DOD and Human Subjects Research Review Board (HSRRB) Unique Requirements

10 United States Code 980

Before writing a research protocol, investigators must consider the requirements of Title 10 United States Code 980, which are applicable to DOD sponsored research. Title 10 United States Code 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless- (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

Furthermore and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained prior to the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in a DOD sponsored experiment unless the research is intended to benefit each subject enrolled in the study.

Recruitment Issues/Ombudsman

Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator who will be familiar with service specific requirements.

A letter of support from the Commander of military facilities or units in which recruitment will occur or the study will be conducted will be requested. Some sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies. The Army, Navy (to include Marine populations) and Air Force all have specific requirements for human research. There may be additional service specific approvals required. For example, there is an approval process to conduct survey research within a specific service or across all three services. Review by an IRB within the service may be required in addition to the PI's institution.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command should not be involved in the recruitment of military personnel and should not encourage or order soldiers to participate in a research study. Per DOD Directive 3216.2, an ombudsman should be employed when conducting group briefings with Active Duty personnel to ensure that volunteers understand that participation is voluntary and may be recommended in other situations as well, especially when young enlisted soldiers are recruited who are trained to follow orders. Soldiers are trained to act as a unit, so peer pressure should also be considered and minimized if possible.

Payment to Military Personnel

Under 24 USC 30, payment to Active Duty military personnel for participation in research is limited to blood donation and may not exceed $50 per blood draw. Active Duty research volunteers may not receive any other payment for participation in a research study, unless they are on leave status during study participation.

Confidentiality for Military Personnel

Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties or discharge. Information regarding alcohol or drug abuse, drunk driving, sexual or spousal abuse and sexual orientation can lead to actions under the Military Code of Justice including incarceration and dishonorable discharge. For aviators, loosing flight status due to a physical or psychological concern is an issue. For military volunteers, the consent form must contain a statement that complete confidentiality cannot be guaranteed because information bearing on a soldier's health may be required to be reported to appropriate medical or command authorities.

Medical Monitor Requirement

Per DOD Directive 3216.2, all greater than minimal risk studies require a medical monitor. The name of the medical monitor must be included in the protocol and curriculum vitae must be provided. Note that the DOD definition of a medical monitor differs from the industry definition.

This individual should be a qualified physician, other than the Principal Investigator, not associated with the protocol, able to provide medical care to research volunteers for conditions that may arise during the conduct of the study, and who will monitor the volunteers during the conduct of the study. In some studies it may be acceptable to have a qualified health care provider other than a physician serve as medical monitor, depending upon the type of risk that might occur in the study (e.g. a clinical psychologist). The medical monitor plays a role in reviewing serious adverse events and unanticipated problems (see below).

Reporting of Adverse Events and Unanticipated Problems

The protocol must describe the procedures for reporting of adverse events and unanticipated problems. The HSRRB reporting requirements must be included:

All protocols should contain the following language (Note that unanticipated problems can occur in a study that does not require a research/clinical intervention):

"Unanticipated problems involving risk to volunteers or others, serious adverse events related to participation in the study and all volunteer deaths should be promptly reported by phone (301-619-2165), by email (hsrrb@amedd.army.mil), or by facsimile (301-619-

7803) to the U S Army Medical Research and Materiel Command's Human Subjects Research Review Board. A complete written report should follow the initial notification. In addition to the methods above, the complete report can be sent to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZB-P, 504 Scott Street, Fort Detrick, Maryland 21702-5012."

For protocols that have a medical monitor assigned, the following language should also be included:

"The medical monitor is required to review all unanticipated problems involving risk to volunteers or others, serious adverse events and all volunteer deaths associated with the protocol and provide an unbiased written report of the event. At a minimum, the medical monitor should comment on the outcomes of the event or problem, and in the case of a serious adverse event or death, comment on the relationship to participation in the study. The medical monitor should also indicate whether he/she concurs with the details of the report provided by the study investigator. Reports for events determined by either the investigator or medical monitor to be possibly or definitely related to participation and reports of events resulting in death should be promptly forwarded to the HSRRB."

Protocol Modifications

As a second level review Board, the HSRRB continues to monitor protocols after the initial approval notification. All modifications to the protocol, consent form and/or questionnaires must be submitted to the HSRRB for review and approval prior to implementation. A list of proposed modifications or amendments to the protocol and an explanation of the need for these modifications should be submitted. The level of review required for approval depends on the nature of the modifications.

Include a statement in the protocol that describes the procedures for modifications to the protocol. This should include approval of the local IRB and HSRRB prior to implementation of the modification. (Note that the requirements are slightly different for USAMRMC intramural laboratories. Intramural investigators should contact their local HUC/HURC for assistance with these requirements).

Protocol Deviations

Include a statement in the protocol that describes the procedures for reporting deviations from the protocol. This should include the procedures for reporting deviations to the local IRB and HSRRB. Any deviations that fit the category of "unanticipated problems involving risks to volunteers or others" should be promptly reported. The HSRRB only requires that deviations that involve risk to volunteers or affect the scientific integrity of the study be promptly reported.

Review of Research Records

Include a statement in the protocol and consent form that representatives of the U S Army Medical Research and Materiel Command (USAMRMC) are authorized to review research records as part of their responsibility to protect human research volunteers. In the event that a HIPAA authorization is required, include the representatives of USAMRMC as one of the parties to whom private health information may be disclosed.

Medical Care for Research Related Injury

The Common Rule requires that for greater than minimal risk research, volunteers be informed what medical care is available in the event of a research related injury and who will be responsible for covering the cost of any such injury. The USAMRMC can commit to providing treatment to research volunteers free of charge in an Army medical facility, therefore the HSRRB requires that the following language be included in consent forms for greater than minimal risk studies as a supplement to any standard institutional language.

"If you are hurt or get sick because of this research study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk to the principal investigator for this study, (name and telephone number of principal investigator). If you pay out-of-pocket for medical care elsewhere for injuries caused by this research study, contact the principal investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221."

Certain military or VA sites may have specific language that may be more appropriate for the consent form. This language can be negotiated on a case-by-case basis.

Exemption Procedures

Certain categories of research are exempt from review by the HSRRB in accordance with Federal guidelines. If your research fits in one or more of these categories, you may request exempt status for your protocol. Your protocol and Claim of Exemption form will be reviewed to evaluate your claim of exemption.

Investigators who believe that their protocol is exempt from review should submit (1) a completed Claim of Exemption Form (found at the Office of Research Protections [ORP] website) and (2) documentation from the local IRB stating that the protocol has been determined to be exempt.

USAMRMC and HSRRB Cadaver Policy

Although the Common rule defines a human subject as a living individual, the USAMRMC and the HSRRB both have policies that require IRB review of research involving human cadavers. Review and approval by the HSRRB is required prior to implementation of any research involving human cadavers. Refer to the policies listed on the ORP website for requirements for cadaver protocols.

Multi-Site Protocol Review

For multi-site protocols, the protocol and consent form for the primary site are first reviewed and approved by expedited or full Board review as appropriate. If the same protocol used by the primary site will be used at each of the other sites, each site-specific consent form can receive expedited review after review and approval of the protocol and consent form for the primary site. In addition, all domestic and foreign sites are required to assure compliance with the Federal policy for the protection of human subjects. If an awardee institution or any of the collaborating sites does not have an assurance number, such as a Multiple Project Assurance (MPA) or Federalwide Assurance (FWA) with the DHHS, OHRP, then an application for a DOD single project assurance (SPA) must be completed by each site that does not have an assurance and the application must be submitted to the Human Subjects Protection Branch of USAMRMC. Refer to the ORP website for further details regarding submission of an SPA application.