***LINCOLN UNIVERSITY Reviewer Guidelines for Continuing Review Applications***

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| **1. COntinuing review application submission** | **Yes / No / N/A** |
| 1. Are all consent forms included with the application? |  |
| 1. Is an adequate protocol summary provided? |  |
| 1. Is an adequate status report on the study’s progress provided? |  |
| 1. Are any significant new findings and/or interim report provided? |  |
| 1. If yes, is there any significant info that may change a subject’s willingness to participate? |  |
| 1. Is the continuing review being submitted in a timely manner? |  |
| **2. PROTOCOL CHANGES & AMENDMENTS** | **Yes / No / N/A** |
| 1. Has the protocol changed since the last IRB Review? |  |
| 1. If yes, have all changes been documented and approved by the IRB? |  |
| 1. **\*** Is the PI requesting new changes as part of this submission? |  |
| 1. **\*** If yes, do the requested changes alter the risk/benefit ratio of the subjects? |  |
| 1. **\***Are the requested changes updated in all appropriate study materials and included for review? |  |
| **3. PROTOCOL DEVIATION & EXCEPTIONS** | **Yes / No / N/A** |
| 1. Has the PI submitted any new deviations or exceptions since the last IRB review? |  |
| 1. If yes, do the reported deviations/exceptions alter the risk/benefit ratio? |  |
| 1. Are any protocol changes required or recommended to prevent similar events in the future? |  |
| 1. If yes, are all the appropriate study materials updated and included for review? |  |
| **4. SERIOUS ADVERSE EVENTS & UNANTICIPATED PROBLEMS** | **Yes / No / N/A** |
| 1. Have there been any SAEs and/or unanticipated problems reported since the last continuing review? |  |
| 1. If yes, have all SAE/unanticipated problems been reviewed by the IRB? |  |
| 1. Do any of these events alter the risk/benefit ratio? |  |
| 1. Should other subjects be informed of the events and/or change to risk/benefit ratio? |  |
| 1. Should the consent or protocol be amended to include new information resulting from these events? |  |
| **5. SUBJECT ENROLLMENT** | **Yes / No / N/A** |
| 1. What is the target number of subjects to be enrolled? |  |
| 1. How many subjects are currently enrolled? |  |
| 1. Is the enrollment rate as planned or reasonable to meet the goals of the study? |  |
| 1. If enrollment is notably slow, is adequate justification/explanation provided to continue with the study? |  |
| 1. Is there a notable rate of subject withdrawals? |  |
| **6. CHECKLIST OF INFORMED CONSENT/ASSENT ELEMENTS/LANGUAGE** | **Yes / No / N/A** |
| * 1. Overall, is consent/assent written in a language easily understandable to the subject and/or guardian, and void of any exculpatory language? |  |
| * 1. If consent has not been translated, should it be? |  |
| **Ensure the following basic elements are included in the informed consent:** | **Yes / No / N/A** |
| 1. A statement that the study involves research |  |
| 1. An explanation of the purposes of the research |  |
| 1. The expected duration of the subject's participation |  |
| 1. A description of the procedures to be followed |  |
| 1. Identification of any procedures which are experimental |  |
| 1. A description of any reasonably foreseeable risks or discomforts to the subject |  |
| 1. A description of any benefits to the subject or to others which may reasonably be expected from the research |  |
| 1. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |  |
| 1. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |  |
| 1. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained |  |
| 1. An explanation of whom to contact for answers to questions about the research |  |
| 1. An explanation of whom to contact for answers to questions about injury |  |
| 1. An explanation of whom to contact concerning rights as a research subject. |  |
| n. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the subject may withdraw without penalty. |  |
| **If applicable to the study, ensure the following additional elements are also included:** | **Yes / No / N/A** |
| 1. 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. |  |
| 1. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. |  |
| 1. Any additional costs to the subject that may result from participation in the research. |  |
| 1. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. |  |
| 1. 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. |  |
| 1. The approximate number of subjects involved in the study. |  |
| 1. The storage and use of research specimens disclosed. |  |
| 1. Agreement and spaces for signatures/dates for subject, and/or representative (if applicable) and person obtaining consent. |  |
| 1. Is a witness signature required? |  |
| x. If FDA Regulated, a statement that the FDA may inspect the records. (Include if the research is subject to FDA regulations) |  |
| y. The consent from contains contact information for a person independent of the research team for the following:   * + To obtain answers to questions about the research   + In the event the research staff could not be reached   + In the event they wished to talk to someone other than the research staff? |  |
| **7. REVIEW CONSIDERATIONS** | **Yes / No / N/A** |
| 1. Do risks continue to be minimized and reasonable in relation to the benefits & knowledge to be gained? |  |
| 1. Do study procedures ensuring safeguards for vulnerable subjects continue to be adequate? |  |
| 1. Do study procedures ensuring subject privacy and confidentiality continue to be adequate? |  |
| 1. Were any subject complaints documented for this study and raise concern? |  |
| 1. Were any outside reports submitted: monitoring reports, multi-site reports, FDA, or DSM reports? 2. If yes, were there any notable observations or concerns that should raised to the committee? |  |
| 1. If there is a Data Safety Monitoring Plan, is the study adequately following the approved plan? |  |
| 1. Has the source of funding changed? 2. If yes, are there any new conflicts of interests? |  |
| 1. Should the protocol be reviewed more frequently than once per year? |  |
| 1. If this is a multi-center trial in which LINCOLN UNIVERSITY is the coordinating site, has there been evidence of communication among sites? |  |
| 1. Does the protocol need verification from sources other than the investigators that no material changes have occurred since previous IRB review? |  |
| **8. ASSENT FROM CHILDREN** | **Yes / No / N/A** |
| 1. Is assent required? (Assent is required unless the child is not capable (i.e. 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) |  |
| 1. Is assent currently being obtained? |  |
| 1. Is the process of obtaining/documenting assent still adequate? |  |
| **9. PARENTAL PERMISSION** | **Yes / No / N/A** |
| 1. Is consent of one parent appropriate? |  |
| 1. Is consent of both parents required? (Consent from both parents is required when the research is greater than minimal risk, without potential for benefit) |  |
| 1. Is parental permission currently being obtained? |  |
| **10. use of the short form** | **Yes / No / N/A** |
| a. Did the PI report the use of the short form? |  |
| b. If yes, did the PI report if a witness was present during the oral presentation? |  |
| c. If yes, did the PI report if a witness was conversant in both English and the native language of the subject? |  |

*Additional Comments (optional):*