Reviewer:	Submission ID:
Principal Investigator:	**Protocol #:**

COMIRB DEPARTMENT OF DEFENSE RESEARCH CHECKLIST

Please note that COMIRB has signed the addendum for the Department of Navy only. For DoD research through branches other than the Navy, the component DoD IRB reviews all research after COMIRB approval is obtained, and COMIRB will not be the IRB of record.

Please check whether the following elements are adequately addressed in the materials submitted to the IRB and make comments, if necessary.

	Yes	No	N/A	Comments
I. Does the research involve the Department of Defense in one of the following ways? *(If no, do not complete this checklist)* ☐ The research is funded by a component of DoD[(a)] ☐ The research involves cooperation, collaboration or other type of agreement with a component of DoD. ☐ The research uses property, facilities or assets of a component of DoD. ☐ The subject population will intentionally include personnel (military and/or civilian) from a component of DoD, or data or specimens from DoD personnel.	☐	☐	☐	
II. Does the research qualify for exemption? *(If yes, do not complete the rest of this checklist)*	☐	☐	☐	
III. Human subjects				
Does the subject population involve prisoners of war? *(If yes, the research cannot be approved)*	☐	☐	☐	
Does the subject population involve military personnel?	☐	☐	☐	
Does the intended subject population include women AND minorities? If no, has a waiver been granted by the Secretary of Defense in accordance with Section 2358 note of title 10, USC?	☐	☐	☐	
IV. Procedures				
Does the research involve surveys of DoD personnel (military members, families, and civilian military employees)? If yes, has the survey been approved by the respective DoD component?	☐	☐	☐	

Does the research involve the testing or use of chemical or biological agents[(b)]? If yes, check which of the following apply (MUST check one): ☐ The research is for any peaceful purpose that is related to a medical, therapeutic, pharmaceutical, agricultural, industrial, or research activity. ☐ The research is for any purpose that is directly related to protection against toxic chemicals or biological weapons and agents. ☐ The research is for any law enforcement purpose, including any purpose related to riot control.	☐	☐	☐	
V. Potential risks to subjects				
Does the research present greater than minimal risk to subjects?	☐	☐	☐	
VI. Recruitment methods				
For research enrolling military personnel, are appropriate procedures in place to avoid coercion from unit officers and noncommissioned officers? ☐ Unit officers and senior NCOs in the chain of command shall not be present at the time of research subject solicitation and consent during any research recruitment sessions in which members of units under their command are afforded the opportunity to participate as research subjects. ☐ When applicable, officers and NCOs so excluded shall be afforded the opportunity to participate as research subjects in a separate recruitment session. ☐ During recruitment in group settings, an ombudsperson will be present (required for research involving more than minimal risk, at IRB discretion for minimal risk research). The ombudsperson has been identified by the DoD IRB. The ombudsperson must be present during recruitment in group settings, monitoring that the recruitment and informed consent 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 ombudsperson will be available to address DoD-affiliated personnel's concerns about participation.				
Will U.S. military personnel be reimbursed for their participation as subjects in the research? If yes, check all that apply. Other reimbursement of military personnel is not allowed. ☐ U.S. military personnel will be on leave or off-duty status during participation ☐ Payment to federal employees while on-duty and non-federal employees is for blood draws for research and does not exceed $50 per blood draw. ☐ Non-federal persons are compensated for research participation other than blood draws in a reasonable amount according to local prevailing rates and the nature of the research.	☐	☐	☐	
VII. Informed consent				
For "research involving a human being as an experimental subject" [(c)], informed consent may not be waived or altered except by DOHRP as described below. Will informed consent be obtained from all subjects prior to any research procedures? If no, check which of the following applies (MUST check one): ☐ The requirement for prior informed consent has been waived by the DoD Office for Human Research Protections (DOHRP) for this specific research project (1) to advance the development of a medical product necessary to the DoD, (2) because the research project may directly benefit the individual experimental subject, and (3) the research is conducted in compliance with all other applicable laws and regulations. ☐ The waiver is requested only for the review of subjects' medical records for the purposes of pre-screening or research involving retrospective	☐	☐	☐	

chart reviews. Is documentation of consent waived or the consent altered? ☐ If so, the research poses minimal risk, does not involve a human being as a research subject [(c)], and the consent document indicates the subject's participation in the research is voluntary and informs the subject of the research risks.	☐	☐	☐	
Is consent by LAR, proxy or legal guardian requested? If yes, is there a potential for direct benefit to the individual subjects? *(If no, LAR, proxy or legal guardian consent cannot be approved)*	☐	☐	☐	
If the research poses more than minimal risk, the consent form includes a statement that subjects may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond participants' participation in the study to such time after the study has ended.	☐	☐	☐	
If the research enrolls DoD-affiliated personnel and if the research involves any risks to their fitness for duty (e.g. health, availability to perform job, data breach), the consent form discloses those risks and advises participants to seek command or Component guidance before participating.	☐	☐	☐	
If the research enrolls DoD-affiliated personnel, the consent form includes, <u>if applicable</u>, potential risks for the revocation of clearance, credentials, or other privileged access or duty.	☐	☐	☐	
Does the consent state that representatives of the DoD are authorized to review research records?	☐	☐	☐	
If the research enrolls DoD-affiliated personnel, the provisions for research-related injury follow the requirements of the DoD component.	☐	☐	☐	
The consent form documents how institutions will care for subjects with research-related injuries, including injuries that are a direct result of activities performed by DoD-affiliated personnel.	☐	☐	☐	
VIII. Large-Scale Genomic Data [(d)]				
If the research involves large-scale genomic data from DoD personnel, a Certificate of Confidentiality is	☐	☐	☐	

required and will be obtained.				
If the research involves large-scale genomic data from DoD personnel, the protocol describes administrative, technical, and physical safeguards commensurate with the risk level of the research, including (if applicable), the secondary use or sharing of de-identified data or specimens.	☐	☐	☐	
IX. Acknowledgement				
For initial applications, has the Protocol Application undergone scientific review by an appropriate review committee (grant peer-review, SARC, PI's Department)?	☐	☐	☐	
Have substantive amendments undergone scientific review by undergone scientific review by an appropriate review committee (grant peer-review, SARC, PI's Department)?	☐	☐	☐	
	YES	**NO**	**N/A**	
Dept of Navy (continue only if this research is funded by the DON)	☐	☐	☐	
Secretary of Defense approval is required for any classified human subject research (cannot receive Expedited review).				
Secretary of Navy approval is required for research involving (check which apply): ☐ Waiver of consent ☐ Emergency exception to informed consent ☐ Waive of any of the required human subject protections **Under Secreatry of Navy approval is required for research involving (check which apply):** ☐ Severe or unusual intrusions (physical or psychological), such as conscience-altering drugs or mind control techniques ☐ Prisoners ☐ Potentially or inherently controversial topics (that could attract media or other public attention)	☐	☐	☐	
For research requiring an IND (for drugs) or IDE (for devices), the Navy Surgeon General, a Commander, or a Commanding Officer is the designated IND/IDE Sponsor (not a local investigator).	☐	☐	☐	

(a) DoD Components include the following (Pentagon Website, http://pentagon.afis.osd.mil/dod-components.html, accessed July 13, 2011):

- **United States Deputy Secretary of Defense**
  - Office of the Secretary of Defense
    - Defense Policy Board Advisory Committee
    - Office of Net Assessment
    - Pentagon Force Protection Agency
    - Office of General Counsel
      - Defense Legal Services Agency
    - Office of Inspector General
      - Defense Criminal Investigative Service
  - Under Secretary of Defense for Intelligence
    - Defense Intelligence Agency
    - Defense Security Service
    - Defense Information Systems Agency
    - Counterintelligence Field Activity
    - National Geospatial-Intelligence Agency
    - National Reconnaissance Office
    - National Security Agency
  - Under Secretary of Defense for Policy
    - Defense Security Cooperation Agency
    - Defense Prisoner of War/Missing Personnel Office
  - Under Secretary of Defense for Acquisition, Technology and Logistics
    - Defense Advanced Research Projects Agency
    - Missile Defense Agency
    - Defense Contract Management Agency
    - Defense Logistics Agency
    - Defense Threat Reduction Agency
    - Office of Economic Adjustment
    - Defense Acquisition University
    - Business Transformation Agency
  - Under Secretary of Defense for Personnel and Readiness
    - Defense Commissary Agency
    - Defense Human Resources Activity
    - Department of Defense Education Activity
    - Department of Defense Dependents Schools
    - Tricare Management Activity
    - Uniformed Services University of the Health Sciences
    - Defense Equal Opportunity Management Institute
    - Office of the Chancellor for Education and Professional Development
  - Under Secretary of Defense Comptroller
    - Defense Contract Audit Agency
    - Defense Finance and Accounting Service
  - Assistant Secretary of Defense for Networks and Information Integration
  - Assistant Secretary of Defense for Public Affairs
    - Washington Headquarters Services
- **Military Departments***
  - United States Secretary of the Army
    - Department of the Army including the U.S. Army
  - United States Secretary of the Navy
    - United States Department of the Navy including the U.S. Navy and U.S. Marine Corps
  - United States Secretary of the Air Force
    - Department of the Air Force including the U.S. Air Force
- **Joint Chiefs of Staff**

*The US Coast Guard is under the jurisdiction of the Department of Homeland Security.

(b) ''Chemical agent'' means an agent that, through its chemical properties, produces lethal or other damaging effects on human beings, except that such term does not include riot control agents, chemical herbicides, smoke and other obscuration materials (50 USC 1521).

''Biological agent" means any micro-organism (including bacteria, viruses, fungi, rickettsiac, or protozoa), pathogen, or infectious substance, and any naturally occurring, bioengineered, or synthesized component of any such micro-organism, pathogen, or infectious substance, whatever its origin or method of production, that is capable of causing— (1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (2) deterioration of food, water, equipment, supplies, or materials of any kind; or (3) deleterious alteration of the environment (50 USC 1520a).

(c) Research Involving a Human Being as an Experimental Subject means "An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f)). Research involving a human being as an experimental subject is a subset of research involving human subjects. (DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," April 15, 2020).
(d) Data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc. Research involving LSGD may or may not also constitute HSR. Examples of research involving LSGD includes, but is not limited to, projects that involve generating the whole genome sequence data for more than one gene from more than 1,000 individuals, or analyzing 100 or more genetic variants in more than 1,000 individuals. (DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," April 15, 2020).

Note to coordinators: The following statements must be included in the feedback letter for all DoD research:

1) *DoD may require additional human subject training beyond that required by COMIRB. Researchers and appropriate research staff should plan to take the refresher modules through CITI for this purpose.*

2) *Please submit the approval letter from the DoD component IRB (or HRPP office), when available.*

The following statement must be included in the feedback letter if the research involves collection of large-scale genomic data from DoD-affiliated personnel:

Please note that research involving large-scale genomic data collected from DoD-affiliated personnel is subject to DoD component security review to ensure the adequacy of the proposed administrative, technical and physical safeguards, including the secondary use or sharing of de-identified data or specimens.



_____ _____

Reviewer Signature Date

Signature above verifies this checklist was used in the review of this protocol.