**Request for Exemption Form**

Some research involving human subjects may be exempt from the regulations. The categories below describe these exemptions. Please note that an exemption can be invoked only if **all** components of the research fit the category as described. You might find the following decision charts helpful: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

If you believe that your research may fall into one of the exempt categories, please indicate the relevant category in the space next to the category number below, and the IRB Chairperson or IRB designee will review your research to determine if an exemption can be granted. If granted, your exemption request will be returned to you with an approval signed by the IRB Chairperson, and you may begin your research. You must notify the IRB if your research changes in any way, because the exemption may no longer apply. The IRB may request periodic follow-up. If an exemption cannot be granted, your exemption request will be returned to you with the reason stated, and your research will be reviewed by the IRB. Please direct questions to the IRB Office at: [irbadmin@ursinus.edu](mailto:irbadmin@ursinus.edu).

Principal Investigator: Click here to enter text.

Student Investigators: Click here to enter text.

Project Title: Click here to enter text.

Dates of Proposed Research (mm/yy- mm/yy): Click here to enter text.

**Section 1: Categories eligible for Exemption (Please indicate the relevant category and subcategory in the space provided)**

*NOTE: These exemptions do not apply to research involving prisoners, pregnant women, human fetuses, or human in-vitro fertilization.*

|  |  |  |
| --- | --- | --- |
|  | 1. Research, conducted in established or commonly accepted educational settings, involving 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. | |
|  | 1. Research only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior, if at least one of the following criteria is met:   *NOTE: The exemption for parts involving educational test is also applicable to* ***children; however,*** *it does NOT apply to surveys, interview procedures, or observation of the public behavior of children if the investigator(s) participate(s) in the actions being observed.* | |
|  | * 1. Information obtained is recorded in such a manner that human subjects cannot be readily identified, directly or through identifiers linked to the subjects (NOTE: Codes constitute identifiers.); |
|  | * 1. Any disclosure of the subjects’ responses outside of 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; |
|  | * 1. The information obtained is recorded in such a manner that the human subjects can readily be identified, 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). |
|  | 1. 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:   *NOTE: 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.* | |
|  | 1. Information obtained is recorded in such a manner that human subjects cannot be readily identified, directly or through identifiers linked to the subjects (NOTE: Codes constitute identifiers.); |
|  | 1. Any disclosure of the subjects’ responses outside of 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; |
|  | 1. The information obtained is recorded in such a manner that the human subjects can readily be identified, 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). |
|  | 1. 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: | |
|  | a. The identifiable information or biospecimens are publicly available, |
|  | 1. The information is recorded by the investigator in such a manner that human subjects cannot readily be identified, directly or through identifiers linked to the subjects, the investigator does not contact the subjects or re-identify subjects; |
|  | 1. The investigator’s use of identifiable private information is regulated under HIPAA as ‘healthcare operations’, ‘research’, or ‘public health’. Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens); |
|  | 1. The research is conducted by or on behalf of a federal department or agency, using data collected or generated by the government for non-research purposes. The information is subject to federal privacy standards and other requirements specified in the exemption. |
|  | 1. Research and demonstration projects that are designed to study, evaluate, improve, or otherwise examine:   *NOTE: This exemption applies to research that is either conducted or supported by a federal department or agency (for example, through grant funding). Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site, 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.* | |
|  | * 1. Public benefit or service programs; |
|  | * 1. The procedures for obtaining benefits or services under such programs; |
|  | * 1. Possible changes in or alternatives to such programs or procedures; |
|  | * 1. Possible changes in methods or levels of payment for benefits or services under such programs. |
|  | 1. Taste and food quality evaluation and consumer acceptance studies, which meet at least one of the following conditions: | |
|  | * 1. If wholesome foods without additives are consumed; |
|  | * 1. 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 of the US Department of Agriculture. |
|  | 1. 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. | |
|  | 1. 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: | |
|  | * 1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained; |
|  | * 1. Documentation of informed consent or waiver of documentation of consent was obtained; |
|  | * 1. An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent that the investigator does not include returning individual research results to subjects as part of the study plan. |

**Section 2: Additional Information and Materials**

**A: NON-TECHNICAL RESEARCH PLAN**

State concisely the aims and specific objectives of the research, and procedures to be used to accomplish these aims. Describe what will happen to subjects and what they will be expected to do. State why you believe the research involves no more than minimal risk to subjects. *(If additional space is needed, attach a separate sheet).*

Click or tap here to enter text.

**B: Please attach the following materials:**

* Informed Consent document (if applicable)
* Survey Tools or questionnaires

Signature of Principal Investigator: Click here to enter text.

Date: Click here to enter text.

**FOR IRB USE ONLY**

Exemption Allowed (Category Click here to enter text.)

Exemption Not Allowed (please see comments)

Comments: Click here to enter text.

IRB Chair Signature: Click here to enter text.

Date: Click here to enter text.