

IRB DISPOSITION - WORKSHEET: EXPEDITED REVIEW

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| **Research Title:**  |       |
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| **Researcher(s):** |
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| 2. |       |
| 3. |       |
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| 6. |       |
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| **Reviewer:** |       |

**Approval Criteria**

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| **The study falls within one or more of the following categories: (One or more categories must be checked.)** |
|[ ]  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 **confidential** surveys, interviews, oral histories, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies. |
|[ ]  Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). |
|[ ]  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). |
|[ ]  Collection of data from voice, video, digital, or image recordings made for research purposes.  |
|[ ]  Clinical studies of drugs and medical devices only when condition (i) or(ii) is met:1. Research on drugs for which an investigational new drug application (IND) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product **is not eligible** for expedited review.)
2. Research on medical devices for which (a) an investigational device exemption application (IDE) is not required; or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling
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|[ ]  Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:* 1. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than two times per week; or
	2. from other adults and childrenof at least 18 years of age, 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. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than two times per week.
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|[ ]  Prospective collection of biological specimens for research purposes by noninvasive means. |
|[ ]  Continuing review of research previously approved by the convened IRB as follows:* 1. where (a) the research is permanently closed to the enrollment of new subjects; (b) all subjects have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of subjects; or
	2. where no subjects have been enrolled and no additional risks have been identified; or
	3. where the remaining research activities are limited to data analysis

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|[ ]  Continuing review of research not conducted under an IND application or IDE 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 minimal risk and no additional risks have been identified. |

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| **Approval criteria: (Check the appropriate answer)** |
|[ ]  Researchers have completed human subject protection training.  |
|[ ]  The research presents no more than Minimal Risk to subjects. |
|[ ]  Has obtained Site Permission Letter (An approval letter from an institution where research will be conducted). |
|[ ]  The study is appropriate for the subjects being studied)  |
|[ ]  Participants recruitment procedure appropriate. |
|[ ]  Risks to participants are reasonable in relation to anticipated benefits and the importance of the expected knowledge.  |
|[ ]  Participants selection procedure is fair and appropriate for the study. |
|[ ]  Informed consent will be obtained from each participant or their legal representative, documented according to federal regulations.  |
|[ ]  Adequate safeguards are in place to ensure participant safety during data collection. |
|[ ]  Participants' right to privacy and confidentiality is protected.  |

**(Check the appropriate answer)**

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| **Yes** | **No** | **N/A** | **Criteria**  |
|[ ] [ ] [ ]  **Risks to subjects are minimized by using procedures which:** are consistent with sound research design. |
|[ ] [ ] [ ]  **Risks to subjects are minimized by using procedures which:**do not unnecessarily expose subjects to risk (pregnant women excluded from exercise). |
|[ ] [ ] [ ]  **Risks to subjects are minimized by using procedures which:**when appropriate, are already being performed for diagnostic or treatment purposes. |
|[ ] [ ] [ ]  Risks to subjects are reasonable in relation to anticipated benefits. |
|[ ] [ ] [ ]  Selection of subjects is equitable, and subjects will be selected from the least vulnerable population possible given the nature of the planned research. |
|[ ] [ ] [ ]  **Risk/benefit ratio of exposure to** deception is acceptable. |
|[ ] [ ] [ ]  **Risk/benefit ratio of exposure to** coercion is acceptable. |
|[ ] [ ] [ ]  Plan for desensitization and/or dehoaxing is acceptable. |
|[ ] [ ] [ ]  Subjects are protected from coercion related to researcher-subject relationship. |
|[ ] [ ] [ ]  Procedures for maintenance of subjects’ data are acceptable for the planned design. |
|[ ] [ ] [ ]  All subjects have equitable access to research findings. |

**(Check the appropriate answer)**

| **Yes** | **No** | **N/A** | **Required elements of INFORMED CONSENT:** |
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|[ ] [ ] [ ]  Statement that the study involves research. |
|[ ] [ ] [ ]  Name of primary researcher. |
|[ ] [ ] [ ]  Title of research or general topic of research. |
|[ ] [ ] [ ]  Explanation of the purposes of the research. |
|[ ] [ ] [ ]  Expected duration of the subject’s participation. |
|[ ] [ ] [ ]  Description of the procedures to be followed. |
|[ ] [ ] [ ]  Identification of any experimental procedures to be used. |
|[ ] [ ] [ ]  Description of possible risks and/or discomforts. |
|[ ] [ ] [ ]  Description of realistic benefits to the subject or others. |
|[ ] [ ] [ ]  Disclosure of appropriate alternate procedures and/or treatments, if any, that might be advantageous to subjects. |
|[ ] [ ] [ ]  Extent to which confidentiality or anonymity will be maintained. |
|[ ] [ ] [ ]  Statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which subject is otherwise entitled. |
|[ ] [ ] [ ]  Statement that subject may withdraw participation and when and how subject can do |
|[ ] [ ] [ ]  Contact person for questions about research and subject’s rights. |

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| **Overall Comments and Recommendations:** |
| ***Please provide your written feedback and recommendations for improvement on each section of the protocol.*** |
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| **Disposition: Check the appropriate disposition**  |
|[ ]  Full Approval (no changes required)  |
|[ ]  Approval with recommendation: Proceed with Suggestions (minor improvements recommended)  |
|[ ]  Approval with Conditions: (There are severe and many concerns)  |
|[ ]  Disapproval (major revisions required) |
|[ ]  Approval ID (Administrator use only):  |