Department of Defense (DoD) IRB Reviewer Checklist

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

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

☐ 2) 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

1) Limitations or Modifications to standard Vulnerable Subject Subpart B, C, & D regulatory requirements provided by the supporting Component are met.

☐ Yes  ☐ No  ☐ N/A

2) Prisoner research is reviewed by convened IRB.

☐ Yes  ☐ No  ☐ N/A
3) 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.

- Yes
- No
- N/A

INTERNATIONAL POPULATIONS

1) Knowledge of local context is met by standing or ad hoc IRB member or cultural consultant.

- Yes
- No
- N/A

2) Research is compliant with any local applicable laws, regulations, customs, and required local ethics review as identified by investigator or DoD Component.

- Yes
- No
- N/A

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)

- Not Applicable
- 1) Informed Consent is obtained.
- 2) 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

1) If study is a clinical investigation including Armed Services personnel, women and minorities are
2) 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.

- Yes
- No
- N/A

3) 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

4) 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.

- Yes
- No
- N/A

5) 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.

- Yes
- No
- N/A

**COMPENSATION FOR DoD PERSONNEL [active duty military or civilian DoD employees]**

**On Duty:**
- 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 from a Federal source.

- Yes
- No
- N/A

WAIVER OF INFORMED CONSENT CONSIDERATIONS/LIMITATIONS

* 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 [NIH Glossary (https://www.ncbi.nlm.nih.gov/books/NBK236819/#gloss1)].

1) Unless granted by the Secretary of Defense, waiver of informed consent is prohibited in Research involving Humans as Experimental Subjects*.

- Yes
- No
- N/A

2) Waiver of informed consent is also prohibited in “Classified Research”.

- Yes
- No
- N/A

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

- Yes
- No
- N/A

4) 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.

- Yes
- No
- N/A

CLASSIFIED RESEARCH [Research involving classified information requires prior approval from the Secretary of Defense]
1) Research involving classified information includes description of information and implications in informed consent.

2) 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]

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
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