**Institutional Review Board**

**Determining Expedited Review Worksheet**

The purpose of this worksheet is to help Researchers and Reviewers determine if the protocol falls under the criteria for expedited review procedures as laid out in the [Common Rule](https://www.ecfr.gov/cgi-bin/text-idx?m=07&d=19&y=2019&cd=20190807&submit=GO&SID=83cd09e1c0f5c6937cd9d7513160fc3f&node=pt45.1.46&pd=20180719).

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| **Protocols fall under the criteria for Expedited Review when: (all must be checked)** | | |
|  | The study involves no more than minimal risk | |
|  | The study involves prisoners as human subjects  N/A if the study does not involve prisoners | |
|  | The review involves minor changes in previously approved research during the period of approval  N/A | |
|  |  | The modifications do not affect the design of the research |
|  |  | The modifications add no more than minimal risk to subjects |
|  |  | The added procedures fall under the categories for expedited review |
|  | The research falls under one or more of the categories for Expedited Review (below) | |

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| **Section A: Expedited Review Categories (check all that apply)** | | |
|  | 1. Clinical studies on drugs or medical devices for which an IND application or IDE is not required OR a study with a cleared/approved medical device that is being used in accordance with its cleared/approved labeling | |
|  | 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture: | |
|  |  | (i) From health, non-pregnant adults who weigh at least 110 lbs where the blood drawn does not exceed 550 ml in an 8 week period not occurring more frequently than 2 times per week |
|  |  | (ii) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. The amount of blood drawn does not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period not occurring more frequently than 2 times per week |
|  | 3. Prospective collection of biological specimens for research purposes by noninvasive means | |
|  | 4. Collection of data through noninvasive procedures routinely employed in clinical practice provided that: | |
|  |  | (i) The noninvasive procedure must not involve general anesthesia or sedation routinely employed in clinical practice or procedures involving x-rays or microwaves |
|  |  | (ii) Where medical devices are employed, they must be cleared/approved for marketing |
|  | 5. Research involving the use of educational tests, survey procedure, interview procedures or observation of public behavior, when: | |
|  |  | (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects |
|  |  | (ii) 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 |
|  |  | (iii) The study involves children or vulnerable adults as research subjects[[1]](#footnote-1) |
|  | 6. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens that are not publicly available or if the information is recorded by the PI/Researcher in such a manner that subjects can be identified, directly or through identifiers linked to the subjects | |
|  | 7. Research involving data, documents, records, or specimens that have been collected or will be collected solely for non-research purposes (such as, for medical treatment or diagnosis) and that is not classified as exempt | |
|  | 8. Collection of data from voice, video, digital, or image recordings made for research purposes | |
|  | 9. 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 that is not classified as exempt | |

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| **Section B: Additional Considerations for Expedited Review** | |
|  | The study fits under one of the categories under Section A but involves more than minimal risk |
|  | If so, explain your rationale:  Click or tap here to enter text. |

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| **If the project fits under one of the categories listed above, but also involves any of the factors below, the project may be reviewed under full review procedures:** | |
|  | The project involves vulnerable populations |
|  | The project takes place internationally (particularly those with little or no provisions for protecting human subjects) |
|  | The study involves information that, if disclosed, could require mandatory legal reporting (e.g., child/elder abuse, drugs, etc.) |
|  | The study involves deception which raises the risk level for subjects |
|  | The study is regulated by the FDA |

1. The Common Rule specifies that expedited procedures must be used in this instance when children are involved as research subjects. Saint Mary’s University of Minnesota has specified that these additional safeguards should also be applied when vulnerable adults are involved as research subjects. [↑](#footnote-ref-1)