Checklist for RSRB Review of Research Supported by the DoD Sample Template

Checklist for RSRB Review of Research Supported by the Department of Defense

Consistent with OHSP Policy 609 Research Supported by the Department of Defense, the following checklist will be used by the RSRB to ensure compliance with DoD regulatory requirements when reviewing research supported by DoD, or research that recruits DoD personnel.

Additional Criteria for DoD Research (Check if **"Yes"** or **"N/A"**. All must be checked)

☐	The investigator and research staff are aware of the specific DoD requirements and have been educated about these requirements. **The following language is included in the initial approval letter (should be placed after the OHSP requirements in the letter):** "As the Principal Investigator on a Department of Defense supported research study, you are responsible for ensuring compliance with DoD regulatory requirements in addition to your responsibilities for reporting to UR RSRB as listed above and adherence to the University and OHSP policies and guidelines applicable to the conduct of human subject research. You are responsible for notifying the DoD's Component Office of Human Research Protection (COHRP), within 30 days of the following, for non-exempt research, when: • The RSRB has approved the research protocol and before the activities involving human subjects can begin (e.g., human subject recruitment and data collection), the COHRP must perform an administrative review of the research known as a Component Level Administration Review (CLAR); see section 5.3 of Policy 609 for when a CLAR review must be conducted. • Significant changes to the research protocol are approved by the RSRB. • The RSRB completes a continuing review. • There is any change in the IRB of record. • Any component of the DoD-funded study is investigated by any federal department body, state agency, the official governing body of a Native American or Alaskan native tribe, other entity, or foreign government. • Any problem involving risks to participants or others, suspensions or termination of IRB approval, or any serious or continuing non-compliance • Any unanticipated problems involving risks to participants or others and any subsequent action taken based on the findings • Change in status when a previously enrolled participant becomes pregnant, or when the researcher learns that a previously enrolled participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46, Subpart B • Change in status when a previously enrolled participant becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with 32 CFR 219, Subpart C • Closure of a DoD-supported study."
☐	The review has considered the scientific merit of the research (ensure scientific review is conducted according to Policy 505 Scientific Review Standards, including for modifications with substantive revisions).
☐	The review should confirm that Civilian Investigators seeking to recruit military subjects are collaborating with a military researcher familiar with service-specific requirements.
☐	The research does **NOT** involve prisoners of war as subjects.

☐	The research does **NOT** involve the creation of a human embryo or embryos for research purposes, including gene editing research.
☐	The research does **NOT** involve research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of suffering, injury, or death greater than that allowed for research on fetuses in utero in accordance with Section 46.204(b) of Title 45, CFR, and Section 289g(b) of Title 42, U.S.C.
☐	The research does **NOT** involve the testing of chemical or biological agents.
☐	Only permit consent to be obtained from a legally authorized representative when the research will benefit the subject.
☐	Additional protections are in place to minimize undue influence when military personnel are included in the research. See Section 7.4 of Policy 609 Research Supported by DoD for examples of protections, such as: If the research involves DoD-affiliated personnel, the researcher must receive Command or Component approval to conduct the research. When recruitment involves a percentage of a unit, an independent ombudsperson must be present. If any potential military subject is under 18 years of age, carefully consider the research's recruitment process and the necessity of including them. There are additional requirements for supervisors/officers approval.
☐	When conducting international research, the researcher must obtain permission to conduct the research by certification or local ethics review and provide assurance that the proposed project will follow all local laws, regulations, customs, and practices, as per the *Guideline for Conducting International Research*.
☐	For **greater than minimal risk research** involving DoD personnel when recruitment and consent occur in a group setting, the Reviewing IRB will appoint an ombudsperson, based on the recommendation of the PI (see section 5.8 of Policy 609 for ombudsperson requirements).
☐	For **minimal risk research**: level of risk should consider inherent occupational risks that certain participants face in their everyday life (e.g., service members). See section 6.1.7 of Policy 609.
☐	RSRB may waive or alter some elements of informed consent so long as it preserves the informed consent of the participant (i.e., the consent indicates that participation is voluntary, and the participant/representative is informed of research risks); informed consent must be obtained prior to any research activity. DoD Office for Human Research Protections (DOHRP) may waive the requirements for *prospective* consent for research when all the following are met: ○ The research is necessary to advance the development of a medical product for the Military Services. ○ The research may directly benefit the individual experimental subject. ○ The research complies with all other applicable laws and regulations. ○ If the research subject does not meet the definition of "experimental subject," the RSRB may waive the consent process without approval from the DOHRP.

☐	Limit payment/dual compensation for participation: • Prohibit payment for research conducted during duty hours. • Only pay for research if the subject is involved in the research when not on duty, provided payment does not conflict with prohibitions about dual compensation or other prohibitions in federal law. • Federal employees 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 as approved by the Reviewing IRB according to local prevailing rates and the nature of the research.
☐	Investigators are required to submit any surveys to be completed by DoD personnel to the DoD Information Management Control Officer (IMCO) for review and approval after the research protocol is reviewed and approved by the Reviewing IRB, and before any recruitment of subjects. When a survey crosses DoD components, additional review is required.
☐	Research involving Large-Scale Genomic Data (LSGD) collected on/from DoD-affiliated personnel will apply for a DHHS Certificate of Confidentiality (CoC); will require DoD administrative and DoD Component security reviews before research may begin and may be subject to additional requirements (see section 6.6 of Policy 609).
☐	For DoD research involving vulnerable populations, refer to section 7 of Policy 609.
Consent Form Requirements	
☐	The consent includes a statement that the DoD or DoD organization is funding the study.
☐	The consent includes a statement that representatives of the DoD are authorized to review research records.
☐	The consent includes a statement that DoD-affiliated personnel should seek command or component guidance before participating in research that involves risks to their fitness for duty (e.g., health, availability to perform job, data breach).
☐	The consent includes a statement of potential risks, if applicable, for the revocation of clearance, credentials, or other privileged access or duty.
☐	For research involving **Greater than Minimal Risk,** the consent form includes the provision for research-related injury, which is consistent with 32 CFR 219.116. See 6.1.8 of Policy 609.
☐	Prohibit the exception from consent in emergency medicine research, unless a waiver of advanced informed consent is obtained from the Secretary of Defense.
☐	Prohibit waivers of consent for DoD classified research.