**RQ-2: IRB reviewer and OHR checklist for research sponsored entirely or partially by the Department of Defense (DoD)**

Research sponsored or funded by the DoD must be reviewed by the IRB under an additional set of regulations found at 32 CFR 219 and in DoD Instruction 3216.02 accessible at the following web address <http://dtic.mil/whs/directives/corres/pdf/321602p.pdf>. The research must meet these additional DoD requirements prior to initiation of the research.

1. Scientific merit of study.

Does the OHR-2, Part A, 1-6 provide sufficient information regarding study design and statistical analysis to assess scientific merit?

YES NO

If no, reviewer comments will be forwarded to the investigator as per OHR policy.

2. With respect to scientific merit should the opinion of an outside expert be sought?

YES NO

3. Is the proposed research being conducted internationally?

YES NO

OHR - The proposal must include copies of the permissions (i.e., Ethics Committee or other approvals), certifications and other documents from the specified country or countries.

The researcher must specify s/he will follow all local laws, regulations, customs, and practices pertinent to conducting research in the specified country or countries.

4. Does the research involve surveys done on DoD personnel?

YES NO

OHR - Surveys must be approved by the DoD after local IRB approval.

5. Is the research multisite?

YES NO

OHR - Formal agreements defining roles and responsibilities of the parties must be in place.

6. Is the research greater than minimal risk?

YES NO

OHR – For greater than minimal risk studies there is a requirement for appointment of an independent study monitor who has the authority to stop the research, remove individuals from the study or take steps to protect the safety and well-being of subjects until assessed by the IRB.

7. Will Service members be recruited for the study?

YES NO

OHR - Officers are not permitted to influence decisions of their subordinates

Officers and senior non-commissioned officers may not be present at the time of recruitment

Officers and senior non-commissioned officers must have a separate opportunity to participate

8. Will service members be compensated for participation?

YES NO

OHR - Service members may not be compensated for research during duty hours.

Federal employees while on duty and non-federal persons may be compensated up to $50 for each blood draw.

Non-federal persons may be reasonably compensated as approved by the IRB.

9. Are potential enrollees experimental subjects as defined by the DoD (i.e., undergoing interactions or interventions for research purposes)?

YES NO

OHR - Disclosure for research-related injury must follow DoD requirements.

If waiver of consent process is proposed the Assistant Secretary of DoD for Research and Engineering must approve the waiver.

The IRB may waive the consent process for subjects who are not “experimental subjects”

10. Will consent be obtained from a subjects’ legally authorized representative?

YES NO

OHR – Research must intend to benefit the individual subject.

11. Is research classified (a government body has determined that aspects of the research are sensitive or secret with respect to national security)?

YES NO

OHR - If yes, consent may not be waived

12. Will research be done on pregnant women or fetuses?

YES NO

OHR - OHR-27 must be provided (Subpart B).

13. Will research be conducted on prisoners?

YES NO

OHR - IRB Reviewer Questionnaire C-1 (Subpart C) must be provided.

Prisoner advocate must be present at the IRB meeting.

Research on prisoners of war is not permitted.

14. Does research involve children?

YES NO

OHR - OHR-26 must be provided (Subpart D).

15. Does research involve fetal tissue?

YES NO

OHR – Fetal research must comply with 42 USC § 289g (2011) §289g. Fetal research

(a) Conduct or support by Secretary; restrictions: The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

16. Does the research fall under the exception from consent in emergency medicine research?

YES NO

OHR – Waiver from the Secretary of DoD must be provided.