Saint Louis University Institutional Review Board

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| Additional Criteria for Department of Defense (DOD) Research (Check if “Yes” or “N/A”)  *Note: All must be checked for final approval* | |
|  | The protocol has undergone scientific review prior to IRB review and the review was done outside of the IRB.  *Note: The required scientific review does not have to be completed at SLU. The review requirement is satisfied by a number of internal and external review processes including, but not limited to: Departmental review, chair review, college or center level review, and external review (VA, DOD, NIH, etc).* |
|  | The research involves a survey performed on DOD personnel and the PI has received DOD approval. |
|  | The research involves interventions or interactions with research subjects and (MUST check one):  Consent will be obtained prior to research.  The PI is requesting a waiver of consent and has received an approved waiver from the Secretary of Defense. |
|  | The research involves military personnel as research subjects and it is clear that unit officers and senior NCOs in the chain of command will not be present at the time of solicitation and consent during any research recruitment sessions involving members of units under their command. |
|  | Active Duty military personnel will be reimbursed for their participation as subjects in the research and eligibility for payment will be limited in the following way(s):  Subjects will be on leave or off-duty status during participation and will not receive payment from federal funds.  Payment will **only** be providedfor blood donation and will not exceed $50 per blood draw. |
|  | The protocol complies with the DOD component’s requirements for research ethics training.[[1]](#endnote-1) |
|  | The research is greater than minimal risk[[2]](#endnote-2) and the PI has identified an independent research monitor who fulfills all of the following requirements:[[3]](#endnote-3)  Has been appointed by name;  Is a healthcare provider, i.e. physician, dentist, psychologist, nurse, or other provider;  Has expertise relating to the nature of the risk(s) present in the research protocol;  Is independent of the team conducting the research;  Has been provided an IRB approved written summery of duties, authority, and responsibility specific to the research;  Has submitted written confirmation of duties, authority, and responsibilities;  Can and will promptly report observations and findings to the IRB or other appointed official;  Can stop research in progress, remove individuals from the study, and take any necessary steps to protect the safety and well-being of subjects until the IRB can access the monitor’s report. |
|  | Recruitment will be done in a group setting and (MUST check one):  Research greater than minimal risk: An ombudsman not connected in any way with the proposed research or the unit and shall be present during recruitment to monitor that the voluntary nature of individual subjects is adequately stressed and that the information provided about the research is adequate and accurate. The independent research monitor may act as the ombudsman.  Research involving minimal risk: The IRB has discussed and determined whether an ombudsman is necessary, based on the subject population and consent and recruitment processes. |
|  | The research will be conducted outside of the United States, U.S. territories, or possessions, involves human subjects who are not U.S. citizens or personnel of the DOD and complies with all of the following requirements:  Permission of the host country has been obtained;  All laws, customs, and practices of the host country and United States will be followed;  An ethics review by the host country, or a local IRB with host country representation, will take place. |
|  | The protocol and consent form complies with the DOD component’s requirements for “Provisions for Research Related Injury.”[[4]](#endnote-4) |
|  | The protocol is a multisite research study for which a formal agreement been provided, outlining the roles and responsibilities of each participating party, including a Statement of Work (SOW) and specific assignment of responsibilities. |
|  | The research involves classified information and complies with all of the following requirements:  Research approval has been or will be obtained from the Secretary of Defense;  The protocol has been reviewed by the full convened IRB;  The IRB has consulted an expert on classified information;[[5]](#endnote-5)  The IRB determined potential subjects need access to classified information to make an informed consent decision;  The research does not involve a waiver of informed consent and the informed consent process includes the listing of the DOD as a supporting institution of research and a statement that the research is classified and an explanation of the impact of the classification;  The disclosure or use of the classified information complies with federal requirements for access and protection of classified information. |
|  | All IRB members have been informed that they can directly appeal any majority decision approving a project involving classified information. |
| For research involving vulnerable subject populations: | |
|  | The research involves vulnerable subject populations and is in adherence to the DHHS Subparts B, C, and D. |
|  | The research involves pregnant women, human fetuses, and/or neonates and the phrase “biomedical knowledge” has been replaced with “generalizable knowledge.” |
|  | The applicability of Subpart B is limited to research involving pregnant women as subjects in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as subjects. |
|  | The research involves fetal tissue and complies with US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g. |
|  | The research involves prisoners and the protocol has been reviewed by the full convened IRB.  *Note: Research involving prisoners is not eligible for expedited review.* |
|  | The research involves prisoners and at least one prisoner representative was present for quorum during the review by the convened IRB. |
|  | The research is epidemiological and complies with all of the following requirements:  The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease;  The research presents no more than minimal risk; and  The research presents no more than an inconvenience to the subject. |
|  | The research includes a subject that became a prisoner during participation and if the researcher asserts to the IRB that it is in the best interest of the prisoner-subject to continue to participate in the research while a prisoner:  The IRB chair has determined that the prisoner-subject may continue to participate until the convened IRB can review the request to approve a change in the research protocol and until the organizational official and DoD component office review the IRB’s approval to change the research protocol.[[6]](#endnote-6)  The convened IRB, upon receipt of notification that a previously enrolled human subject has become a prisoner, has promptly re-reviewed the research protocol to ensure that the rights and wellbeing of the subject, now a prisoner, are not in jeopardy.  The IRB has consulted with a prisoner representative regarding the request to approve a change in the research protocol.  The convened IRB may approve[[7]](#endnote-7) a change in the study to allow this prisoner-subject to continue to participate in the research if:  The prisoner-subject can continue to consent to participate and is capable of meeting the research protocol requirements;  The terms of the prisoner-subject’s confinement does not inhibit the ethical conduct of the research; and  There are no other significant issues preventing the research involving human subjects from continuing as approved. |
|  | The research does **NOT** involve prisoners of war[[8]](#endnote-8) or detainees[[9]](#endnote-9).  *Note: Research involving prisoners of war or detainees is prohibited.* |
|  | The research involves interventions or interactions with cognitively impaired subjects and is there anticipated direct benefit to the subject.  *Note: The determination that research is intended to be beneficial to the individual subject must be made* *by the full convened IRB.* |
|  | If consent is to be obtained from the experimental subject’s legal representative, the research is intended to directly benefit the individual subject.  *Note: The determination that research is intended to be beneficial to the individual subject must be made* *by the full convened IRB.* |

1. For the Department of the Navy, all research team members and IRB members must complete the [CITI Training + 4 Additional Modules](http://www.med.navy.mil/bumed/humanresearch/Pages/EducationTraining.aspx). [Additional information can be found in the DON Education and Training Policy for Research Ethics and the Responsible Conduct of Research](http://www.onr.navy.mil/en/About-ONR/compliance-protections/Research-Protections/~/media/98B7D1F43E2E4484AEE09D4853A56727.ashx). For other DOD components, the PI should contact their DOD program officer and liaison for specific information about education requirements. [↑](#endnote-ref-1)
2. The definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” must not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life (e.g., soldier in combat zone or chronically ill patient).

   [↑](#endnote-ref-2)
3. If the protocol is a multi-site study, the independent research monitor may be appointed for the overall study. However, they must be able to fulfill all of the above listed requirements at each site and for the overall study. Duties of the monitor are determined on the basis of specific risks or concerns about the research. The monitor may perform oversight functions (e.g., observe recruitment/enrollment/consent process, oversee study interventions/interactions, review monitoring including SAEs/UPs, or oversee data collection and analysis) or may discuss the research with researchers, participants or others outside of the study. [↑](#endnote-ref-3)
4. The PI should work with the DOD Program Officer to identify requirements and inform IRB staff of the DOD component’s requirements for the provision of care in the case of a research-related injury. The PI should include documentation of any additional or stricter requirements in the IRB application. Additional language regarding specific requirements by the DoD should be incorporated into the informed consent document. [↑](#endnote-ref-4)
5. Consult university legal counsel, any subject matter experts in the law school or legal practices, or military consultants. [↑](#endnote-ref-5)
6. Otherwise, the IRB chair must require that all research interactions and interventions with the prisoner-participant (including obtained identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol. [↑](#endnote-ref-6)
7. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants. [↑](#endnote-ref-7)
8. The IRB is aware of the definition of “prisoner of war” for the DoD component granting the addendum. [↑](#endnote-ref-8)
9. This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition. [↑](#endnote-ref-9)