Tarrant County College District Institutional Review Board Frequently Asked Questions

Research Questions:

Will the IRB help me with my research design?

No. The District's IRB does not assist in research design or the writing of dissertation proposals nor does it evaluate the merits or review proposals for contribution to scholarly literature. The IRB is not an editorial service. The role of the TCCD IRB is to review research proposals for standards of compliance in regards to participant risk, informed consent and confidentiality. As part of that process the IRB is obligated to evaluate the study design as well as aspects of the scientific quality because these are ethical issues that affect the rights and welfare of the study participants.

Do student research projects need approval from the IRB?

Yes. If the project meets the definitions of *research* and *human subjects*, IRB approval is required. Students must obtain a faculty or staff member to sponsor their research prior to submitting their research paperwork to the IRB.

I want to conduct a study that involves the deception of my research participants. Is this allowed and if so, what things should I consider?

The use of deception in research is not prohibited by federal or TCCD regulations. However, the use of deception should be well-thought-out, as research deception can violate the trust of research participants. Deception may only occur when it is necessary to ensure valid results and researchers should inform the participants of the deception as soon as possible. In order to obtain approval to use deception, researchers must provide evidence that there are no equally effective non-deceptive techniques available to the researcher.

Informed Consent:

What is informed consent?

Informed consent is the disclosure of a survey's purpose, process, benefits/risks and confidentiality of the information provided by survey respondents. Informed consent should be written at the 6th to 8th grade levels.

When is informed consent required?

All research subjects must give their express consent to participate in a research study. Consent is a necessary element for all research studies, including surveys, interviews and observations of human subjects. Consent is only considered valid if the subjects are

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given enough information to allow them to weigh the study's risks and benefits and if the information is told to them in terms that they can understand. Subjects always have the right to decline or even withdraw from any research study.

Who is responsible for obtaining informed consent?

The lead PI is responsible for obtaining informed consent from all research subjects or their legally authorized representative.

Is there more than one type of informed consent?

Yes. A signed informed consent form is the standard expectation when working with human subjects. However, when research is conducted with minors (subjects under the age of 18), assent of the child and parental permission is required. There is also implied consent, which is a waiver of informed consent. Implied consent verbiage is typically used when conducting surveys that do not ask for any identifying information. Implied consent verbiage typically includes the following statement: *By completing this survey, I am providing my consent to participate in this research study.* Examples of informed consent and assent are available on the District's IRB website.

I am not collecting any personal information from my subjects. Is informed consent still necessary?

Yes. If the proposed research study is anonymous (contains no identifiers), implied consent may be used instead of informed consent.

Are there any informed consent templates?

Yes, informed, assent and implied consent samples are available on the IRB website.

How do I handle informed consent when my study is Internet-based? Phone-based?

Implied consent is often used for Internet-based research. Participants will need to be given consent information and completion of the survey would imply consent. In cases where informed consent needs to be utilized, the informed consent form may be sent via email. The participant can electronically: (a) print their name in the signature block, (b) add the date and (c) return the consent form to the researcher electronically.

Oral consent is typically used in phone-based research. When conducting phone research, the researcher needs to communicate the following to each human subject: (a) study purpose and procedures, (b) what the participant is being asked to do, (c) amount of time the participant is expected to spend, (d) participation is voluntary and participants can withdraw from the study at any time, (e) collected information will remain secure and confidential and (f) contact information of the researcher.

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How do I handle informed consent on non-English speakers?

Federal regulations require informed consent to be presented in language understandable to each participant. To the extent possible, non-English speakers need to be given a fully translated consent document. If a document cannot be translated in writing, a fluent speaker may read the document to the non-English speaker and have the participant sign a *short form*. A short form states that the elements of the informed consent were verbally presented to the participant. The short form must be written in a language that the non-English speaker understands and both the participant and a witness must sign the short form. All foreign language consent documents must be provided to the IRB as a condition of approval.

Are there any recruitment requirements regarding research participants?

Yes. The IRB must review and approve all recruitment materials and processed. Recruitment materials should be written at the 6th to 8th grade reading levels. The following content should be included in recruitment materials: (a) name, affiliation and PI contact information; (b) research purpose; (c) research eligibility requirements; (d) description of participation duration and requirements; (e) description of research risks and benefits and (f) description of compensation or provided incentives.

Do I need to include the exact number of research participants in my IRB proposal?

Yes. To ensure a representative sample, the research proposal should include the number of study participants to be recruited by age, gender and ethnicity. While it is difficult to determine how many recruits will agree to participate, an optimal participation number should be specified.

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