**Duke University Health System Institutional Review Board**

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

**3/01/2016**

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

**Completed By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**For New Studies and Renewals**

**1. Is the research classified?**

No

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

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 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*:

**4. Does the investigator propose 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.

**5. Does the study involve US Military personnel?**

No

Yes. If yes, the following conditions 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

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

If recruitment involves a percentage of a unit, an independent ombudsman is present

Compensation is not offered for research during duty hours

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

No

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

**7. 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.

**8. 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)).

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

No

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

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

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] for reporting.*

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

**For Amendments:**

**1. 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.

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

No

Yes. If Yes, does the amendment include the addition of an independent medical monitor?

Yes

No. If No, this requires a modification.

For research involving more than minimal risk, an independent medical monitor shall be appointed by name. Medical monitors shall be physicians, dentists, psychologists, nurses, or other healthcare providers capable of overseeing the progress of research protocols, especially issues of individual subject/patient management and safety. Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of a research project: subject recruitment, subject enrollment, data collection, or data storage and analysis. At the discretion of the IRB, the medical monitor may be assigned to discuss research progress with the principal investigator, interview subjects, consult on individual cases, or evaluate adverse event reports. Medical monitors shall promptly report discrepancies or problems to the IRB. They shall have the authority to stop a research study in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB can assess the medical monitor's report.

**3. 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*:

**4. 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.

**5. 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.

**6. 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.

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**For UPIRTSO**

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

No

Yes. If yes, please notify [IRB Executive Director] 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] for reporting to DON HRPP Office.

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