**Tarrant County College District**
**Institutional Review Board**
**Frequently Asked Questions**

## IRB Training:

### *Who needs to take IRB training?*

Individuals planning to submit a research project through the IRB must complete training. Training must be completed prior to any IRB submissions for approval.

### *What type of IRB training is available?*

Training is offered online through The Association of Clinical Research Professionals (ACRP).

Go to https://www.acrpnet.org/courses/ethics-human-subject-protection/%20https://www.acrpnet.org/courses/ethics-human-subject-protection/

and:

1. Add the course to your cart.
2. Checkout.
3. Register for an account, if you do not already have one.
4. Complete registration information.
5. Submit order details and register for the course.

Once you have completed the course,

a. Take a screenshot of the course completion page.
b. Email the screenshot to irb.irpe2@tccd.edu.

All training are certificates are valid for 3 years and may be renewed by taking the training again.

## IRB Approval:

### *When is IRB approval needed?*

If you plan to conduct research with human subjects, you must submit a proposal to TCCD's IRB ***before*** you begin your research.

***What is research?***

TCCD defines research as *the systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge* 45 CFR 46102(f).

***What is a human subject, also known as a human participant?***

A human subject is a living person. A researcher typically obtains the following information regarding human subjects: (a) data through an intervention or interaction with the participant and/or (b) identifiable participant information. Examples of participant data collection includes, but is not limited to: (a) questionnaires/surveys, (b) interviews and (c) behavioral and/or classroom observations 45 CFR 46 102(d). If your research involves human subjects or identifiable data on human participants, you must gain IRB approval to conduct your research.

***What are vulnerable populations?***

Vulnerable populations include, but are not limited to: (a) pregnant women, human fetuses and neonates, (b) prisoners, (c) children and/or adolescents, (d) cognitively impaired persons, (e) economically and/or educationally disadvantaged, (f) AIDS/HIV+ individuals or (g) terminally ill individuals. TCCD IRB considers students as a vulnerable population subject to undue influence and coercion. These factors must be considered in legitimizing the use of students in the study. Why that population? The IRB follows the guidelines set forth by the Department of Health and Human Services, Criteria for IRB Approval of Research per 45 CFR 46.111:

(a) *In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:*

(1) *Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures 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 subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.*

(3) *Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research*

*involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.*

***Are college students vulnerable populations?***

Under the Common Rule (45 CFR 46.111) college students as research subjects are not specificaly afforded any special protection afforded other vulnerable populations. However, TCCD, like many other institutions, recognizes students are subject to undue influence, coercion, and confidentiality can be an issue. FERPA and TCCD Directory Policy and Computer Fair Usage rules regulate what Personally Identifiable Information (PII) may be released to researchers whether internal or external to the college. It is often overlooked that students may be under the age of 18 and therefore minors.

A researcher will be expected to explain why that specific (student) population is necessary to the research. As student in a study pool as part of a course should have an alternate assignment available if they do not wish to participate in the research and passive consent in a course curriculum or description will generally not be considered informed consent.

The institution and the regulations do recognize the difference between human subjects research and process improvement when an instructor may be comparing teaching methods but does consider the potential impact on the learning environment of such proposed research.

The new revised Common Rule states: (5 CFR 46.104(d)(1) Research involving normal educational practices is exempt from IRB oversight if: that research is not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. such as: (1) Most research on regular and special education instructional strategies; or (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.

***What is a Principal Investigator?***

A Principal Investigator (PI) is the primary individual responsible for the preparation, conduct and administration of a: (a) research grant, (b) cooperative agreement, (c) training or public service project, (d) contract or (e) other sponsored project. PIs are responsible for ensuring that their research project is in compliance with applicable laws and regulations, including institutional policy.

***How do I know if I should classify my project as research?***

TCCD defines research as *the systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.* If

you plan to share your research with others, you are most likely conducting research. Examples of shared research includes, but is not limited to: (a) presenting human subject data at a conference, (b) publishing human subject data in a journal or (c) using human subject data for a master's thesis or doctoral dissertation. If the possibility exists that you might want to share your human subject data in the future, it is advised that you submit your project to the IRB for approval prior to beginning your research.

***If I am conducting my research at another institution of higher learning, do I need approval from TCCD's IRB to conduct the study?***

If you use TCCD work time or resources to conduct the research or you plan to present your results under your affiliation with TCCD, you must obtain TCCD IRB approval to conduct your study.

***I am writing a federal grant proposal that doesn't involve gathering human subject information. Do I need to get IRB approval for my grant proposal?***

Many granting institutions now require IRB approval of the proposal prior to proposal submission. The 2018 Requirements eliminate the requirement in the pre-2018 Requirements that grant applications or proposals for research undergo IRB review and approval for the purpose of certification. Experience suggests that review and approval of the application or proposal is not a productive use of IRB time. Elimination of that requirement is not expected to reduce protections for human subjects because the research study (e.g. a research protocol) would remain subject to the requirement for IRB review and approval, assuming that an HHS component funds the research.

The 2018 Requirements at 45 CFR 46.103(d) require certification when the research is supported by HHS, and applicability of the regulations is not otherwise waived under 45 CFR 46.101(i) or the study is not exempted under 45 CFR 46.104. For such research, institutions must certify that each proposed research study covered by an OHRP-approved assurance and by 45 CFR 46.103 has been reviewed and approved by an IRB.

***Is there more than one type of IRB review?***

Yes. There are four types of IRB review: (a) exempt, (b) expedited, (c) full and (d) continuing.

An **exempt review** doesn't require monitoring by the 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.** Researchers that believe their project is exempt should submit their research application to the IRB,

selecting exempt for their category of review. Exempt reviews are carried out by the IRB Chair or their designee.

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.

A **full review** is necessary when the IRB Chair deems participant risk is more than minimal or when the Chair disapproves an expedited review and moves the research project to full committee review.

A **continuing review** is necessary when I research project is not complete after one year. A continuing review reevaluates a project's: (a) risks, (b) benefits, (c) informed consent and (d) participant safeguards. If it is deemed that there is less than minimal risk for participants, the continuing review will be reviewed by the IRB Chair. If there is more than minimal risk, the project will be reviewed by the full IRB. Full reviews require the researcher to provide a summary protocol and a status report on: (a) the number of subjects accrued or withdrawn, (b) a summary of adverse events, (c) any research complaints received, (d) new risks that may be present, (e) new informed consent and (f) summary of any new literature regarding the research topic. As part of continuing review, researchers must submit a closure form to the IRB when they have completed their research.

***What factors does the IRB consider when reviewing/approving my research proposal?***

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?

***How long will it take to get my research approved by the IRB?***

The committee will attempt to review proposals within four weeks of their receipt. Proposals submitted during the summer or during District holidays may be delayed. Since a proposal may not be approved as submitted, you should allow sufficient time for the committee to re-review your proposal.

A **limited review** is necessary when certain exemptions and does not require an IRB to consider all of the IRB approval criteria at §46.111. The four exemptions that may require it are #2, #3, #7 and #8.

***How long is my IRB approval valid?***

Federal regulations state that IRB approval is only valid for one year. Prior to the one-year approval expiration, researchers must submit a continuing review package. Continuing review reevaluates a project's: (a) risks, (b) benefits, (c) informed consent and (d) participant safeguards. If it is deemed that there is less than minimal risk for participants, the continuing review will be reviewed by the IRB Chair. If there is more than minimal risk, the project will be reviewed by the full IRB. Full reviews require the researcher to provide a summary protocol and a status report on: (a) the number of subjects accrued or withdrawn, (b) a summary of adverse events, (c) any research complaints received, (d) new risks that may be present, (e) new informed consent and (f) summary of any new literature regarding the research topic. As part of continuing review, researchers must submit a closure form to the IRB when they have completed their research.

***Can the IRB request that I revise my study and/or study forms prior to IRB approval?***

Yes. If a research proposal is not in compliance in regards to participant risk, informed consent or confidentiality, the researcher will be asked to fix the proposal's deficiencies prior to obtaining IRB approval.

***Can the IRB approve a project retroactively?***

No. Research studies cannot begin without IRB approval. This includes screening subjects or mailing out questionnaires. No research may ***begin*** until the researcher receives official approval from the IRB.

***What is an Assurance?***

An Assurance of Compliance is a formal written, binding agreement that is signed by the researcher(s) in which the said researcher(s) promises to comply with applicable regulations governing research with human subjects.

***Can I revise my research plan without IRB approval?***

Changes to expedited or full reviews that involve human subjects must be approved by the IRB **prior to** implementation. If the said change eliminates an immediate hazard to subjects, the changes made based on the immediate hazard must be reported to the IRB immediately. If your research project was approved under the exempt category, minor changes that do not affect the exempt status can be made without IRB approval. If you are unsure whether IRB approval is needed to make a change, please contact the IRB.

***What are a PI's responsibilities after receiving IRB approval to conduct research?***

A PI has the following responsibilities after they receive IRB approval to conduct a study: (a) obtain and secure human subjects' informed consent, (b) obtain research modification approval from the IRB (if required), (c) submit progress reports and/or continuing review documents (if required), (d) report any unanticipated problems involving human subjects to the IRB and (e) keep certain research records (noted in 45 CFR 46.115(b)) for a period of three years after the completion of the study.

***Can research participants be compensated for their time?***

While it is permissible to pay research participants, there are stringent guidelines surrounding participant compensation. The IRB will disapprove proposals that appear to coerce participants through the use of compensation. The amount offered to participants must correspond with the burden of participation. Acceptable forms of compensation include, but are not limited to: (a) reimbursement for transportation or parking charges, (b) meals and (c) minimum wage for hourly participation.

***Who do I contact if I have IRB-related questions?***

Please contact the Office of Institutional Research, Planning and Effectiveness at 817- 515-5904 or irb.irpe2@tccd.edu.