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

☐ **Category 1** - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular and special education instructional strategies; or (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

☐ **Category 2** - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the participants; and (b) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. Note: If the subjects are children, exemption 2 applies only to the research involving educational tests and observations of public behavior when the investigator(s) do not participate in the activities being observed. Exemption 2 does not apply if children are surveyed or interviewed or if the research involves observation of public behavior and the investigator(s) participate in the activities being observed.

☐ **Category 3** - Research involving Benign Behavioral Interventions (BBI) through verbal written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and one of the following criteria are met (1) Recorded information cannot readily identify the subject (directly or indirectly/linked): OR (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 (iii) Information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review. Note: Exemption 3 does not apply if children are surveyed. Exemption 3 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.

☐ **Category 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 the following criteria are met: (i) Biospecimens or Information is Publicly Available; OR (ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify (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 (iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities. Note: HIPAA still applies; HIPAA protections include authorization or waiver of authorization; Does not include Biospecimens (only PHI); Federal guidance needed on how to apply this criterion.

☐ **Category 5** - Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to these programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Category 6 -** Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed; or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ **Category 7.** Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research For Which Broad Consent Is Required. Note: All requirements for Broad Consent must be Met; MUST TRACK REFUSALS –as the IRB may not waive consent for use of identifiable material for any individual who refuses

☐ **Category 8.** Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required. Note: 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.

Step 2:

Please provide additional information as requested in questions 1 – 3. Please attach a Word file of proposal.

1. Purpose or Objectives: Provide a summary of research objectives – what you hope to learn by conducting this research.

2. Research Methodology:
   - Present the time frame of the study along with the research design and sampling method.
   - Be sure to address the specifics of your participant population – including the number of participants to be included and how you will recruit participants (should mention that participants will not be compensated in any way for their participation).
   - Provide details concerning the means of collecting data, with emphasis on the risks to, and protection of, your research participants.
   - Provide information on participant withdraw procedures, such as:
     Participation is voluntary. Participants can withdraw at any time without consequences of any kind. However, once responses have been submitted and anonymously recorded participants will not be able to withdraw from the study. ***(Anonymous research only.)***

3. Confidentiality and Data Analysis:

Describe means of collating and analyzing research data. When human participants are involved, the means of protecting confidentiality is of particular concern.

- Specify how data will be gathered, assessed and stored in a way that maximizes participant confidentiality.
- What the data will be used for (presentation, paper)?
- How the data will be secured throughout the study and what will happen to it upon completion of the study (i.e. shredded)
- Whether the subjects will be kept anonymous or confidential.

Sample Answer:

No signed consent forms will be collected, so that all surveys can remain anonymous. Each participating student will fold up their survey and insert it into a 'ballot box'. No nursing staff will put their name or any other identifying information on their survey. All of the survey responses, when not being collected or analyzed, will be stored in a secure location in_____accessible only to the researcher.

The results of this research will be presented at (classroom, conference, etc.). While individual responses are kept in confidence, aggregate data will be presented representing averages or generalizations about the responses as a whole. Your individual responses will be recorded anonymously. No identifiable responses will be presented in the final form of this study. At the end of the study, all records will be shredded.