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 (Form Z)
- **☐** Consider scientific integrity of study within the scope of human research protections and ethical principles.

### Research Monitor for Greater than Minimal Risk Research

- **☐** Not required: Study does not involve greater than minimal risk or requirement waived by DoD Component.

**If greater than Minimal Risk Research:**

- **☐** independent research monitor(s) approved by name to have required expertise and credentials relative to the nature and disciplinary focus of the study.
- **☐** proposed summary of monitor’s duties, authorities, and responsibilities appropriate for proposed research
- **☐** monitor(s) given authority to:
  - Stop a research study in progress;
  - Observe subject recruitment when conducted in a group setting;
  - Remove individuals from the study;
  - Take any steps to protect the safety and well-being of subjects until the IRB can make an assessment

### Vulnerable Populations

- **☐** Limitations or Modifications to standard Subpart B, C, & D regulatory requirements provided by the supporting Component are met.
- **☐** Prisoner research is reviewed by convened IRB.
- **☐** 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

- **☐** Knowledge of local context is met by standing or ad hoc IRB member or cultural consultant.
- **☐** 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.

### 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

- If study is a clinical investigation including Armed Services personnel, women and minorities are included as subjects. □ N/A
- Research with DoD personnel (military or civilian DoD employees) includes a recruitment plan that incorporates safeguards to minimize undue influence from superiors in the chain of command. □ 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. □ 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. □ 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 considers if a monitor should be present to ensure voluntariness. □ N/A

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

- 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 □ 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 from a Federal source □ N/A

### 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. □ N/A
- Waiver of informed consent is also prohibited in “Classified Research”. □ N/A
- Exception from informed consent in Planned Emergency Research is prohibited unless the DoD has issued a waiver. □ N/A
- 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 would apply standard waiver criteria [DoD 32 CFR 219.116(d)] addressed on the Request for Waiver of Informed Consent Process form. □ N/A

### Classified Research-Research involving classified information requires prior approval from the Secretary of Defense. □ N/A

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

### Classified research is reviewed by convened IRB.

**Note:** DoD Component (Army, Navy, etc) may have additional requirements [It is the Principal Investigator's responsibility to share any Component requirements with ORI/IRB] □ N/A