Tarrant County College District
Institutional Review Board
Quick Reference Guide to Human Subjects Research

Federal regulations and the Tarrant County College District's (TCCD) Federal-Wide Assurance require an Institutional Review Board (IRB) review for all human subject research proposals, regardless of funding. The TCCD IRB was established for the purpose of: (a) protecting the rights and welfare of human research subjects that participate in District research, (b) ensuring that subjects receive appropriate information regarding their participation and informed consent, (c) ensuring that researchers protect private information through anonymity and/or confidentiality and (d) providing oversight of researcher credentials in terms of their qualification to conduct research. District research is conducted in accordance with federal, institutional and ethical guidelines. This *Quick Reference Guide* provides the step-by-step process that TCCD employees and students should follow in regard to submitting IRB research proposals. For a full description of the IRB's processes, please see the IRB Charter.

Step 1: Determine two things: Is your project considered research and does your research involve human subjects?

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).

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 46102(d). If your research involves human subjects or identifiable data on human participants, you ***must*** gain IRB approval prior to conducting your research.

If you can answer yes to both questions, proceed to Step 2.

Step 2: Complete IRB training.

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

Training is offered (free) online through The Association of Clinical Research Professionals (ACRP). Use the following link:

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.

TCCD also accepts CITI training certifications, providing the certificate is current.

Step 3: Determine what type of review you require.

There are three types of initial IRB reviews: (a) exempt, (b) expedited and (c) full.

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.

Step 4. Submit the appropriate review forms to the IRB.

Fill out the appropriate: (a) review form, (b) Principle Investigator Cover Sheet, (c) Informed Consent Form Checklist and (d) any other necessary forms and submit them to the TCCD IRB at irb.irpe2@tccd.edu.

Step 5: Await IRB decision.

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 (if a student): (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?

The IRB 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. The IRB will notify you in writing a decision regarding your proposal.

Step 6: Start your research, maintain related research records, request research modifications (if required) and report any adverse events.

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.

Step 7. If you are still working on your research study at the 11 month mark, you must resubmit your research and obtain continued IRB approval prior to the 1-year anniversary.

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 form. 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.

Step 8: Submit a Research Closure Form.

Once you are finished your research study, you are required to submit an IRB Research Closure form, along with a copy of your final research report to the IRB. This notifies the IRB that its oversight responsibilities are over.