Tarrant County College District
Institutional Review Board
Frequently Asked Questions

Unanticipated Research Problems:

Does the IRB have authority to discontinue my research if an unanticipated problem presents itself?

Yes. If an unanticipated problem poses a risk to any human subject, the IRB can suspend research until the problem has been rectified. If a satisfactory solution does not present itself in a timely manner, the IRB can permanently end the research study. The IRB can also request a PI to revise their study and informed consent as a result of an unanticipated problem. Serious unanticipated events such as death or serious injury of a research participant are to be reported to the IRB within 24 hours of becoming aware of the event. Non-serious unanticipated events are to be reported within two weeks of the PI's awareness of the non-serious, unanticipated event.

How should I handle conflicts of interest or ethical breaches?

Researchers should contact the IRB Chair regarding conflicts of interest or ethical breaches as soon as the existence of the interest or breach presents itself. Researchers should complete an *Unanticipated Event* form and email it to irb.irpe2@tccd.edu.

Does TCCD have a Conflict of Interest form?

Yes. The District uses the Texas Ethics Commission's Local Government Officer Conflicts Disclosure Statement for the disclosure of conflicts of interest.

Post-Research:

What if I don't complete my study in the 1-year time period?

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require the researcher to provide a summary protocol and a status report on: (a) the number of subjects accrued or withdrawn, (b) a summary of adverse events, (c) any research complaints received, (d) new risks that may be present, (e) new informed consent and (f) summary of any new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 are a PI's responsibilities after the study is complete?

A research study is complete when: (a) human subject interaction is complete and (b) all data collection and analysis of private information outlined in the approved IRB research proposal is finished. Investigators must store or dispose identifiable data in a way that is consistent with their IRB approved research plan. PIs must also keep their commitments (if made) to provide research participants the results of the study. Finally, PIs must: (a) complete the District's IRB Research Completion form and (b) submit a copy of their results to the IRB.

What research records do I need to retain?

The Department of Health and Human Services provides regulations specific to what records a researcher needs to retain (45 CFR 46.115(b)). Records include, but are not limited to: (a) informed consent documents, (b) scientific evaluations, (c) correspondence between the IRB and PIs and (d) statements of findings provided to subjects. Researchers also need to comply with the District's record and retention policies. Typically, records need to be retained for a period of three years after the completion of the research.