minimize risks and to ensure confidentiality of sensitive personal data during and after the research.	
I. Explicit information about the recruiting, selection and compensation of subjects. This includes a statement of equitable recruitment procedures for women and minorities.	
J. If women who are pregnant, who may be potentially pregnant or who may potentially become pregnant during the research are used as subjects, then a description of the risks to the fetus must be included. Since a fetus cannot grant informed consent, special caution must be employed for all research that involves more than minimal risk to the fetus.	
K. The text of any questionnaire, evaluative or diagnostic instrument and debriefing protocol designed specifically for the research.	
L. The text of an informed consent form to be signed by each subject before participation.	
M. A statement of whether federal monies will be used in connection with the proposed project.	

Principle Investigator's Statement:

As Principal Investigator, I acknowledge that am responsible for reporting to the TCCD IRB any problems or serious adverse effects or reactions that occur as a consequence of this study. I will submit any proposed procedural modifications to the IRB for its review and approval, and except where necessary to eliminate apparent immediate hazards, no such modifications will be put into effect without prior approval from the IRB. Unless otherwise directed by the Chair of the IRB, I will renew this application with the IRB no less than annually. I certify that the research project will be conducted in compliance with the IRB's understanding and recommendations. I will provide the IRB with all the information on the research project necessary for its complete review. I certify that this research project will not be put into effect until final IRB approval is received.

Investigators' Signatures:

Signature of Principle Investigator	Date	Signature of Research Sponsor (If different from Principal Investigator)
Signature of Co-Investigator	Date	Signature of Co-Investigator

APPENDIX J:

Tarrant County College District
Institutional Review Board
IRB Criteria for Approval

All of the following requirements must be met before research involving human subjects can be approved.

1. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and when appropriate, by using procedures that are already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Selection of subjects is equitable. Particular attention should be paid to the special problems of research involving vulnerable populations, such as: (a) children, (b) prisoners, (c) pregnant women, (d) mentally disabled persons or (e) economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or his legally authorized representative in accordance with official guidelines (see below). Information given to subjects as part of informed consent must also conform to these guidelines. The IRB may require that additional information be given if in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

5. Documentation of informed consent will be carried out in accordance with federal guidelines (see below).

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards must be included to protect the rights and welfare of those subjects.