***LINCOLN UNIVERSITY Reviewer Guidelines for Informed Consent***

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| **Basic ElementS of Informed COnsent (Required)** |  **Yes / No / N/A** |
| 1. A statement that the study involves research
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| 1. An explanation of the purposes of the research
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| 1. The expected duration of the subject's participation
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| 1. A description of the procedures to be followed
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| 1. Identification of any procedures which are experimental
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| 1. A description of any reasonably foreseeable risks or discomforts to the subject
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| 1. A description of any benefits to the subject or to others which may reasonably be expected from the research
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| 1. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
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| 1. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
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| 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
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| 1. An explanation of whom to contact for answers to questions about the research
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| 1. An explanation of whom to contact for answers to questions about injury
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| 1. An explanation of whom to contact concerning rights as a research subject.
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| 1. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the subject may withdraw without penalty.
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| **ADDITIONAL ELEMENTS OF INFORMED CONSENT** | **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.
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| 1. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
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| 1. Any additional costs to the subject that may result from participation in the research.
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| 1. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
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| 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.
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| 1. The approximate number of subjects involved in the study.
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| 1. The storage and use of research specimens disclosed.
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| 1. Agreement and spaces for signatures/dates for subject, and/or representative (if applicable) and person obtaining consent.
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| 1. Is a witness signature required?
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|  x. If FDA Regulated, a statement that the FDA may inspect the records. (Include if the research is subject to FDA regulations) |  |
| **informed consent process and content** | **Yes / No / N/A** |
| 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. Have the informed consent issues for secondary study subjects been addressed? |  |
| f. Will the investigator obtain legally effective informed consent of the participant or the participant’s legally authorized representative? |  |
| g. Will the circumstances of the consent process provide the prospective participant or the representative sufficient opportunity to consider whether to participate? |  |
| h. Will the circumstances of the consent process minimize the possibility of coercion or undue influence? |  |
| i. 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)? |  |
| 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? |  |
| 1. 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?
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| **WAIVER OF INFORMED CONSENT Document** | **Yes / No / N/A** |
| 1. Have the criteria for waiver of informed consent documentation been met?
	1. The consent form would be the only record linking the subject to the research, and a potential sick would be a breach of confidentiality. In such case, it is up to the subject when asked if they want documentation. *(This is not applicable for FDA regulated research)*
	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.
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| 1. If informed consent documentation is waived, should the investigator be required to provide subjects with a written statement regarding the research?
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| 1. If children are included, have the criteria for waiver of parental/guardian consent been met?

 - IRB must determine parental/guardian permission is not a reasonable requirement to protect subjects- Appropriate mechanisms must be implemented to protect children as subjects*(Provisions for waivers of parental permission are not applicable for FDA regulated research)* |  |
| **WAIVER OR MODIFICATION FOR REQUIRED ELEMENTS IN INFORMED CONSENT *(These provisions are Not applicable For FDA regualted research.)*** | **Yes / No / N/A** |
| 1. If waiver or modification to required consent elements proposed, have all the criteria been met?
	1. The research involves no more than minimal risk to the subjects?
	2. The waiver/alternation will not adversely affect the rights and welfare of the subjects.
	3. The research could not practicably be carried out without the waiver or alteration, and
	4. When appropriate, the subject will be provided with pertinent information after participation.
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| **ASSENT FROM CHILDREN** | **Yes / No / N/A** |
| * + - * 1. Is assent required? (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.)
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| * + - * 1. Will assent be documented?
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| * + - * 1. Is the process of obtaining/documenting assent adequate?
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| **CONSENT FOR CHILDREN UNDER THE JURISDICTION OF DEPENDENCY COURT** | **Yes / No / N/A** |
| Has a court order been obtained to allow the child to participate in the research without parental consent? |  |
| Has a court order been obtained to allow the child to participate in the research without parental consent? |  |
| Is the research either related to the children’s status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the children involved as subjects are not wards? |  |
| Has an advocate been appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis? |  |
| **PARENTAL PERMISSION** | **Yes / No / N/A** |
| * + - * 1. Is consent of one parent appropriate?
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| * + - * 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)
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| **CONSEnTING COGNITIVELY IMPAIRED PERSONS** | **Yes / No / N/A** |
| Does the research involve greater than minimal risk? |  |
| If the research involves greater than minimal risk does it present the prospect of direct benefit to the individual subjects? |  |
| 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? |  |
| Is the relation of the anticipated benefit to the risk at least as favorable to the subjects as that presented by available alternative approaches? |  |
| Are there adequate provisions for soliciting the assent of the subject and permission of their legally authorized representative? |  |
| **WAIVER OF INFORMED CONSENT FOR PLANNED EMERGENCY RESEARCH** | **Yes / No / N/A** |
| * + - * 1. Have the criteria for waiver of informed consent for emergency research been met?
	1. The subject must be confronted by a life-threatening situation necessitating the use of the test article.
	2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject.
	3. Time is not sufficient to obtain consent from the subject’s legal representative.
	4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject’s life.
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| **WAIVER OF INFORMED CONSENT FOR PLANNED EMERGENCY ROOM RESEARCH** | **Yes / No / N/A** |
| * + - * 1. Have the criteria for waiver of informed consent for emergency room research been met?
1. The study could not practicably be carried out without the waiver.
2. Consultation with community representatives occurs before the start of the research
3. Public Disclosure is made before and after the study starts
4. A therapeutic window is defined and the researcher commits to trying to locate a surrogate/legally authorized representative who can give consent within the window before proceeding to waive consent.
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***Additional Comments (optional):***