|  |  |
| --- | --- |
| **1. project description and methodology** | **Yes / No / N/A** |
| 1. Are the aims and underlying hypotheses of the research stated clearly?
 |  |
| 1. Does the research use procedures consistent with sound research design?
 |  |
| 1. Does the research design allow the proposed research question to address the proposed study objectives and result in scientifically and statistically valid results?
 |  |
| 1. Does the research contribute to generalizable knowledge?
 |  |
| 1. Is there an adequate justification for involving human subjects?
 |  |
| 1. Is there an adequate explanation of the research issues?
 |  |
| 1. Is there an adequate description of the activities involving human subjects?
 |  |
| 1. Is there a detailed description of the data collection and methods of recording?
 |  |
| 1. Have the questionnaires and interview tools been provided?
 |  |
| 1. Is there an adequate justification for the sample size?
 |  |
| **2. Risk and Benefit Considerations** | **Yes / No / N/A** |
| 1. 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?
 |  |
| 1. Are the risks minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?
 |  |
| 1. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result?
 |  |
| 1. Are the risks to subjects reasonable in relation to the importance of the knowledge that may reasonably be expected to result?
 |  |
| 1. Are both risks and anticipated benefits accurately identified, evaluated, and described?
 |  |
| 1. Have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?
 |  |

|  |  |
| --- | --- |
| **3. selection of subjects** | **Yes / No / N/A** |
| 1. Is the subject selection equitable?
 |  |
| 1. Are the criteria for inclusion/exclusion equitable?
 |  |
| 1. Will the recruitment process alter equitable selection?
 |  |
| 1. Does the nature of the research justify using the proposed subject population?
 |  |
| 1. Are there adequate procedures for identifying those who might be more susceptible to the risks and who therefore ought to be excluded?
 |  |
| 1. Has there been appropriate consideration of any special physiological, psychological, or social characteristics of the subject group that would pose special risks?
 |  |
| 1. 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?
 |  |
| 1. If yes to question 3g, have additional safeguards been included in the study to protect the rights and welfare of these subjects?
 |  |
| 1. If there is a special population (children, prisoners, pregnant women and fetuses), has the appropriate justification been provided?
 |  |
| 1. Is the exclusion of study subjects justified and appropriate?
 |  |
| **4. privacy and confidentiality** | **Yes / No / N/A** |
| 1. Are there adequate provisions to protect the privacy interests of participants?
 |  |
| 1. 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?
 |  |
| 1. If the information obtained about subjects might interest law enforcement or other government agencies, has a certificate of confidentiality been obtained?
 |  |
| 1. Are the investigator's disclosures to subjects about confidentiality adequate?
 |  |
| **5. MONITORING** | **Yes / No / N/A** |
| 1. Does the research plan make adequate provision for monitoring the data collected to ensure the safety of subjects?
 |  |
| 1. Is there documentation indicating appropriate reporting to the IRB in the event that unexpected results are discovered or there are adverse events?
 |  |
| 1. If appropriate has a data safety monitoring committee been established?
 |  |
| 1. If the study is a multi-center study and LINCOLN UNIVERSITY is the coordinating center, is the plan for the management of information that is relevant to the protection of participants, such as reporting of unexpected problems, protocol modifications, and interim results adequate?
 |  |
| 1. If the PI is conducting research at an external site, is their an adequate management and communication plan among the IRBs involved?
 |  |
| **6. INCENTIVES FOR PARTICIPATION** | **Yes / No / N/A** |
| 1. Are the incentives offered reasonable, based upon the complexities and inconveniences of the study and the particular subject population?
 |  |
| 1. Is the compensation or reimbursement appropriately prorated?
 |  |
| **7. CONFLICT OF INTEREST** | **Yes / No / N/A** |
| 1. Is there a conflict of interest that requires management?
 |  |
| **8. informed consent process and content** | **Yes / No / N/A** |
| 1. 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?
 |  |
| 1. Is the language and presentation of the information to be conveyed appropriate to the subject population?
 |  |
| 1. Are the timing of and setting for the explanation of the research and obtaining informed consent conducive to good decision making?
 |  |
| 1. Is it clear who is authorized to obtain informed consent for the study?
 |  |
| 1. Have the informed consent issues for secondary study subjects been addressed?
 |  |
| 1. Will the investigator obtain legally effective informed consent of the participant or the participant’s legally authorized representative?
 |  |
| 1. Will the circumstances of the consent process provide the prospective participant or the representative sufficient opportunity to consider whether to participate?
 |  |
| 1. Will the circumstances of the consent process minimize the possibility of coercion or undue influence?
 |  |
| 1. 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)?
 |  |
| 1. Did the PI report that they plan to enroll non-English speaking subjects?
 |  |
| 1. If yes, did the PI report that they will use the short form?

\*Reminder to IRB staff: PI’s must be notified in IRB correspondence regarding the IRB requirements when using the short form.  |  |
| 1. 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?
 |  |
| 1. 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?
 |  |
| 1. Are subjects informed to take as much time necessary to read the consent form?
 |  |
| 1. 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?
 |  |
| **9. Basic ElementS of Informed COnsent (Required)** | **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.
 |  |
| 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.
 |  |
| **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.
 |  |
| 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?
 |  |
| 1. If FDA Regulated, a statement that the FDA may inspect the records. (Include if the research is subject to FDA regulations)
 |  |
|  y. Are subjects informed to take as much time necessary to read the consent form? |  |
|  z. 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?
 |  |

|  |  |
| --- | --- |
| **10. WAIVER OF INFORMED CONSENT DocumenTATION** | **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.
 |  |
| 1. If informed consent documentation is waived, should the investigator be required to provide subjects with a written statement regarding the research?
 |  |
| 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)* |  |
| **11. 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.
 |  |
| **12. 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.)
 |  |
| 1. Will assent be documented?
 |  |
| 1. Is the process of obtaining/documenting assent adequate?
 |  |

|  |  |
| --- | --- |
| **13. CONSENT FOR CHILDREN UNDER THE JURISDICTION OF DEPENDENCY COURT** | **Yes / No / N/A** |
| 1. Has a court order been obtained to allow the child to participate in the research without parental consent?
 |  |
| 1. 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?
 |  |
| 1. 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?
 |  |
| **14. 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.)
 |  |
| **15. CONSEnTING COGNITIVELY IMPAIRED PERSONS** | **Yes / No / N/A** |
| * + - * 1. Does the research involve greater than minimal risk?
 |  |
| 1. If the research involves greater than minimal risk does it present the prospect of direct benefit to the individual subjects?
 |  |
| 1. 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?
 |  |
| 1. Is the relation of the anticipated benefit to the risk at least as favorable to the subjects as that presented by available alternative approaches?
 |  |
| 1. Are there adequate provisions for soliciting the assent of the subject and permission of their legally authorized representative?
 |  |
| 1. Is the proposed plan for the assessment of the capacity to consent adequate?
 |  |

|  |  |
| --- | --- |
| **16. WAIVER OF INFORMED CONSENT FOR EMERGENCY USE 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.
 |  |
| **17. WAIVER OF INFORMED CONSENT FOR PLANNED EMERGENCY 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.
 |  |
| **18. RESOURCES** | **Yes / No / N/A** |
| 1. Does the IRB have the appropriate expertise to review this research? If no to question , should a consultant be used to assist in the review of the research
 |  |
| 1. Will the Investigator have access to a population that will allow recruitment of the required number of participants?
 |  |
| 1. Will the Investigator have sufficient time to conduct and complete the research?
 |  |
| 1. Will the Investigator have adequate numbers of qualified staff?
 |  |
| 1. Will the Investigator have adequate facilities?
 |  |
| 1. Does the Investigator have an adequate process to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions?
 |  |
| 1. Will the Investigator have adequate medical or psychological services available that participants might require as a consequence of the research, when applicable?
 |  |
| **19.** **INVESTIGATOR ASSURANCE** | **Yes / No / N/A** |
| a. Is the PI the holder of the IND/IDE? |  |
| b. If yes, has the PI assured that they are knowledgeable about additional regulatory requirements of sponsors? |  |
| **20. CONTINUING REVIEW** | **Yes / No / N/A** |
| 1. Does the research require more than annual continuing review? If yes, how often\_\_\_\_\_\_\_\_\_\_\_\_\_?
 |  |
| 1. Should continuing review be conducted under the expedited review process? (Study meets the definition of minimal risk?)
 |  |
| **21. DoD Sponsored Research** | **Yes / No / N/A** |
| **21.1 Informed Consent** |  |
| 1. Will prior consent be provided by the subject\*?

\*For research intended to be beneficial to the subject, the informed consent of a legal representative of the subject is acceptable.\* If the research involves cognitively impaired adults, there must be anticipated direct benefit to the subject\* If the research involves an interventions or interactions with subjects, a waiver of consent or parental permission is prohibited unless a waiver is obtained from the Secretary of Defense. |  |
| **21.2 Protection of Subject Population** |  |
| 1. Does the project involve prisoners of war (e.g. civilian interness, retained persons, lawful and unlawful enemy combatants) as human subjects?

 *“Research supported or conducted by the DoD that affects vulnerable classes of subjects shall meet the additional protections of 45 CFR Part 46, Subparts B,C, and D (reference (f)) (e.g. fetuses, pregnant women, human in vitro fertilization, prisoners, or children)”. (DoDD 3216.02 4.4.1)* |  |
| 1. If the research will involve more than minimal risk to subjects, has a medical monitor (physician, dentist, psychologist, nurse, or other healthcare provider), independent of the study been appointed?

Note: The monitor must be capable of overseeing the progress of research protocols and issues of individual subject/patient management and safety. |  |
| 1. If the project involves military personnel, unit officers, or noncommissioned officers (NCOs), are there provisions to exclude senior officers and NCOs in the chain of command during subject solicitation, consent or recruitment sessions in which members of their units are afforded the opportunity to participate in research?
 |  |
| **21.3 Restricted Use Materials** |  |
| 1. Does the project involve fetal tissue?[[1]](#footnote-1)

In the event that fetal tissue will be used in a DOD funded study numerous additional contingencies apply, contact the IRB. |  |
| 1. Does the research involve testing of chemical or biological reagents on humans?

In the event that chemical or biological reagents will be used in a DOD funded study numerous additional contingencies apply, contact the IRB. |  |
| **21.4 Education** |  |
| 1. All key personnel participating in Human Subjects Research at USC are required to take CITI online Human Subjects training every three years. This is required whether or not the study is DoD funded.
 |  |
| 1. Investigators conducting DoD sponsored research must be familiar with the Nuremberg Code, the Belmont Report, 32 CFR Part 219 (reference (c)), DoDD 3216.02, and any related requirements
 |  |
| **21.5 Required Injury Statement** |  |
| 1. Every research protocol involving greater than minimal risk shall provide an arrangement for emergency treatment and necessary follow-up of any research-related injuries to subjects.

Has an IRB/DoD approved injury statement been included in the informed consent? Does the DoD funding document/research protocol address DoD’s injury statement requirements. |  |
| **21.6 Potential For Undue Influence** |  |
| 1. Investigators should be alert to the potential for undue influence in research with those in employer-employee status, teacher-student, supervisor-subordinate relationships, or deployed active duty personnel.
 |  |
| **21.7 Scientific merit review** |  |
| 1. At ***Lincoln University*** the IRB, IRB chair, and/or IRB consultant shall evaluate the scientific merit of DOD funded studies.
 |  |
| **21.8 Institutional Monitoring** |  |
| 1. DoD funded research shall be subject to post-approval monitoring, periodic assessments by the IRB or OPRS using the existing continuous quality improvement procedures.
 |  |
| **21.9 Non-Compliance/ Misconduct and Unanticipated Problems Involving Risks to Subjects** |  |
| 1. Issues related to non-compliance with DoDD 3216.02 shall be referred initially to the next higher management echelon to take deliberate action to resolve. All findings of serious non compliance shall be reported to the Director, Defense Research Engineering.
 |  |
| 1. The IRB must review and, if appropriate, take action on any allegations of non-compliance with human subject protections and any allegations of research misconduct, and report to DoD as required.
 |  |
| 1. According to the terms of 45 CFR Part 46, DoD and FDA regulation all unanticipated problems involving risks to subjects or others and serious events, as determined by the IRB, must be reported to the appropriate DoD/OHRP/FDA officials.

Significant communication about DoD funded projects reported to other federal departments regarding compliance and oversight must also be reported to DoD officials.  |  |
| * 1. **Multi Site Research**
 |  |
| 1. In multi-site research, a formal agreement between institutions is provided that specifies the roles and responsibilities of each party
 |  |
| **21.11 Compensation** |  |
| 1. Are limitations on dual compensation for US Military personnel addressed?
 |  |
| **21.12 Survey Research** |  |
| 1. Are the requirements for additional review for survey research or survey research within DoD addressed?
 |  |
| **21.13 International Research (DON Sponsored Research)** |  |
| A. If the research involves Human Subjects who are not U.S. citizens or Department of Defense personnel, and is conducted outside the United States, and its territories and possessions: (“N/A” if no category applies)* The permission of the host country has been obtained.
* The laws, customs, and practices of the host country and the United States will be followed.
* An ethics review by the host country, or local Naval IRB with host country representation, will take place.
 |  |
| * 1. **DoD Components**
 |  |
| 1. Support oversight by the sponsoring DoD Component (which may include DoD Component review of the research and site visits)
 |  |

***Additional Comments (optional):***

1. The Department of Defense defines human fetal tissue as “*tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth*” [↑](#footnote-ref-1)