**Navicent Health Institutional Review Board**

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**EXEMPT Review Request**

This questionnaire can assist in making a preliminary assessment of whether your research **MAY** be eligible for EXEMPT Status

**\*\*\*NOTE\*\*\***

Only the IRB has authority to determine which activities qualify for exempt status. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt.

Study Title: 

Principle Investigator: 

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| **INITIAL SCREENING QUESTIONS:** | **YES** | **NO** |  |
| Will the research expose participants to discomfort or distress beyond levels encountered in daily life (i.e., does research involve minimal risk)? |  |  |  |
| Will the collected data include identifiers **and** be potentially damaging to a participant’s financial standing, employability, or reputation? |  |  |  |
| Will your research participants include pregnant women (where the research would put the pregnancy or fetus at risk), prisoners, cognitively, economically, or educationally impaired participants? |  |  |  |
| Does the research involve focus groups? |  |  |  |
| Does the research include any video recording or photography? |  |  |  |
| Does any part of the research require deception or incomplete disclosure of information to your participants? |  |  |  |
| * *If you answered* ***YES*** *to* ***any*** *of these questions, your research does* ***NOT*** *qualify for exempt review.* * *Complete the “Expedited or Full Board Protocol Application” for IRB review* | | |  |

**Under 45 CFR 46.101 (b) (Department of Health and Human Services (DHHS)) the IRB may determine a research activity to be exempt where the only involvement of human subjects will be in one or more of the following categories:**

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| *(Select the Category for which you think your study applies)* | | |
| **Category (1)**    **EDUCTATION** | Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |  |
| **Category (2)**  **TESTS, SURVEYS, INTERVIEWS** | Research involving the use of educational testes (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.   1. Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects;   AND   1. 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; or 2. 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 subjects, and an IRB conducts limited IRB review to make the determination required by §46.111(a)(7) that there are adequate provisions for protecting privacy and maintaining confidentiality. |  |
| **Category (3)**  **BENIGN BEHAVIORAL INTERVENTIONS** | Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:   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:    1. 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    2. Any disclosure of the human subject’ 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    3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily by ascertained, directly, or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make determination required by §46.111(a)(7) that there are adequate provisions for protecting privacy and maintaining confidentiality.   OR   1. For the purposes 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 normal amount of received cash between themselves and someone else. 2. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is 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 research. |  |
| **Category (4)**  **SECONDARY RESEARCH/**  **EXISTING DATA** | 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:   1. The identifiable private information about biospecimens are publicly available; 2. 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; 3. 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 4. 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.* |  |
| **Category (5)**  **DEMONSTRATION PROJECTS** | Research and demonstration projects which 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 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 payment for benefits or services under those programs. Such programs 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.   1. 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 just be published on this list prior to commencing the research involving human subjects. 2. [Reserved] |  |
| **Category (6)**  **FOOD** | Taste and food quality evaluation and consumer acceptance studies,   1. If wholesome foods without additives are consumed 2. 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 INFORMATION/BIOSPECIMENS FOR FUTURE RESEARCH COLLECTED UNDER BROAD CONSENT** | 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). |  |
| **Category 8**  **USE OF DATA OR BIOSPECIMENS COLLECTED UNDER BORAD CONSENT** | 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 in accordance with §46.116(a)(1) through (4), (a)(6), and (d); 2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; 3. An IRB conducts 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. |  |
| * *If your research does not fit into any of the above categories, your research does* ***NOT*** *qualify for exempt review. STOP COMPLETING THIS FORM and complete the “Expedited or Full Board Protocol Application” for IRB review.* | | |

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| **FINAL SCREENING QUESTIONS** | **YES** | **NO** | **N/A** |
| For research proposed under category 1, will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices? |  |  |  |
| For research proposed under category 2, will the research involve or interview procedures with children (minors under the age of 18yrs)? |  |  |  |
| For research proposed under category 2, will the research involve observations of the public behavior of children (minors under the age of 18yrs), during which an investigator will participate in the activities being observed? |  |  |  |
| For research proposed under category 2, will your research participants include your own **current** students (i.e. you are currently in charge of their grade) or current employees who report to you (i.e. supervisor, manager, etc.)? |  |  |  |
| For research proposed under category 4, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that participants could be identified directly or through identifiers linked to the participants? (for example, will you create a link list for follow-up purposes or to compare data from multiple sources?) |  |  |  |
| * *If you answered* ***YES*** *to* ***any*** *of these questions, your application does* ***NOT*** *qualify for exempt review. STOP COMPLETING THIS FORM and complete the “Expedited or Full Board Protocol Application” for IRB review.* | | | |

If your protocol meets all the above criteria for possible EXEMPT Status by the IRB, submit this completed form with your application to the IRB.