

**Questionnaire—New IRB Protocol**

**In order to qualify for Exempt Review, all of the research procedures in your study must fit into one or more of the 6 categories below. If all procedures in the research do not fall into at least one of these categories, the study does not qualify for Exempt Review and must be submitted for Expedited or Full Board Review. Please answer "yes" or "no" to all of the following category questions. Check Yes to continue.**

**Category 1:** Will your research be conducted in an established or commonly accepted educational setting, 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? \*\*Research involving minors as participants is acceptable under Category 1.

**Category 2:** Will your research only include interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) where 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. \*\*When research involves minors as participants, Category 2 is ONLY applicable under (i) and (ii) when the research involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Item (iii) may not be applied to research involving minors.

**Category 3:** Will your research include 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. \*\*This exemption cannot be used if any participants are minors.

**Category 4:** Will your study by using secondary research data 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.

**Category 5:** Will your study include 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, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs?

**Category 6:** Will your research include taste and food quality evaluation and consumer acceptance studies (without additives or safety questions)?

**Will your research include any procedures that do not fit into one of the 6 categories above?**

* If you answered NO… (*Exempt Research*)

1. Give details of the procedures that relate to the subjects' participation.
2. Describe the recruitment and enrollment procedures. State the mode of communication and attach a final copy of any recruitment letter, advertisement, e-mail, transcript of verbal recruitment announcement, audio/video recording, etc. in the Notes & Attachments section.
3. Describe the process for obtaining consent from participants. Projects eligible for Exempt Review must include the following four disclosures to participants unless there is justification for not doing so: (1) a statement that the study involves research, (2) the procedures of the study, (3) contact information for the researcher (and advisor, if applicable), and (4) that participation is voluntary. Describe how consent will be obtained or provide justification for why consent will not be obtained. While documentation of consent is not required, projects involving (but not limited to) interactions with participants must include a consent process. Please attach all consent materials in the Notes & Attachments section.
4. Will the study involve recording identifiable information, including direct identifiers (such as name, date of birth, Bear number, etc.) or indirect identifiers (such as demographics sufficient to identify individuals considering the study population)?
5. Describe provisions to protect the privacy of participants during the course of the study, including recruitment and data collection activities. For example, might participants be publicly identified or embarrassed (i.e., "outed"), or during the conduct of the study, might participants' responses be overheard or observed by individuals outside the research team (e.g., might participants see other participants' responses on a survey in a crowded classroom or overhear interview responses)?
6. Is there any additional information you would like to provide?

* If you answered YES… (*Expedited/Full Review Research*)

1. Please provide a brief description of the general purpose of the project.
2. In your view, what benefits (individual and/or societal) may result from the study that would justify asking the subjects to participate?
3. Give details of the procedures that relate to the subjects' participation. What is the research question or hypothesis to be addressed? If the procedures involve observation, please include the type of behavior or action you expect to observe and record. If the procedures involve an interview or survey, attach a copy of the questions you plan to ask in the Notes & Attachments section. Describe all interactions (contacts, interventions, observations, etc.) between the researchers and participants. Describe procedures being performed already for diagnostic or treatment purposes, if any.
4. With regards to the populations that are to be included in the study, will any prospective participants be in a subordinate position to or otherwise vulnerable to coercion or undue influence of anyone involved in the study (e.g, students in an investigator's class or employees supervised by one of the researchers)?
5. Describe selection (inclusion/exclusion) criteria for participation (i.e., salient characteristics of subjects such as age range, gender, diagnosis, institutional affiliation, and/or other pertinent characterizations).
6. How many individuals will participate in this study?
7. Describe the recruitment and enrollment procedures. State the mode of communication and attach a final copy of any recruitment letter, advertisement, e-mail, transcript of verbal recruitment announcement, audio/video recording, etc. in the Notes & Attachments section.
8. Describe any inducement or incentive that will be offered, including the amount and timing of payments to participants. Provide justification for any inducement other than those of trivial benefit.
9. Federal regulations require that informed consent be obtained from individuals prior to their participation in research, unless the IRB grants a waiver of consent. How is consent being obtained? When and where will the consent process take place?
10. Is a waiver of documentation (signature) of informed consent being requested?

* If you answered YES…

1. In order to waive the signature requirement, ONE OF THE FOLLOWING must be applicable to the study. Please indicate which of the following (a, b, and/or c) applies and provide further explanation if needed. (a) The only record linking a participant to the research is the consent form in studies where the principle risk is a breach of confidentiality. (b) The research is minimal risk and only involves procedures for which consent is not normally sought. (c) Participants will be wary of signing documents from a cultural perspective or are physically unable to sign their name or even make an 'x'.
2. Is a waiver or alteration of informed consent being requested? An exclusion of one or more of the required elements of consent (such as omission of the true purpose in a study involving deception) would be considered an alteration of consent.

* If you answered YES…

1. In specific instances, any of the elements of consent may be waived. In rare cases, the entire consent process can be waived. For either of these to be considered, ALL OF THE FOLLOWING must be met. If ALL apply please explain how and reasoning for your request. (a) The research in its entirety involves no more than MINIMAL RISK to participants. (b) The waiver or alteration will not adversely affect the rights or welfare of participants. (c) The research could not practically be carried out without the waiver or alteration. (d) Wherever appropriate, participants will be provided with additional pertinent information after participation.
2. Describe any physical, psychological, social, employability, or insurability risks associated with the research.

1. Describe any deception of participants (If any, be sure to request a waiver or alteration of consent):
2. Do you see any other chance that subjects might be harmed in any way?
3. Describe how you will control for the risks you've identified (e.g., confidentiality procedures, emergency response plan, referral for medical care, counseling resources, data and safety monitoring plan):
4. Who will have access to the data?
5. Where will data be stored?
6. What provisions are in place to protect the confidentiality of the data (e.g., physical measures such as locked offices and filing cabinets, and/or electronic measures such as secured networks, data encryption, password protection) during storage, use, and transport/transmission (if applicable) of data?
7. Where will signed consent forms be stored (be specific regarding location)?
8. What direct identifiers (such as name, date of birth, Bear number, etc.) or indirect identifiers (such as demographics sufficient to identify individual participants considering the study population) will be collected?
9. What purpose do the identifiers serve?
10. When will identifiers be removed or "de-linked" from the data? (Identifiers include a code number, which may be linked to another document containing names or other identifying information.)
11. Will the data be retained indefinitely or destroyed?
12. If the data will be destroyed, how and at what point in time (be as specific as possible)?
13. Is there any additional information you would like to provide?