CALDWELL UNIVERSITY™

**Institutional Review Board**
**Reviewer Worksheet: Expedited Procedures**

**Note to reviewers: Before beginning your review of the application, check to make sure that:**

1. **The application is signed.**
2. **That the researcher has completed and sent in proof of training in the protection of human subjects.**
3. **That all necessary supplemental documents (i.e., consent forms, assent forms, measures, recruitment posters, etc.) have been included. Note that some applications may be requesting waivers for consent/assent.**
4. **That all documents requiring stamps (application, consent/assent, posters) are in doc/docx format.**
5. **Do not review an application if the above is not met and let the IRB chair know.**

| **1. Justification and Methods** | **Yes** | **No** | **Notes** |
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| a. Are the aims and hypotheses of the research study clearly stated? | ☐ | ☐ | |
| b. Does the research design adequately address the proposed study objectives and allow for scientifically and statistically valid results? | ☐ | ☐ | |
| c. Does the research contribute to generalizable knowledge? | ☐ | ☐ | |
| d. Is the need for human subjects justified? | ☐ | ☐ | |
| e. Is there an adequate description of the activities human subjects will engage in? | ☐ | ☐ | |
| f. Is there a detailed description of the data collection and methods of recording? | ☐ | ☐ | |
| g. Have the questionnaires and interview tools been provided? | ☐ | ☐ | |
| h. Is the proposed sample size justified? | ☐ | ☐ | |
| **2. Risks and Benefits** | **Yes** | **No** | **Notes** |
| a. Are the risks for the human subjects more than minimal? **Note: Minimal risk is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"** | ☐ | ☐ | |
| b. Are the risks (physical, psychological, legal, economic, and social) to subjects minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk? | ☐ | ☐ | |

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| c. Are both the risks and anticipated benefits accurately identified, evaluated, and described?<br>Have you identified any risks not considered by the researchers? | ☐ | ☐ | |
| **3. Selection and Recruitment of Subjects** | **Yes** | **No** | **Notes** |
| a. Is the selection of subjects equitable? | ☐ | ☐ | |
| b. Are the criteria for inclusion/exclusion equitable? | ☐ | ☐ | |
| c. Will the recruitment process alter equitable selection? | ☐ | ☐ | |
| d. Does the nature of the research justify using the proposed subject population? | ☐ | ☐ | |
| e. Are there adequate procedures for identifying those who might be more susceptible to the risks and who therefore ought to be excluded? | ☐ | ☐ | |
| f. Has there been appropriate consideration of any special physiological, psychological, or social characteristics of the subject group that would pose special risks? | ☐ | ☐ | |
| g. Are some or all of the subjects likely to be vulnerable to coercion or undue influence, such as children prisoners, pregnant women, mentally disabled persons or economically disadvantaged persons? | ☐ | ☐ | |
| h. If yes to question 3g, have additional safeguards been included in the study to protect the rights and welfare of these subjects? | ☐ | ☐ | |
| i. If there is a special population (children, prisoners, pregnant women and fetuses), has the appropriate justification been provided? | ☐ | ☐ | |
| j. Is the exclusion of study subjects justified and appropriate? | ☐ | ☐ | |
| **4. Privacy and Confidentiality** | **Yes** | **No** | **Notes** |
| a. Are there adequate provisions to protect the privacy interests of participants? | ☐ | ☐ | |
| b. Are there adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study? | ☐ | ☐ | |

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| c. If the information obtained about subjects might interest law enforcement or other government agencies, has a certificate of confidentiality been obtained? | ☐ | ☐ | |
| d. Are the investigator's disclosures to subjects about confidentiality adequate? | ☐ | ☐ | |
| **5. Safety Monitoring** | **Yes** | **No** | **Notes** |
| a. If necessary, does the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects? | ☐ | ☐ | |
| b. Is there documentation indicating appropriate reporting to the IRB in the event that unexpected results are discovered or there are adverse events? | ☐ | ☐ | |
| **6. Incentives for Participation** | **Yes** | **No** | **Notes** |
| a. Are the incentives offered reasonable, based upon the complexities and inconveniences of the study and the particular subject population? | ☐ | ☐ | |
| b. Is the compensation or reimbursement appropriately prorated? | ☐ | ☐ | |
| **7. Conflict of Interest** | **Yes** | **No** | **Notes** |
| a. Is there a conflict of interest that requires management? | ☐ | ☐ | |
| **8. Informed Consent process** | **Yes** | **No** | **Notes** |
| a. Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described? | ☐ | ☐ | |
| b. Is the language and presentation of the information to be conveyed appropriate to the subject population? | ☐ | ☐ | |
| c. Are the timing of and setting for the explanation of the research and obtaining informed consent conducive to good decision making? | ☐ | ☐ | |
| d. Is it clear who is authorized to obtain informed consent for the study? | ☐ | ☐ | |
| e. Will the investigator obtain legally effective informed consent of the participant or the participant's legally authorized representative? | ☐ | ☐ | |
| f. Will the circumstances of the consent process provide the prospective | ☐ | ☐ | |

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| participant or the representative sufficient opportunity to consider whether to participate? | | | |
| g. Will the circumstances of the consent process minimize the possibility of coercion or undue influence? | ☐ | ☐ | |
| h. Will the individuals communicating information to the participant or the representative during the consent process provide the information in language understandable to the participant or the representative (individuals talking to the participants and answering questions will be able to communicate in a manner that is understandable to the participant)? | ☐ | ☐ | |
| i. If yes, did the PI report that they will use the short form? | ☐ | ☐ | |
| j. Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights? | ☐ | ☐ | |
| k. Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the representative releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence? | ☐ | ☐ | |
| l. Are subjects informed to take as much time necessary to read the consent form? | ☐ | ☐ | |
| m. Are subjects informed that they will receive a copy of the consent form? | ☐ | ☐ | |
| **9. Basic Elements of Informed Consent (Required)** | **Yes** | **No** | **Notes** |
| a. A key information section with the following:<br>➨ The fact that consent is being sought for research and that participation is voluntary;<br>➨ The purposes of the research, the expected duration of the prospective subject's | ☐ | ☐ | |

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| participation, and the procedures to be followed in the research;<br>➨ The reasonably foreseeable risks or discomforts to the prospective subject;<br>➨ The benefits to the prospective subject or to others that may reasonably be expected from the research; and<br>➨ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. | | | |
| b. A statement that the study involves research | ☐ | ☐ | |
| c. An explanation of the purposes of the research | ☐ | ☐ | |
| d. The expected duration of the subject's participation | ☐ | ☐ | |
| e. A description of the procedures to be followed | ☐ | ☐ | |
| f. Identification of any procedures which are experimental | ☐ | ☐ | |
| g. A description of any reasonably foreseeable risks or discomforts to the subject | ☐ | ☐ | |
| h. A description of any benefits to the subject or to others which may reasonably be expected from the research | ☐ | ☐ | |
| i. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject | ☐ | ☐ | |
| j. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained | ☐ | ☐ | |
| k. One of the following statements:<br>(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from | ☐ | ☐ | |

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| the subject or the legally authorized representative, if this might be a possibility; or<br>(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies | | | |
| l. An explanation of whom to contact for answers to questions about the research | ☐ | ☐ | |
| m. An explanation of whom to contact for answers to questions about injury | ☐ | ☐ | |
| n. An explanation of whom to contact concerning rights as a research subject. | ☐ | ☐ | |
| o. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the subject may withdraw without penalty. | ☐ | ☐ | |
| **Additional Elements of Informed Consent (As Required)** | **Yes** | **No** | **Notes** |
| p. A statement that the particular treatment or procedure may involve risks to the subject or to the embryo or fetus, if the subject is or may become pregnant which are currently unforeseeable. | ☐ | ☐ | |
| q. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. | ☐ | ☐ | |
| r. Any additional costs to the subject that may result from participation in the research. | ☐ | ☐ | |
| s. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. | ☐ | ☐ | |
| t. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject. | ☐ | ☐ | |
| u. The approximate number of subjects involved in the study. | ☐ | ☐ | |
| v. The storage and use of research specimens disclosed. | ☐ | ☐ | |

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| w. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; | ☐ | ☐ | |
| x. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and | ☐ | ☐ | |
| y. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). | ☐ | ☐ | |
| z. Agreement and spaces for signatures/dates for subject, and/or representative (if applicable) and person obtaining consent. | ☐ | ☐ | |
| aa. Is a witness signature required? | ☐ | ☐ | |
| **10. Waiver of Informed Consent: Documentation** | **Yes** | **No** | **Notes** |
| a. Have the criteria for waiver of informed consent documentation been met?<br>**1. The consent form would be the only record linking the subject to the research, <u>and</u> a potential sick would be a breach of confidentiality. In such case, it is up to the subject when asked if they want documentation.*)***<br>2. **Study is no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.** | ☐ | ☐ | |
| b. If informed consent documentation is waived, should the investigator be required to provide subjects with a written statement regarding the research? | ☐ | ☐ | |
| c. If children are included, have the criteria for waiver of parental/guardian consent been met?<br>- **IRB must determine parental/guardian permission is not** | ☐ | ☐ | |

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| **a reasonable requirement to protect subjects**<br>- **Appropriate mechanisms must be implemented to protect children as subjects** | | | |
| **11. Waiver/Alteration of Required Elements of Informed Consent** | **Yes** | **No** | **Notes** |
| a. If waiver or modification to required consent elements proposed, have all the criteria been met?<br>**1. The research involves no more than minimal risk to the subjects?**<br>**2. The waiver/alternation will not adversely affect the rights and welfare of the subjects.**<br>**3. The research could not practicably be carried out without the waiver or alteration, and**<br>4. **When appropriate, the subject will be provided with pertinent information after participation.** | ☐ | ☐ | |
| **12. Assent From Children** | **Yes** | **No** | **Notes** |
| a. Is assent required?<br>**(Assent is required unless the child is not capable (due to age, psychological state, sedation), or the research holds out the prospect of direct benefit that is only available within the context of the research.)** | ☐ | ☐ | |
| b. Will assent be documented? | ☐ | ☐ | |
| c. Is the process of obtaining/documenting assent adequate? | ☐ | ☐ | |
| **15. Consenting Cognitively Impaired Individuals** | **Yes** | **No** | **Notes** |
| a. Does the research involve greater than minimal risk? | ☐ | ☐ | |
| b. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonable be expected to result? | ☐ | ☐ | |
| c. Is the relation of the anticipated benefit to the risk at least as favorable to the subjects as that presented by available alternative approaches? | ☐ | ☐ | |
| d. Are there adequate provisions for soliciting the assent of the subject and | ☐ | ☐ | |

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| permission of their legally authorized representative? | | | |
| e. Is the proposed plan for the assessment of the capacity to consent adequate? | ☐ | ☐ | |
| **18. Resources** | **Yes** | **No** | **Notes** |
| a. Does the IRB have the appropriate expertise to review this research? If no, note whether a consultant should be used to assist in the review of the research | ☐ | ☐ | |
| b. Will the Investigator have access to a population that will allow recruitment of the required number of participants? | ☐ | ☐ | |
| c. Will the Investigator have sufficient time to conduct and complete the research? | ☐ | ☐ | |
| d. Will the Investigator have adequate numbers of qualified staff? | ☐ | ☐ | |
| e. Will the Investigator have adequate resources to complete the research? | ☐ | ☐ | |
| f. Will the Investigator have adequate medical or psychological services available that participants might require as a consequence of the research, when applicable? | ☐ | ☐ | |
| **20. Continuing Review** | **Yes** | **No** | **Notes** |
| a. Should continuing review be conducted under the expedited review process? **Continuing review is only necessary if the reviewer feels there are circumstances requiring continued IRB oversight.** | ☐ | ☐ | |