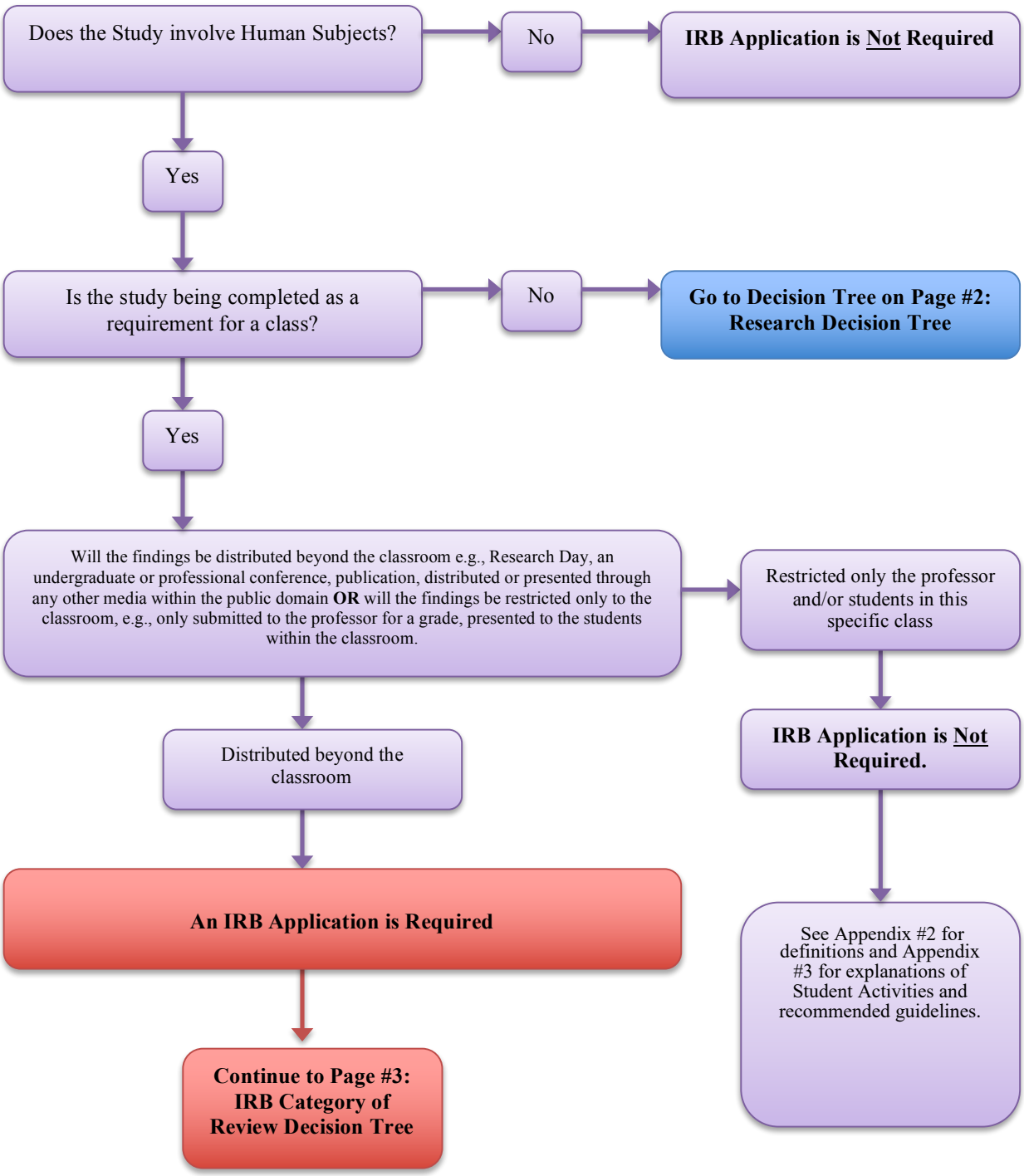
Research/Review Category Decision Trees

Tennessee Tech Institutional Review Board for the Protection of Human Subjects

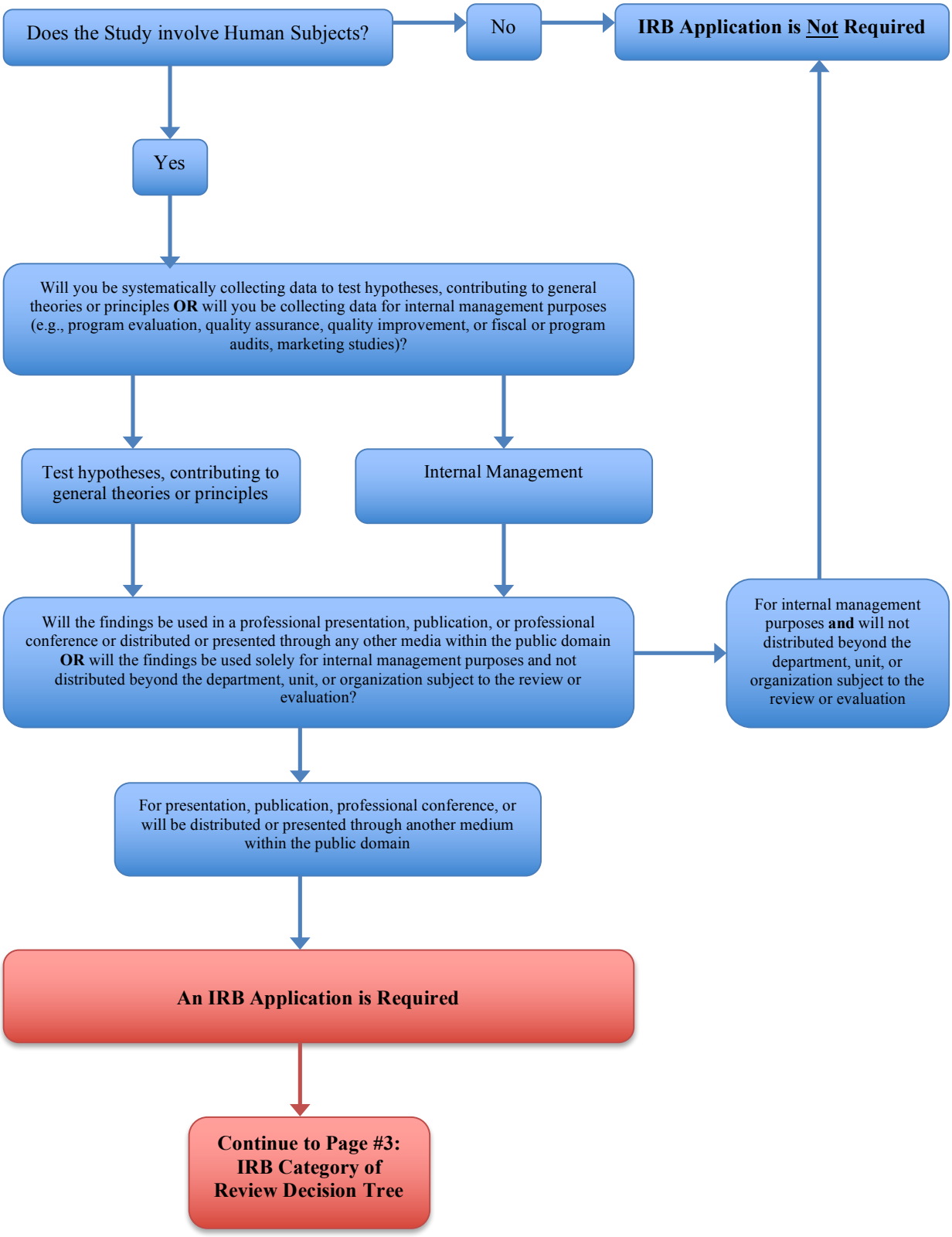
Undergraduate/Graduate Students: Begin on page #1
Faculty/Staff: Begin on page #2

Additional information is available on the Getting Started page.

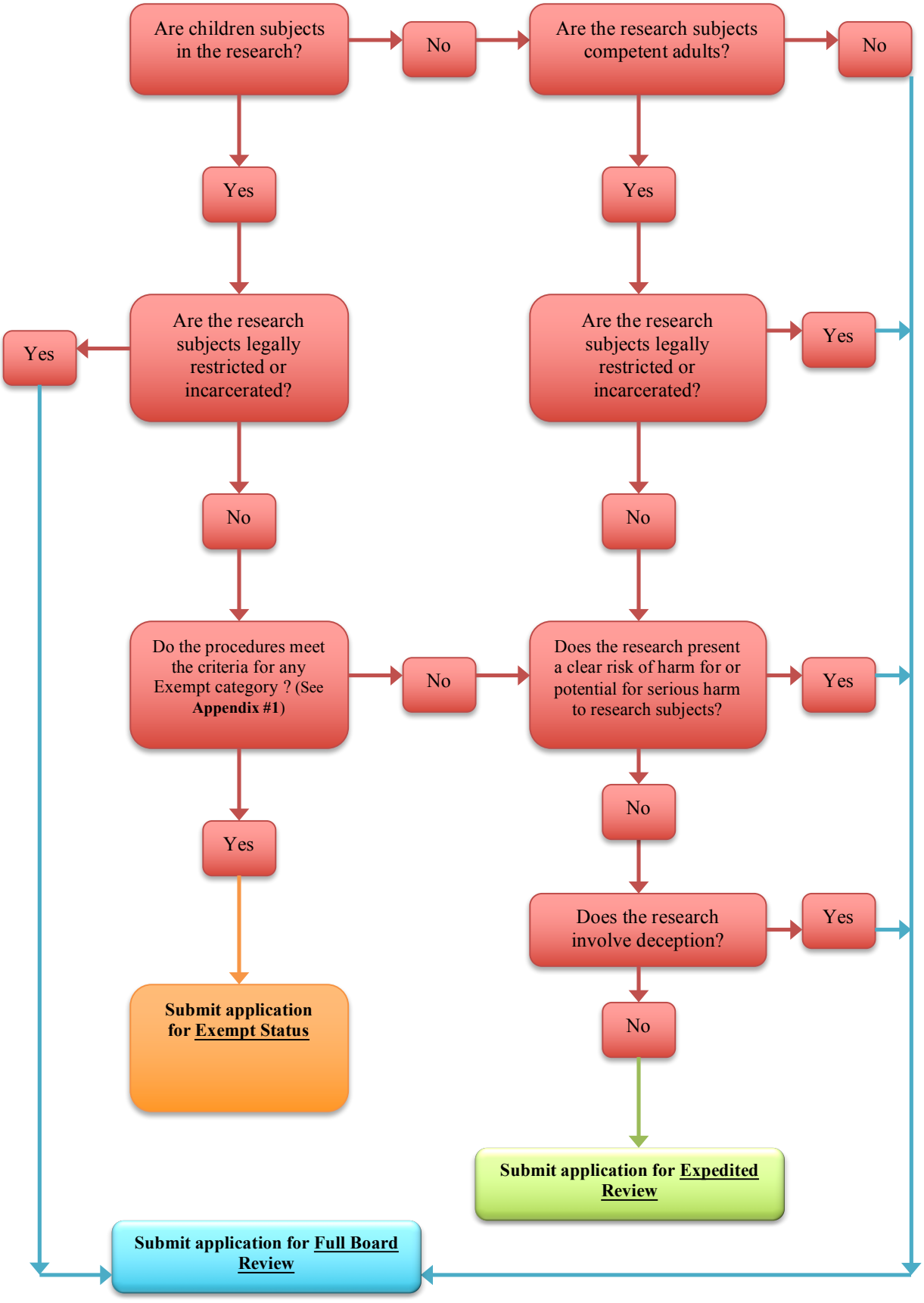
Undergraduate/ Graduate Student (Only) Decision Tree:



Research Decision Tree:



IRB Category of Review Decision Tree:



Appendix #1: Categories of Exempt Status

To be classified as Exempt from Review, the project must involve **no more than minimal risk** to the subject(s) and must satisfy one or more of the following criteria, per 45 CFR 46.104:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(3)
(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the

purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) 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.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Appendix #2: Definitions:

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human subject: a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

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.

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.

A ***systematic*** study occurs when a researcher implements or uses commonly accepted scientific methods of data collection and analysis. This collection and analysis allow for the researcher to methodically and objectively interpret the results to explore answers to predetermined questions or testing predetermined hypotheses. The approach to a study alone does not determine the need for IRB review. In many cases, people conduct interviews or draw blood for reasons that have nothing to do with research.

The statement ***"designed to develop or contribute"*** is interpreted as a study that produces results that are intended for dissemination outside of the University via poster presentations, professional or student conferences, any form of publication, or in any online media.

Generalizable knowledge is results intended to (1) have predictive value, (2) provide scientific clarity, and (3) be applied to a larger population in order to further scientific knowledge or inform policy. Generalizable knowledge would be applicable to a scientific community beyond the classroom and beyond the participants in the study.

From TTU IRB website: Definitions

For additional assistance, please contact IRB@tntech.edu.

Appendix #3: Student Activities Involving Human Subjects:

The IRB has identified three categories of student activities involving human subjects:

1. ***Student Research***
    1. "Student research" is defined as an activity undertaken by undergraduate or graduate students which meets the DHHS definition of research: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." "Student research" can take place in a class or as a faculty-directed independent study.
    2. "Student research" meets the DHHS criteria for research; therefore, it is subject to IRB review at the appropriate level.
2. ***The Classroom Project***
    1. The "classroom project" is a class project of significant length and scope that is included in the course syllabus. The "classroom project" may involve systematic data collection and analysis and may be referred to as "research," but does not meet the DHHS definition of "research," as it is not intended to contribute to generalizable knowledge. (See I.A.1).
    2. The purpose of the "classroom project" is to function as a learning tool designed to facilitate the student's mastery of research theory and practice. The purpose is NOT to "develop or contribute to generalizable knowledge," which places it outside of the definition of "research." Results of the "classroom project" may not be presented outside of the department in which the activity takes place, including publication, inclusion in theses, dissertations, or presentations in public fora.
3. ***The Student Assignment***
    1. The "student assignment" is a required out-of-class activity involving interviews or surveys and is one component of many in a given course. The assignment is completed and submitted for a grade in the course. It is not typically a systematic investigation, and it is not designed to contribute to generalizable knowledge.
    2. Results of the "student assignment" may not be presented outside of the department in which the activity takes place, including publication, inclusion in theses, dissertations, or presentations in public fora.

Suggested Guidelines for Student Activities with Human Subjects

1. "Student Assignments" and "Classroom Projects," are activities involving human subjects that do not meet the OHRP and IRB definitions of "research." These activities, therefore, are not subject to IRB review. Such activities are identified and monitored by the Department Review Committee in the department in which the activities take place.
2. It is recommended that all faculty members and students who participate in the conduct of Student Assignments and Classroom Projects, as defined by the IRB, be familiar with the IRB definitions of these activities, and with the definition of "research" adopted by the OHRP and the TTU IRB.
3. It is recommended that all faculty members and students who participate in the conduct of Student Assignments and Classroom Activities complete CITI training for activities with human subjects, at the level suggested by the IRB. (See website training page.)
4. A Determination Form for Human Subjects Activities (DFHSA) is offered for use or adaptation at the departmental level to identify a project as belonging to the category of Student Assignment or Classroom Project. Neither the use nor the submission of this form is required by the IRB. This form may, however, be adapted for use within the department, at its discretion, and procedures for the use of the form determined by the department chair or departmental review committee.
5. Please note that any proposed student activity involving human subjects which does not meet all of the requirements and qualifications for Student Assignment or Classroom Project is considered to be "research," under the OHRP definition, and "Student Research," as defined by the IRB. The proposal for such a project must be submitted to the IRB for approval at the appropriate level of review, prior to commencement of contact with human subjects.
6. The class instructor or project supervisor should report to the Office of Research any suspected adverse events or effects involving human subjects that take place during, or as a result of, the conduct of the project or assignment.
7. Unless unavoidable, we discourage the use of human subjects that are under the age of 18 or are members of "vulnerable populations," such as pregnant women, people with mental or physical disabilities, or prisoners. Moreover, we discourage any activities that present more than minimal risk for the participants,

involve participation in illegal activities, involve the collection of sensitive private information, or involve the use of deception.

8. If the class instructor or supervisor feels that the use of human subjects under the age of 18 or from a "vulnerable" population or that activities involving elevated risk for the participants, illegal behavior, collection of sensitive information, or deception are necessary to fulfill the learning objective for the classroom project or student assignment, we strongly encourage them to consult with their department chairperson and other faculty within the department or college to establish internal guidelines for overseeing the activities and ensuring the safety of the human subjects and that they are treated ethically and professionally.
9. The course instructor or supervisor is solely responsible for all aspects of classroom projects and student activities. Anyone conducting any type of non-research activities should work closely with their departmental chairpersons and departmental faculty to maintain the highest professional and ethical standards."