**Duke University Health System Institutional Review Board**

**Checklist for Research Funded by the Department of Defense (DOD)**

**6/17/2024**

**IRB Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Submission: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Completed By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**For New Studies and Renewals**

**1. Is the research classified?**

No

Yes. If yes, have the following required conditions been met (both required):

Prior approval from the Secretary of Defense

Full board review (may not be expedited)

**2. Has the study undergone scientific review?**

Yes. Please specify: CRU Review;  Specialty Committee Review;  IRB review process; Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No. If no, this requires a modification. Scientific review must be performed prior to final IRB approval.

**3. Does the investigator plan to obtain consent using a legally authorized representative?**

No

Yes. If yes, the following conditions must be met (both required):

There is the prospect of direct benefit.

*State the benefit*:

The subject lacks capacity, due to age, condition, or other reason, to make a decision regarding consent to participate in the research.

*State the reason(s) for lack of capacity*:

**4. Does the investigator propose waiving consent to perform the research?**

No

Yes. If yes, the following conditions must be met (both required):

There is the prospect of direct benefit.

The requirement for informed consent has been waived by the Head of the DOD Component involved in the research.

**5. Consent documents must include:**

* A statement that the DOD or a DOD organization is funding the study
* A statement that representatives of the DOD are authorized to review research records

Are both of these statements included in the consent document?

Yes

No. If no, please require a modification.

**6. Does the study involve DOD-affiliated personnel (e.g., Service Members, Reserve Service Members, National Guard Members, DOD Civilians, DOD Contractors) as research subjects?**

No

Yes. If yes, the following conditions all must be met:

Officers are not permitted to influence the decision of subordinates

Officers and senior non-commissioned officers (NCOs) may not be present at the time of recruitment or during the consent process

If applicable, officers and senior NCOs have a separate opportunity to participate

The consent document must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty

For research involving recruitment of DOD-affiliated personnel in research determined greater than minimal risk, and when recruitment occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:

* + Must not have a conflict of interest with the research or be a part of the research team
  + Must be present during the recruitment, 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
  + Should be available to address DOD-affiliated personnel’s concerns about participation If recruitment involves a percentage of a unit, an independent ombudsman is present

**7. Compensation Limitations**

* An individual may not receive pay from more than one position for more than 40 hours of work in one calendar week. (This is a limitation on dual compensation.)
* Individuals may receive compensation for research activities if the research activities take place outside of scheduled work hours.
* Federal employees (US Military personnel) 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 participation other than blood draws in a reasonable amount approved by the IRB according to local prevailing rates and the nature of the research.

Have the four conditions above been satisfied?

No. If no, require a modification

Yes

**8. Does the study involve Prisoners of War?**

Research involving a detainee or a prisoner of war as a human subject is prohibited. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions of Title 21, CFR, when the purpose is for diagnosis or treatment of a medical condition in a patient. Such treatment may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to Title 21, CFR, and only when the same product may be available to DOD-affiliated personnel consistent with established medical practices. A prisoner of war is any person captured, detained, held, or otherwise under the control of Department of Defense personnel (military and civilian, or contractor employee) except DOD personnel held for law enforcement purposes.

No

Yes. If yes, the study is not approvable. The involvement of prisoners of war as human subjects of research is prohibited.

**9. Does the study involve international research?**

No

Yes.

If yes, the study submission must include local IRB/ethics committee approval and documentation that permission of the host country has been obtained and that the laws, customs, and practices of the host country will be followed.

Included Still Needed - this requires a modification.

**10. Does the study involve research on chemical or biological weapons?**

No

Yes. If yes, the study is not approvable, subject to certain exceptions for prophylactic, protective, or other peaceful research. See 50 U.S.C. 1520a (reference (g)).

**11. Is this collaborative multi-site research?**

No

Yes. If yes, is there documentation that DUHS ORC/ORA have satisfied the Statement of Work requirements?

**12. Large Scale Genomic Data (LSGD):** Data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc.

When research involves large scale genomic data (LSGD) collected on DOD-affiliated personnel, additional protections are required:

* Additional administrative, technical, and physical safeguards to prevent disclosure of DOD affiliated personnel’s genomic data commensurate with risk (including secondary use or sharing of de-identified data or specimens)
* The study team will apply for an HHS Certificate of Confidentiality
* The research is subject to DOD Component security review and approval

**Have all three conditions above been satisfied?**

No. If no, require a modification

Yes

**13. DOD Human Research Protection Officer**

At initial review please confirm via a modification:

* the PI will notify their DOD Human Research Protection Officer before the study begins, and
* the PI will check with their DOD Human Research Protection Officer to find out if there are any additional education requirements for the PI/study team to complete.

Yes - modification will be requested

No - this was completed during initial review

**14. Is the study funded by the Department of the Navy? (**Reference: SECNAV INSTRUCTION 3900.39D and 3900.39E)

No

Yes. a. Does the study involve surveys performed on DOD personnel?

No

Yes. If yes, DOD approval is required after IRB approval and before study activation.

b. Does the data and safety monitoring plan include notifying the Department of Navy Human Research Protection Program of Serious Adverse Events?

Yes

No. Modifications required to add this.

c. Does the study involve a test article for which there is an IND or IDE?

No

Yes. If Yes,

Is there an appropriate sponsor of the IND?

Yes  No

For studies funded by the Dept. of Navy, only the Surgeon General of the Navy, Commanders, and Commanding Officers may be designated as sponsors for INDs and IDEs. Investigators may not be designated as sponsors for INDs and IDEs.

**For Department of Navy renewals:**

Have any of the following occurred?

Suspensions or terminations of previously approved research

Investigations of alleged non-compliance with human subject protections

Unanticipated problems involving risks to subjects or others (UPIRTSO)

Serious Adverse Events

Audits, investigations or inspections of DON-supported research protocols

*If yes to any of the above, these must be reported to the DON Human Research Protection Program. Please notify [the IRB Executive Director and IRB Compliance] for reporting.*

**Go to next page for the Amendment Checklist.**

**For Amendments:**

**1. Is DOD funding being added or modified?**

No. Continue to #2 below.

Yes. Complete checklist above as if this were a new study.

**2. Is this a substantive amendment (one that involves more than minimal risk and thus requires full board review)?**

No

Yes. If yes, has the amendment undergone scientific review, either through CRU review, specialty committee review, or the IRB review process?

Yes. Please specify:

No. If no, this requires a modification. Scientific review must be performed prior to final IRB approval.

**3. Does the amendment increase the risks so that a previously minimal risk study is now greater than minimal risk?**

No

Yes. If Yes, has this amendment been reviewed at convened board?

Yes

No.

**4. Does the amendment add obtaining consent by using a legally authorized representative?**

No

Yes. If yes, the following condition must be met:

There is the prospect of direct benefit.

*State the benefit*:

The subject lacks capacity, due to age, condition, or other reason, to make a decision regarding consent to participate in the research.

*State the reason(s) for lack of capacity*:

**5. Does the amendment involve waiving consent to perform the research?**

No

Yes. If yes, the following conditions must be met:

There is the prospect of direct benefit.

The requirement for informed consent has been waived by the Head of the DOD Component involved in the research.

**6. Does the amendment add an IND or IDE?**

No

Yes. If yes,

Is there an appropriate sponsor of the IND?

Yes  No

For studies funded by the Dept. of Navy, only the Surgeon General of the Navy, Commanders, and Commanding Officers may be designated as sponsors for INDs and IDEs. Investigators may not be designated as sponsors for INDs and IDEs.

**7. Does the amendment add international research sites?**

No

Yes. If yes,

If yes, the study submission must include local IRB/ethics committee approval and documentation that permission of the host country has been obtained and that the laws, customs, and practices of the host country will be followed.

Included Still Needed - this requires a modification.

**Go to next page for the UPIRTSO Checklist.**

**For UPIRTSO**

**Does this represent serious or continuing noncompliance?**

No

Yes. If yes, please notify [IRB Executive Director and IRB Compliance] for reporting to the Director, Defense Research and Engineering.

**If funded by the Department of Navy, this must also be reported to the DON HRPP Office.**

See below for additional reporting for Department of Navy studies.

The event involves suspension or termination of previously approved DON-supported research.

This event represents an unanticipated problem involving risks to subjects or others (UPIRTSO) or is a Serious Adverse Event.

The event involves an audit, investigation or inspection of DON-supported research, including audits conducted by outside agencies (e.g., FDA or OHRP).

If any of the above are checked, please notify [IRB Executive Director and IRB Compliance] for reporting to DON HRPP Office.

Previous Version Dates: 6/3/2011, 7/1/2012, 3/1/2016