**CHECKLIST: DO I NEED TO SUBMIT A PROPOSAL TO THE IRB?**

***Check any of the following that are true of your planned research project:***

This project involves research that will collect data ONLY from extant (already published) sources (e.g., published articles; existing data sets such as those included in SPSS; research databases such as EBSCOhost, Google Scholar, etc.). As such, this project will not involve interaction with living human subjects or access to data that include identifying information of living persons.

This project is a class project (individual or group) will involve interaction with living human subjects or access to data that include identifying information of living persons. HOWEVER, the class project is designed for pedagogical purposes only, in which the primary purpose of the activity is skill development.

*Examples:*

* *learning how to conduct interviews, both structured and unstructured*
* *learning how to analyze research data*
* *learning how to conduct ethnographic research*

(These activities usually involve a research question, but there is no intent to contribute to a field of knowledge because the results will NOT be disseminated in any way).

If the results of the project activity will be shared in class, but will NOT be presented publicly in senior theses, websites, social media sites, blogs, conference presentations, or journal articles by EITHER the student(s) or the faculty (Note: students may present their results internally at the college ONLY as a pedagogical exercise to learn how to present research, but neither the student nor the faculty may ever present the results externally).

*Please note that in the case of pedagogical exercises:*

* It is the responsibility of the instructor to ensure that class projects are conducted ethically. For example, if students collect data from other students for the purposes of learning how to do statistical analyses, instructors are responsible for ensuring that the students providing the data cannot be identified, directly or indirectly.
* Any person who agrees to take part in student projects needs to be told that the projects are being conducted to meet a course requirement and that any data collected will not be made public, now or in the future.
* The results may NOT be disseminated publicly in any way, either now or in the future, by either the student or the instructor.

***If you checked any of the boxes above, then your research might not fall under the purview of the IRB. Please proceed to confirm whether you need to submit a proposal to the IRB.***

***Check any of the following that are true of your planned research project:***

This project is student research that is designed to answer a research question and contribute to a field of knowledge, and involves one or more of the following:

* Interactions with individuals in person, via mail, email, web survey, or telephone
* Interventions (manipulations of the subjects or the subjects’ environment)
* Access to private identifiable information

This project is a pilot study that may be used to support future, more in-depth research, either by the student or by the instructor.

This project is individual student research that may be included in any larger project that may be published or presented to the public, either by the student, by the class as a group, or by the instructor.

This project is a student-led classroom project, but the instructor may use data gathered by students (for either pedagogical or research purposes) in their own research, either now or in the future.

This project is a class project (individual or group) that is undertaken as both an educational experience AND as research, and which involves collection of data from human subjects.

***If you checked ANY of the above, you must submit a research proposal to the IRB. Please proceed to determine whether your research qualifies for an exempt review.***

**DOES MY RESEARCH PROJECT QUALIFY FOR AN “EXEMPT REVIEW”?**

Per federal regulations [45 CFR 46. 110 (b)], **ALL** of the following criteria must apply in order for proposals to be exempt from IRB review. At least two members of the IRB must be in agreement that the proposal has met the criteria. There can be no members who disagree that the proposal meets criteria to be considered exempt.

***Check any of the following that are true of your planned research project:***

**Part A**

The research does not involve participants who are prisoners, fetuses, pregnant women, the seriously ill, those at identified risk of serious illness (e.g., by genetic profile or other personal information), or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.

The research does not involve the collection or recording of behavior that, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

The research does not involve the collection of information regarding sensitive aspects of the subjects’ behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

The research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B). Category B2 (see below) studies that include minors can be eligible for expedited review.

The research does not involve deception.

The procedures of this research are generally free of foreseeable risk to the subject.

Per federal regulations [45 CFR 46. 110 (b)], **AT LEAST ONE** of the following criteria must apply in order for proposals to be exempt from IRB review:

***Check any of the following that are true of your planned research project:***

**Part B**

Research conducted in established or commonly accepted educational settings, such as research on regular and special education, instructional strategies, or cognitive processes, or research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, or any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the researcher in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Research and demonstration projects that are conducted by, or subject to the approval of, department or agency heads and that are designed to study, evaluate, or otherwise examine public benefit or service programs; 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.

Taste and food evaluation and consumer acceptance studies, if either wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient, agricultural chemical, or environmental contaminant that is present at or below the level and for a use found to be acceptable by one of the following: The U.S. Food and Drug Administration, the U.S. Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

***If you checked ALL of the boxes in Part A above AND at least ONE of the boxes in Part B above, then your project qualifies for an exempt review. You may stop here in this document.***

***If ANY of the boxes in Part A are NOT checked, or if NONE of the boxes in Part B were checked, then your proposal is NOT exempt. Please proceed to determine whether your research qualifies for an expedited review.***

**DOES MY RESEARCH PROJECT QUALIFY FOR AN “EXPEDITED REVIEW”?**

An expedited review will be conducted by at least two members of the IRB. When evaluating the proposal, the reviewer or IRB Chair has all the authority of the IRB except that of disapproving the research. Per federal regulations [45 CFR 46. 110 (b)], all of the following criteria must apply for expedited review of the research:

***Check any of the following that are true of your planned research project:***

**Part A**

The research does not involve participants who are prisoners, fetuses, pregnant women, the seriously ill, those at identified risk of serious illness (e.g., by genetic profile or other personal information), or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.

The research does not involve the collection or recording of behavior that, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

The research does not involve the collection of information regarding sensitive aspects of the subjects’ behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

The procedures of this research present no more than minimal risk to the subject, where “no more than minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Per federal regulations [45 CFR 46. 110 (b)], at least one of the following criteria must apply for expedited review of the research:

***Check any of the following that are true of your planned research project:***

**Part B**

Research that collects data from voice, video, digital, or image recordings.

Research on individual or group characteristics or behavior, including but not limited to survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodology as follows:

* *Involving adults, where the research does not involve stress to subjects and where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.*
* *Involving children, where the research involves neither stress to subjects nor sensitive information about themselves or their family, where no alteration or waiver of regulatory requirements for parental permission has been proposed, and where identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.*

Continuations of projects previously approved by the IRB if no new human subjects are enrolled in the study, all research-related interventions on human subjects have been completed, and the research remains active only for long-term follow up of subjects; OR no additional risks to subjects have been identified or the remaining research activities are limited to data analysis.

Certain classes of clinical studies of drugs or medical devices (i.e., clinical studies of drugs for which a new investigational drug application is not required or research on medical devices for which an investigational device application is not required or the device is approved for marketing and is being used according to approved labeling).

Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected prior to the research for a purpose other than the proposed research. These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or videotapes, names will be recorded, even if they are not directly associated with the data).

Collection of data through use of the following procedures:

* *Non-invasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc.).*
* *Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy.*
* *Weighing, testing sensory acuity, electrocardiography, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, Doppler blood flow, and echocardiography.*
* *Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving subjects.*
* *Collection of blood samples by finger stick or venipuncture.*

Continuations of projects that do not fall into the above categories and have been previously subject to the full review process by the IRB, which has determined that the research involved poses not more than minimal risk and no additional risks have been identified.

***If you checked ALL of the boxes in Part A above AND at least ONE of the boxes in Part B above, then your project qualifies for an expedited review. You may stop here in this document***

***If ANY of the boxes in Part A are NOT checked, or if NONE of the boxes in Part B were checked, then your proposal is NOT eligible for an expedited review and must undergo a full review.***

A FULL REVIEW requires all IRB members vote to approve the proposal. Per federal regulations [45 CFR 46], if any of the following criteria apply, the research must undergo a full review by the IRB:

1. The research involves participants who are prisoners, fetuses, pregnant women, the seriously ill, those at identified risk of serious illness (e.g., by genetic profile or other personal information), or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.
2. The research involves the collection or recording of behavior that, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.
3. The research involves the collection of information regarding sensitive aspects of the subjects’ behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of the research involve more than minimal risk to the subject, where “more than minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
5. Any research that does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.