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|  | **IRB INVESTIGATOR/IRB CHECKLIST FOR****Department of Defense (DoD) Research** |
| **Project Title** Enter text. | **IRB#:** Enter text. | **Principal Investigator:** Enter text. |
| **PI/study staff complete this worksheet and upload it in the eIRB study record.** The Emory IRB will rely on the information provided here to conduct a review compliant with DoD regulations. Other special agency requirements may also apply[[1]](#footnote-1). If you have questions, please contact the IRB Director at irb@emory.edu. |

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| Section 1- Ensure that the information below is stated in the protocol/submission as attachments. Check all boxes as applicable.  |
|[ ]  The study PI and research staff have been trained in the additional DoD requirements. [[2]](#endnote-1) Attach documentation with this completed checklist that the initial requirements have been met by all research team members. |
|[ ]  The research does NOT involve Prisoners of war or detainees as subjects.[[3]](#endnote-2) If your research involves these populations, and this is not a treatment study with a drug or device stop when the same product would be available to DOD-affiliated personnel consistent with established medical practice, STOP and contact the IRB at irb@emory.edu.  |
|[ ]  Military personnel will not be paid for research conducted while on duty.[[4]](#endnote-3) |
| Section 2- Check the below boxes as applicable and add this information to the protocol/ICF/submission. If you do not check the following boxes, you are stating that this information does not apply to your protocol. |
|[ ]  For research that involves DOD-affiliated personnel, the key investigator **has received** approval from the DOD-affiliated personnel’s command or DOD Component to conduct the research.  |
|[ ]  For research that takes place on a DOD facility, the key investigator **has received** approval from the command or DOD Component responsible for the facility.  |
| [ ]  | If the research involves DOD-affiliated personnel as subjects, the study PI must receive command or Component approval to execute the research. |
| [ ]  | If the research is subject to Section 980 of Title 10, U.S.C., consent will be obtained unless waived by ASD(R&E).[[5]](#endnote-4) |
| [ ]  | The protocol details that, if the research involves Interventions or Interactions with cognitively impaired subjects, there is anticipated direct benefit to the subject. |
| [ ]  | The protocol explains that military and civilian supervisors, officers, and others in the chain of command will not influence the decisions of their subordinates regarding participation in research if military personnel is enrolled in the study. |
| [ ]  | When a subject is a Service member, all Research Component, and/or National Guard members in a federal duty status are adults. If a Service Member, Research Component, or Guard member in federal duty status, a student at a Service Academy, or trainee is under 18 years of age, the recruitment process and the necessity of including such member as a human subject is considered during IRB review. |
| [ ]  | For more than minimal risk research, the disclosure regarding provisions for research-related injury follows the requirements of the DOD component, and it is detailed in the informed consent document.[[6]](#endnote-5) |
| [ ]  | When conducting multi-site research, a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities.* 1. list the roles and responsibilities of each party at each site participating in the research:
	2. A written agreement must be in place between Emory and the other sites. Do you have an agreement with each site? Choose an item. If not, please explain:
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| [ ]  | Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.[[7]](#endnote-6) |
| [ ]  | If the research involves emergency medicine research, the Secretary of Defense must approve a waiver of the advance informed consent in accordance with provision 10 USC 980. Provide the waiver approval in your submission.  |
| If the research involves Human Subjects who are not U.S. citizens or personnel of the DOD and is conducted outside the United States, its territories, and its possessions: (Check if “Yes”. All must be checked.) Please attach documentation of approval and certification of such compliance with this completed checklist. |
| [ ]  | 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 IRB with host country representation, will take place. |
| If the research involves DOD-affiliated personnel as subjects, the following is required: (Check if “Yes.” Check as applicable): |
| ☐ | If the research includes risks to their fitness for duty (e.g. health, availability to perform a job, data breach), then an informed consent form must inform DOD-affiliated personnel about these risks and that they should see command or Component guidance before participating.  |
| [ ]  | Research involves more than Minimal Risk: The IRB has appointed an ombudsman who does not have a conflict of interest with the research or be a part of the research team and will be present during the recruitment to explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials. The ombudsman should be available to address concerns about participation. Please provide the ombudsman's name and qualifications. |
| ☐ | If the study involves Large-scale genomic data (LSGD) collected from DoD-affiliated personnel (including the secondary uses or sharing of de-identified data or specimens) then the following is required:* The research is subject to DOD Component security review and DOHRP approval.
* The research will apply an HHS Certificate of Confidentiality
* Administrative, technical, and physical safeguards are considered, as the disclosure of the data may pose a risk to national security.
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| Additional Criteria for Department of Defense (DOD) Research Involving Classified Information[[8]](#endnote-7) (Check if “Yes”. If you do not check the following boxes, you are stating that this information does not apply to your protocol) |
| [ ]  | The convened IRB approved the research. (Use of an expedited review procedure is prohibited.) |
| [ ]  | DOHRP approval will be obtained.[[9]](#endnote-8) |
| [ ]  | No DoD agency within the Intelligence Community may sponsor, contract for, or conduct non-exempt HSR except in accordance with Paragraph 2.10 of Executive Order 12333 and DoD 5240.1. |

**NOTE FOR STUDY TEAM AND IRB:**

**Reporting Requirements:** DoD-supported research requires notification to DoD units of serious and/or continuing non-compliance, as well as other events. See Emory IRB Policy & Procedure – Reporting to Governmental Regulatory Authorities for additional information regarding these requirements

**Research Related Injury:** DoD supported research requires the research site to make arrangements for the provision of treatment for research-related injuries and some DoD components require that participants not bear any costs related to such treatment. Researchers should contact their DoD funding unit’s liaison to determine specific requirements. See IRB Policy and Procedure – Informed Consent Policy for additional information regarding research-related injury requirements. Please see Emory Policies and Procedures Chapter 18, and your DoD grant, for further requirements.

**By attaching this form with your submission, you are attesting that you will be complying with the Department of Defense requirements as stated above**

1. Source: Chapter 18, Emory IRB Policies and Procedures. [↑](#footnote-ref-1)
2. In addition to completing the Emory IRB education requirements, conduct initial and continuing research ethics education for personnel who are engaged in human subject research. This training must be completed by all study team members initially and on a continuing basis every three years. Documentation of this completion must be uploaded with the IRB application (or maintained in the research record).

Research under the purview of the Under Secretary of State (Personnel and Readiness): Requires annual training on human subject protections for all investigators and research staff directly involved in human subject research. Be prepared to document how annual human subject protection training is maintained. For other military branches (e.g. Army, Air Force), contact your program officer for specific information about their respective education requirements. [↑](#endnote-ref-1)
3. This includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person, and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes. It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions when the purpose is for diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and only when the same product be available to DOD-affiliated personnel consistent with established medical practice. [↑](#endnote-ref-2)
4. Although federal personnel participating as human subjects in DOD-conducted research while on duty may be compensated up to $50 for each blood draw for scientific and research purposes in connection with the care of any person entitled to treatment at government expense, this IRB allows no such compensation when compensation is otherwise prohibited. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research. [↑](#endnote-ref-3)
5. Section 980 of Title 10, U.S.C. applies to research financed by DOD appropriated funds. The requirement for consent may be waived by the ASD(R&E) if the following three conditions are met: (1) The research is necessary to advance the development of a medical product for the Military Services. (2) The research may directly benefit the individual experimental subject. (3) The research is conducted in compliance with all other applicable laws and regulations. The ASD(R&E) may delegate the waiver authority. [↑](#endnote-ref-4)
6. Research Related Injuries: In greater than minimal risk research, provisions for emergency treatment and necessary follow-up care of any research-related injury is required.

The name of the responsible physician(s), the name of the medical facility to which the subject will be referred, and the plan for follow-up must be

specified in the IRB application.

The arrangements must be clearly described in the consent form. [↑](#endnote-ref-5)
7. See: <http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g> (This is the enabling statute for 45 CFR 46.205. Compliance with Subpart B complies with this statute.) See also: <http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-1>, and <http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-2> [↑](#endnote-ref-6)
8. DOD-supported research is considered classified when:

Classified information is required for IRB review and oversight of the research.

Classified information must be provided to human subjects, or their guardians, during the HSR recruitment or informed consent process in order to achieve fully effective legal consent.

Classified information is provided to, or by, research subjects.

DOD-conducted or -supported research is not considered classified when:

	* The research is a part of a classified program, but the research itself is not classified; if the information required in the research protocol is not classified; if the information needed by the IRB is not classified; or if the information required by the human subject is not classified. For the purposes of the annual report for classified research, unclassified HSR that falls into the criteria listed in this paragraph should be included in the report.Research that requires subjects to hold a clearance as a means of creating ease of entry or access to controlled spaces where the research will occur does not constitute classified HSR unless one of the conditions described in Sections 3.13.b.(1) or (3) also exist.

If the research constitutes an authorized operation activity, then it is not HSR. [↑](#endnote-ref-7)
9. The DOHRP is the final approval authority for all DoD-conducted or DoD-supported **classified** HSR. The SDO prospectively conducting or supporting the HSR must submit a package to the DOHRP for approval to conduct the classified HSR. [↑](#endnote-ref-8)