Department of Defense (DoD) Supported Research: Checklist

IRB #:_____ Title of Project:_____

Checklist of requirements for ORI/IRB use to facilitate review of human subject research supported by the DoD.
Instructions: Review and check to indicate criteria have been considered and/or are met for items applicable to the proposed research.

Scientific Review

☐ Scientific review completed by Department Chairperson, Faculty Advisor, or equivalent as documented by Signed Signature Assurance Sheet

☐ Consider scientific integrity of study within the scope of human research protections and ethical principles.

Risk Determination

☐ When making the minimal risk determination, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

Vulnerable Populations

○ Yes ○ No ○ N/A Limitations or Modifications to standard Vulnerable Subject Subpart B, C, & D regulatory requirements provided by the supporting Component are met.

○ Yes ○ No ○ N/A Prisoner research is reviewed by convened IRB.

○ Yes ○ No ○ N/A If study includes active duty or reserve members under the age of 18, the IRB considers if such members are necessary or appropriate to include in proposed research.

International Populations

○ Yes ○ N ○ N/A Knowledge of local context is met by standing or ad hoc IRB member or cultural consultant.

○ Yes ○ N ○ N/A Research is compliant with any local applicable laws, regulations, customs, and required local ethics review as identified by investigator or DoD Component.

Detainees

☐ Detainees are not included as potential subjects, except in cases of investigational drug per FDA regulations.

☐ Not applicable **Humans as Experimental Subjects** [research conducted for the purpose of obtaining data regarding the effect of an **intervention or interaction** (includes planned emergency research)]

☐ Informed Consent is obtained.

☐ If consent is likely to be obtained from Legally Authorized Representative, research must offer potential benefit to study subject.

Armed Services personnel, Military or Civilian DoD Employees

○ Yes ○ No ○ N/A If study is a clinical investigation including Armed Services personnel, women and minorities are included as subjects.

○ Yes ○ No ○ N/A Research with DoD personnel (military or civilian DoD employees) includes a recruitment plan

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that ensures no undue influence from superiors in the chain of command.

○ Yes ○ No ○ N/A When required by DoD Component, PI has obtained local command permission for subjects to participate on and/or off duty in research that could impact his/her military duties.

○ Yes ○ No ○ N/A Recruitment of DoD/military personnel (and/or informed consent) occurring in a group setting for a greater than minimal risks study will be monitored to ensure voluntariness which cannot include participant's supervisor.

○ Yes ○ No ○ N/A If civilian DoD employees will be recruited (and/or consented) in a group setting for a greater than minimal risks study the IRB assigns an ombudsperson to ensure voluntariness and address participant concerns. The ombudsperson is unaffiliated from the research.

Compensation for DoD personnel [active duty military or civilian DoD employees]

○ Yes ○ No ○ N/A

On Duty: Compensation limited to blood draws

- May participate in research during work or duty hours with supervisor approval and no compensation other than $50 per blood draw
- Compensation can be from Federal or non-Federal source

○ Yes ○ No ○ N/A

Off Duty:
No restrictions as long as the source of compensation is not Federal dollars, but compensation for up to $50 per blood draw can be a from a Federal source

☐ Not applicable **Waiver of Informed Consent Considerations/Limitations**

☐ Unless granted by the Secretary of Defense, waiver of informed consent is prohibited in Research involving Humans as Experimental Subjects. Research Involving Humans as Experimental Subjects is defined as *research involving intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.*

☐ Waiver of informed consent is also prohibited in "Classified Research".

☐ Exception from informed consent in Planned Emergency Research is prohibited unless the DoD has issued a waiver.

☐ Waiver of informed consent may be considered if research is exempt; or research is minimal risk, and does NOT involve Research with Humans as Experimental Subjects. For example, the IRB may consider a request for waiving informed consent for a retrospective study of existing data, documents, or records. The IRB applies standard waiver criteria.

☐ Not applicable **Classified Research**-Research involving classified information requires prior approval from the Secretary of Defense.

☐ Research involving classified information includes description of information and implications in informed consent.

☐ Classified research is reviewed by convened IRB.

☐ Not applicable **Note: DoD Component (Air Force, Army, Navy, etc) may have additional requirements** [It is the Principal Investigator's responsibility to share any Component requirements with ORI/IRB]

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Source: Department of Defense Instruction 3216.02, Protection of Human subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research, April 15, 2020
Updated 8-3-2020