**Not Human Subjects Research Guidance**

**Introduction**

The Office of Research Compliance (**ORC**) provides guidance documents to help Texas Christian University investigators better understand the expectations and requirements set forth by federal regulations, concerning research that involve Human Subjects. The TCU Institutional Review Board (**IRB**) is responsible for protecting the rights and welfare of human subjects in research. Texas Christian University requires all projects/studies involving human subjects to be submitted, reviewed and approved by the TCU IRB. Therefore, it is crucial for the investigators (faculty, staff and students – both undergraduate and graduate) to consider if their project/study meets the standards of the federal regulation by definition.

**What is a Human Subjects Research?**

The federal regulations as stated in 45 CFR 46.102, define the following as such:

**Research** is “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”

* **Systematic investigation** whereby any activities include the methodical plan of collecting and analysing data for the purpose of answering a question(s) or hypothesis(ses)
* **Generalizable knowledge** whereby the outcomes of the research project/ study are meant for expanding the knowledge base of a scientific discipline or other scholarly field of study. Another way of interpretation, is sharing and applying the findings to populations or situations beyond those studied; which can then draw up conclusions, design programs, or inform policies.

*Note: the intent to develop or contribute to generalizable knowledge will deem an activity as research – it does not need to be published or presented to meet this definition.*

**Human Subjects** is “a living individual about whom an investigator conducting research; i) obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies, or analyses the information or biospecimens, or; ii) obtains, uses, studies, analyses, or generates identifiable private information or identifiable biospecimens.”

* **About whom** is understood as the collection of information or biospecimens to be about the living individual.
* **Intervention** is the inclusion of physical procedures, manipulations of the subject or of the subjects’ environment, for the purposes of the research.
* **Interaction** is the methods of communication or how interpersonal contact is established between investigator and the subject.
* **Private information** is where information about an individual is obtained in a manner where no external observation or recording is taking place, or whereby the information provided can be reasonably expected not to be made public. Where it becomes **identifiable private information** is when the identity of the subject is or may readily be ascertained by the investigator or associated with the information. The same goes for **identifiable biospecimen** whereby the identity of the biospecimen is or may readily be ascertained by the investigator or associated with the biospecimen.

**Therefore, if a project/study satisfies both regulatory definitions as stated above, then it is deemed as Human Subjects Research.** Should an investigator be unsure if their project is a human subjects research or not, contact the ORC to clarify. Federal guidelines do not recommend investigators to make this determination themselves. Instead, the TCU IRB makes determinations based on regulatory and institutional polices, as currently set.

**Not Human Subject Research (NHSR)**

There are instances where certain projects/studies under specific circumstances may involve human subjects, but do not meet the regulatory definitions or may not need TCU IRB oversight beyond an initial human subject determination. On the other hand, TCU acknowledges that some projects/studies which are student-led or meant to fulfil course-related requirements or facilitate internal programs, may include components which might fall under the definition of human subject research. To help with this distinction, the following are examples that must be reviewed and approved by the TCU IRB as applicable:

* Doctoral Dissertations
* Funded Research
* Collaborative Research with external institutions (outside of TCU)
* Master Theses
* Honours Theses

In general, the above examples are in line with independent research in order to contribute to generalizable knowledge. A thesis or dissertation involving human subjects must obtain TCU IRB approval. It should be noted, that some disciplines may involve human subjects without any intent to contribute to generalizable knowledge (such as record oral history, write a biography, or create a work of art). Thus, it is recommended for the students and their advisors to contact the ORC for guidance and clarity well in advance.

Projects/studies that are deemed as **Not Human Subject Research (NHSR)** will not need TCU IRB oversight beyond the initial determination, but will be provided with a formal determination letter that states the project does not require TCU IRB oversight. This letter will provide useful for individuals or entities that may request proof of a formal determination letter.

Student Projects/ Classroom Activities

For Course-Related Research or Research Methods Training/ Curriculum, whereby the primary focus is the learning experience and teaching of research methods and procedures, can be assigned as **NHSR**. Class activities/ projects may include administrating surveys, interviews, questionnaires, and other interactions with human subjects. **Faculty PI’s may submit a blanket NHSR application in Cayuse for the work your students will conduct**. Each project does not need to submit a separate application However, the end goal of such activities/projects is practical appreciation and understanding of research procedures, also, the end result of these activities/projects is purely for presentation within classroom and not for any outside publication or public presentation.

As such, the following conditions must be met in order to be deemed as NHSR:

1. The activity/ project involves minimal risk to human subjects (no more than what may be encountered in daily life experiences) [45 CFR 46.102(j)].
2. The activity/ project is limited to surveys or questionnaire procedures, interviews, observations, or educational exercises as taught/ studied within the respective classes.
3. The activity/ project does not involve sensitive topics or questions (inquiries about alcohol or drug use; criminal activity, sexual attitudes or behaviours, medical or financial status) or confidential information, that could place the human subject at risk if disclosed.
4. The activity/ project does not involve members of vulnerable populations [45 CFR 46 Subpart B, C & D]
5. The activity/ project must allow for voluntary participation and recruited without coercion or undue influence (it might be advantageous to include a consenting process along with a consent document/ research information sheet).
6. The activity/ project does not collect identifiers.
7. The activity/ project’s study team members are not receiving any monetary compensation or any type of support from external organisation, institution or agency.

Studies that are Not Human Subject Research

Any of following types of studies are examples of data collection procedures that would be deemed as Not Human Subject Research:

**Data Collection** – used for metrics of a specific object or subject; such as university administrative purposes, internal departmental, teaching evaluations, customer service surveys

**Service Surveys** –issued or completed by University personnel for the intent and purposes of improving services and programs of the university, or for developing new services or programs for students, employees, or alumni; so long as privacy is protected, confidentiality is maintained, and the nature of participation was voluntary [see Quality Improvement]. *Note: should the data be used for future opportunities, or a new study, that may contribute to generalizable knowledge, then TCU IRB review and approval may be required before the data can be used.*

**Quality Improvement (QI)** – the systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of education or processes in a particular setting. QI involves deliberate actions to improve processes, guided by data reflecting the effects (e.g., types of practical problem solving; an evidence-based management style; the application of the science of how to bring about system change; review of aggregate data at the organizational level to identify a process or management change that can be expected to improvements).

**Information-Gathering Interviews** – to pose questions in order to gather feedback on things, products, or policies rather than people themselves or their thoughts/ personal opinions. For example: gathering feedback on the policy of keeping the library open twenty-four hours during the week, or the impact of smart classrooms on teaching and learning.

**Course-Related Activities** – restricted to purely educational and teaching purposes whereby the data collected from or about human subjects is only intended for in-class presentation to peers, group work, or an assignment, and not for outside-classroom purposes or uses [see Academic Projects].

**Academic Projects** - projects or student assignments involving the collection of data from human subjects when the data is used solely for the purpose of learning research methods and not intended to be used to develop or contribute to generalizable knowledge. *Note: should the data be used for future opportunities, or a new study, that may contribute to generalizable knowledge, then TCU IRB review and approval may be required before the data can be used.*

**Publicly Available Data** – already made accessible to the public via websites or documents/ records. For example: census data and labor statistics.

**Secondary Data Analysis** – the analysis of data that was collected by someone else for another primary purpose. The aggregate data does not contain any identifiers (de-identified), meaning the dataset has been stripped of all identifying information and there is no way it could be linked back to the participants from whom it was originally collected (through a key to a coding system or by other means). See ***Secondary Data guidance document for more information.***

**Case Reports** – the use of information collected from a clinical or educational activity rather than a research activity and presented on no more than three (3) participants. Case reports are generally done by retrospective review of the medical record and highlight a unique treatment, case, or outcome. The examination of the case is usually not systematic and there is usually no data analysis or testing of a hypothesis. Investigators must ensure that the HIPAA privacy rules are followed with respect to using or accessing PHI.

Exempt Determination vs Not Human Subject Research Determination

Exempt and NHSR determinations are different. Exempt determinations are applied to human subject research as applicable based on one or more categories stated in 45 CFR 46.104(d) (such as taking place in educational settings or interactions with the use of educational tests). Whereas, NHSR determinations are based on not meeting the definitions set by federal regulations.

Faculty/ Advisor Responsibilities

Those who lead a class or advise a student, over classroom-based activitiy or course-related project, are responsible for determining whether or not said activity/ project will require TCU IRB review. This guidance document serves to inform faculty, staff and students (both undergraduate and graduates) about assuring the guidelines outlined here are met, and should any activity/project fall outside of these stated guidelines, then necessary steps are taken to submit for TCU IRB review and obtain approval. Contact the ORC for any assistance and further clarification

In addition, it is the responsibility of the faculty/ advisor to ensure the rights and welfare of human subjects recruited in any activity/ project, are protected. That standard research practices are enforced; such as obtaining consent, ensuring privacy and confidentiality is maintained, voluntary nature is always granted and clearly understood, responsible fieldwork, and pertinent contact information for further reference and inquires.

The following information can be used for disclosure purposes to human subjects being recruited for classroom-based activities or course-related projects (if providing a consent document or research information sheet, it is recommended to include these as well):

* The student makes known that they are a TCU student who is conducting this activity/ project for sole purpose of a course/ educational requirement – proceed to state what the specific course/ educational requirement is.
* The name and contact information for the supervising faculty/ advisor.
* A statement about who will have access to the collected data and/or aggregated dataset (i.e: faculty/ advisor and student only).
* Emphasis on the voluntary nature to participate, can skip any questions that they do not wish to answer, and can stop participation or withdraw at any point during or after the performance of the activity/ project.
* Informing the participants, the extent to which their identities, and/or collected data, will be kept confidential.

*Credit is given to the respective institutions for supplementing key information and content for this guidance document:* **University of Texas at Austin, University of Texas at El Paso, Baylor University, Iowa State University, & Northwestern University**