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: itaneja@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 46.104 (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 46.104(d) (2) (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 46.104(2).

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 45.104(d))

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 indentifiers *(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)

INSTITUTIONAL REVIEW BOARD

RESEARCH EXEMPTION WORKSHEET & APPLICATION

Who Must Apply? If you are planning a research project that includes the use of human subjects, then your protocol must be approved by East Tennessee Children's Hospital's Institutional Review Board (IRB) before you can begin the research. Federal regulations define some categories of research as "exempt" from prior review by the full IRB

Step 1:

Federal regulations (45 CFR 46) permit the exemption of some types of research from IRB review.
If the research can be described by one or more of the categories listed below, check the appropriate category(ies). If the research cannot be described by any of these categories, the research is not exempt, and the researcher must submit a complete protocol and application. The IRB chair (or his designee) will determine whether the research qualifies for exemption.

Exemption Categories Tool

- Subpart B: Studies Involving Pregnant Women, Fetuses & Neonates are Eligible for Exempt Under All 8 Categories
- Subpart C: Exemptions Do Not Apply to Research Involving Prisoners Except "for Research Aimed at Involving a Broader Subject Population that Only Incidentally Includes Prisoners"
- **Subpart B: Children are allowed in categories 1,4,5,6,7, & 8; Limitations & Exclusion of Children in Category 2 & 3**

Category	New Citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations
1 ☐	**104(d)(1)**	**Research in Established or Commonly Accepted Education Settings that Involves Normal Educational Practices**	N/A	**Not Likely to Adversely Impact Students' Opportunity to Learn or Assessment of Educators Providing Instruction**
2 ☐	**104(d)(2)**	**Research only includes interactions involving Educational Tests, Surveys, Interviews, Public Observation if at least ONE of the following criteria met:**	N/A	**Data Collection Only;** **May include visual or auditory recording; May NOT include Intervention;** **Only includes Interactions**
		(i) Recorded information cannot readily identify the subject (directly or indirectly/linked); **OR**	N/A	**Surveys & Interviews: No Children;** Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed
		(ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR**	N/A	**Surveys & Interviews: No Children;** Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed
		(iii) Information is recorded with identifiers or code linked to identifiers & IRB conducts Limited	Privacy and Confidentiality Review	NO Children
3 ☐	**104(d)(3)(i)**	**Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who**	N/A	**NO Children;** **May Not include Medical Interventions; Subject prospectively agrees;** **(ii)BBI must be:** ☐ **Brief in Duration** ☐ **Painless/Harmless** ☐ **Not Physically Invasive** ☐ **Not Likely to Have a Significant Adverse Lasting Impact on Subjects** ☐ **Unlikely that Subjects Will Find Interventions Offensive or Embarrassing** **(iii)No deception unless participant prospectively agrees**
		A. Recorded information cannot readily identify the subject (directly or indirectly/linked): **OR**	N/A	
		B. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR**	N/A	
		C. Information is recorded with identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review	
4 ☐	**104(d)(4)**	**Secondary Research for Which Consent is Not Required: Use of Identifiable Information or Identifiable Biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, if ONE of following criteria met:**		**No Primary Collection from subjects for the research;** **Allows Both Retrospective and Prospective Secondary Use**
		(i) Biospecimens or Information is Publically Available; **OR**	N/A	Must be publically available
		(ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects; **OR**	N/A	PI does not contact: Will not re-identify

Category	New Citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations
		(iii) Collection and Analysis involving Investigators Use of Identifiable Health Information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"; **OR**	N/A	HIPAA still applies; HIPAA protections include authorization or waiver of authorization; Does not include Biospeciments (only PHI); Federal guidance needed on how to apply this criterion
		(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities	N/A	If research generates identifiable private information it is subject to specified federal privacy laws (see iv for list)
5	**104(d)(5)**	**Research and demonstration projects supported by a Federal Agency/Dept. AND Designed to study…improve… public benefit or service programs.**	N/A	**Must be posted on a Federal Web Site**
6	**104(d)(6)**	**Taste and Food Quality**	N/A	
7	**104(d)(7)**	**Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research For Which Broad Consent Is Required**	-Broad consent is obtained --Documented or documentation waived - If there is a change made for research purposes in the way material stored or maintained, Privacy and confidentiality review	**All requirements for Broad Consent Met;** **MUST TRACK REFUSALS –as the IRB may not waive consent for use of identifiable material for any individual who refuses**
8	**104(d)(8)**	**Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required**	-Privacy and confidentiality review & -research is within the scope of the broad consent & -PI does not plan to return research results	Privacy and Confidentiality protections adequate; Broad consent was obtained**;** Documented or documentation waived **No plan to return research results;** **MUST TRACK REFUSALS as the IRB may not waive consent for use of identifiable material for any individual who refuses**

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