TN Department of Health
Office of Informatics and Analytics

Determination of Research Guide

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Section A: General Guidance and Definitions

If the definitions of research and human subjects are applicable to your project than an Institutional Review Board (IRB) will be necessary. This checklist is designed as a guide to assist in deciding if an IRB Initial Application should be submitted for review. If you have additional questions or would like additional information please contact the Tennessee Department of Health Institutional Review Board at 615-257-2557 or TDH-IRB.Health@tn.gov

Section B: Human Subjects Determination Questions

Does the activity involve human subjects? (45 CFR 46.102(f)) ***Human Subjects*** *means a living individual about whom an investigator (1) Obtains information or bio-specimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or bio-specimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio-specimens.*			
	Yes	No	Not Sure
1. Is the data being obtained about living individuals?			
2. Is the data collected through intervention(s) or interactions with individuals?			
3. Does the data to be used contain identifiable private information? ***Identifiable private information*** *is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.*			

- If ANY answer in Section B is "YES", continue to Section C.
- If ANY answer in Section B is "Not Sure", continue to Section C.
- If ALL answers in Section B are "NO", the activity does not involve human research, IRB review is not required. A Data Request may be made at: https://www.surveygizmo.com/s3/1879037/DATA-REQUEST-FORM

Section C: Research and IRB Review Determination Questions

Is this activity research? ***Research*** *means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.*			
	Yes	No	Not Sure
1. Is the activity a systematic investigation, including research development, testing, and evaluation? ***Systematic Investigation*** *means an activity that includes research development (research question), testing, evaluation or data collection to answer the research question.*			
2. Is the activity designed to generate or contribute to generalizable knowledge? ***Generalizable Knowledge*** *is information that expands the knowledge base of a scientific discipline or information that can be applied beyond the situation studied.*			
3. Does the interview or survey focus on experiences, opinions, and sensitive information about people?			
4. Is the activity a class related project that will lead to publication or poster presentation?			

- If ANY answer in Section B is "YES" and ANY answer in Section C is "YES" an IRB Initial Application is required. This may be completed at https://www.tn.gov/health/health-program-areas/tennessee-department-of-health-institutional-review-board
- If ALL answers in section C are "NO", IRB Review is NOT required. A data request may be made at https://www.surveygizmo.com/s3/1879037/DATA-REQUEST-FORM
- If ANY answer in Section C is "NOT SURE" contact TDH-IRB.Heath@tn.gov

Section D: Examples of Non-Research Activities

https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-resources/index.html

Public Health surveillance activities, including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). Public health surveillance activities are deemed not to be research.	Scholarly and journalistic activities (e.g. oral history, journalism, biography, literally criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individual about who the information is collected.
Course related activities/class assignments (may not be research where the data collected and findings are not intended for use outside of the classroom).	Publically available data
Research involving cadavers, except genetic studies providing private or medical information about relatives.	Coded specimen and/or data sets that were not collected for the currently proposed projects do not need IRB review as long as the investigator receiving the data/specimens cannot link the data/specimens back to the individual subject
Biography or oral history	Case histories
Information gathering interviews e.g. what do you think about the new policy?	Data collection for internal purposes

This checklist is a guide to assist researchers in determining if an activity should be reviewed by the TDH IRB. The checklist is not an IRB determination. Decisions on whether IRB review is required for activities can only be made by the TDH IRB. For an official determination, please submit the TDH IRB application.

Section E: Resource/Reference Sites

Common Rule https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-resources/index.html

Federal Policy for Protection of Human Subjects (Common Rule) https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

Office of Human Research Protection https://www.hhs.gov/ohrp

Office of Human Research Protection https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-Definitions

Tennessee Department of Health IRB Resource Folder https://www.tn.gov/health/health-program-areas/tennessee-department-of-health-institutional-review-board.html