**Navicent Health Institutional Review Board**

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**EXPEDITED PROTOCOL REQUEST**

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

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

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

Study Title: 

Principle Investigator: 

|  |  |  |
| --- | --- | --- |
| *Studies Must meet* ***ALL*** *of the following:* | **YES** | **NO** |
| The research activities present no more than minimal risk to the subject defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.?  *(does not apply to category (8b) below)* |  |  |
| Identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal?  *(does not apply to category (8b) below)* |  |  |
| The research is not classified (designated as “Classified” by the Federal funding sponsor or other governmental agency) |  |  |
| * *If you answered* ***NO*** *to* ***any*** *of these questions, your application does* ***NOT*** *qualify for expedited review. STOP COMPLETING THIS FORM and submit your protocol for Full Board review.* | | |
| *Studies must also fit into* ***one*** *of the following categories:* | **YES** | **N/A** |
| (category 1a)  Research on drugs for which an investigational new drug application is not required. |  |  |
| (category (1b)  Research on a medical device where an investigational device exemption application is not required. |  |  |
| (category 1b)  Research on a medical device where:   * The device is cleared/approved for marketing;   **AND**   * Is being used in accordance with its cleared/approved labeling |  |  |
| (category 2a)  Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults where:   * The participants weigh at least 110 pounds   **AND**   * The amounts drawn will not exceed 550mL in an 8-week period   **AND**   * Collection does not occur more frequently than 2 times per week |  |  |
| (category 2b)  Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected where:   * The amount drawn will not exceed the lesser of 50mL or 3mL per Kg in an 8-week period.   **AND**   * Collection will not occur more frequently than 2 times per week |  |  |
| *Categories Continued* | **YES** | **N/A** |
| (category 3)  Prospective collection of biological specimens for research purposes by noninvasive means |  |  |
| (Category 4)  Collection of data through noninvasive procedures routinely employed in clinical practice where:   * The procedures do not involve general anesthesia or sedation   **AND**   * The procedures do not involve x-rays or microwaves   **AND**   * If medical devices are employed, they are cleared/approved for marketing |  |  |
| (category 5)  Research involving materials (data, documents, records, or specimens) that have been collected OR will be collected solely for non-research purposes (such as medical treatment or diagnosis) |  |  |
| (category 6)  Collection of data from voice, video, digital, or image recordings made for research purposes |  |  |
| (category 7)   * Research on individual or group characteristics or behavior (including, but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior)   **OR**   * Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies |  |  |
| (category 8a)  Continuing review of research previously approved by the convened IRB as follows:   * The research is permanently closed to the enrollment of new participants   **AND**   * All participants have completed all research-related interventions   **AND**   * The research remains active only for long-term follow-up of participants |  |  |
| (category 8b)  Continuing review of research previously approved by the convened IRB as follows:   * No participants have been enrolled   **AND**   * No additional risks have been identified |  |  |
| (category 8c)  Continuing review of research previously approved by the convened IRB as follows:   * The remaining research activities are limited to data analysis |  |  |
| (category 9)  Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than risk and no additional risks have been identified |  |  |
|  |  |  |
| * *If your research does NOT fit into one of the above categories, your application does* ***NOT*** *qualify for exempt review.* * *STOP COMPLETING THIS FORM and submit your protocol for Full Board review.* | | | |

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