Tarrant County College District
Institutional Review Board
Exempt Research Form
Revised New Common Rule Effective January 19, 2019

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 that specifically involves normal educational practices ***that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction*.** This includes most research on: (a) regular and special education instructional strategies and (b) research on the effectiveness of, or the comparison among, instructional techniques curricula or classroom management methods. (Refer to 45 CFR 46.104(d)(1))

II. 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: (Refer to 45 CFR 46.104(d)(2))

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

(ii) 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

(iii) 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 make the determination required by §46.111(a)(7).

III. 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: (Refer to 45 CFR 46.104(d)(3))

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

(ii) 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

(iv) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly

IV. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens collection and at least one of the following criteria is met: (Refer to 45 CFR 46.104(d)(4))

(i) 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

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b)

(iv) Or 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.

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. (Refer to 45 CFR 46.104(d)(5))

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. (Refer to 45 CFR 46.104(d)(6))

VII. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8). (Refer to 45 CFR 46.104(d)(7))

VIII. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (Refer to 45 CFR 46.104(d)(8))

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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 ☐ 7 ☒ 8 ☐

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.