



DETERMINING IF ACTIVITIES INVOLVE HUMAN SUBJECTS RESEARCH – EXEMPTION DETERMINATION

This checklist is intended to assist investigators in determining if their activity is considered human subjects research and would therefore require IRB review. Please forward this form to the IRB at the following email address for tracking and verification of exempt classification. IRB office: jaudenhove@etch.com or call the IRB office at (865)541-8290. **Please attach a summary of proposed project and Principal Investigator (PI) contact information.**

Title of Project/PI: _____

SECTION A: IS IT RESEARCH?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).

Generalizable Knowledge: Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), or inform policy. For conclusions to be generalizable, they must actually be disseminated for research purposes (or be part of a program of investigation that will be disseminated).

- 1. Is your activity a systematic investigation designed to develop or contribute to generalizable knowledge? YES NO

If you answered YES, your activity is considered research. Continue to section B to determine if your research involves human subjects. If you answered NO, your activity is not research and IRB review is not required.

SECTION B. DOES YOUR ACTIVITY INVOLVE HUMAN SUBJECTS?

- 1. Is the data being collected about living individuals? YES NO

If you answered NO, your research does not involve human subjects and IRB review is not required. If you answered YES, continue to question 2.

- 2. Is the data being collected through intervention or interaction with the individuals? YES NO

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject (45 CFR 46.102(f)) (e.g., surveys, focus groups, interviews).

If you answered YES, your research does involve human subjects and IRB review is required. If you answered NO, continue to question 3.

- 3. Does the data contain individually identifiable information? See "de-identified data" on next page YES NO

Meaning, the identity of the subject is or may be readily ascertained by the investigator or associated with the information (45 CFR 46.102(f)).

If you answered NO, your research does not involve human subjects and no IRB review is required. If you answered YES, continue to question 4.

- 4. Is the information private? YES NO

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (45 CFR 45.102(f))

If you answered YES, your research involves human subjects and IRB review is required. If you answered NO, your research is not human subjects and no IRB review is required.

Please note there are other activities that are not considered Human Subjects Research:

Classroom activities solely to fulfill course requirements or to train students in the use of particular methods or devices and, for which you have no desire to publish or share this information outside the classroom (e.g., at conference, on website, etc.).

Internal data collection for East Tennessee Children's Hospital administrative purposes only (i.e., educational purposes, customer service surveys) and for which you have no desire to share or publish outside the hospital.

Information-gathering where questions focus on things, products, or policies rather than about people or their thoughts.

De-identified/ Coded data that were not collected for the currently proposed projects as long as the investigator receiving the data cannot link the data back to the individual (e.g., national dataset with no identifiers).

Both of the following conditions must be satisfied to be categorized as de-identified:

- 1) The data, in its entirety, was collected for purposes other than this project (e.g., the data was collected solely for clinical purposes or for unrelated research purposes, with no "extra" data collected for use in this project).
- 2) The data is given to the researcher without any HIPAA identifiers *(e.g., no codes or links of any sort may be maintained, either by the researcher or the person releasing the data). The researcher will have NO WAY of identifying who the data came from.

OR

- 1) The researcher will delete all HIPAA identifiers*, including codes, prior to initiation of the research. The researcher will have NO WAY of identifying who the data came from.

***Listing of HIPAA identifiers**

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

