

Informed Consent in Military Medical Research: A Guide for Military Service Members



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—From a declaration of the American Bar Association



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Introduction

Each military branch conducts and/or sponsors medical research. Active-duty service members and Reserve Component members may participate in research that is conducted or funded by the Department of Defense. This guidebook will provide useful information about the informed consent process if you decide to volunteer for a military medical research study funded or conducted by the Department of Defense. This guidebook will not address non-Department of Defense funded or conducted research, which you can also participate in as an active-duty service member.

What is informed consent?

“Informed consent” is generally a conversation or series of conversations that take place between you and the research study’s investigator(s). The informed consent process involves two parts: (1) your right as the research participant to determine what happens to your body, and (2) the investigator’s duty to provide you with enough information to make an educated decision about whether you want to participate in the research study or not. The process of understanding the risks, benefits and alternatives to the research study is known as informed consent. In medical research conducted by the military, the rules about informed consent are similar to the core principles and regulations that govern medical research in the civilian population. However, some special and unique regulatory requirements arise in connection with Department of Defense-funded or conducted research.

Participating in medical research as an active-duty service member

Recruitment of volunteers to participate in military medical research is monitored very closely to ensure that participation is truly voluntary. Service members, by virtue of training and experience, may view a request to participate in military medical research as more a matter of duty than of choice. Superiors (for

example, military and civilian supervisors, unit officers and noncommissioned officers) must not influence their subordinate’s decision (for example, junior enlisted personnel and equivalent civilians) about participating in medical research.

To protect against undue influence, superiors must not be present at any medical research recruitment session or during the informed consent process where unit members are given the opportunity to participate. Superiors must attend a separate recruitment session when offered an opportunity to participate in medical research.

Generally, you will obtain a letter of support from the commander of a military facility or unit in which the recruitment occurs. Some sites may also require that you obtain written permission from your supervisor. Department of Defense personnel, including anyone in



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any branch of the military, must follow command policies that require command permission before participating in medical research while on active duty. Participation in research can affect your ability to fulfill military duties. Therefore, when deciding to participate in research while off-duty, it is necessary to follow the applicable Department of Defense component policy regarding approval for off-duty activities.

Informed consent—the process and the informed consent document

Medical research involving humans can pose complex ethical issues that require careful thought and consideration by both the researchers and the research participant. As a service member, you cannot truly be regarded as a voluntary research participant unless you are fully informed of the study's nature, risks, benefits and alternatives. Accordingly, the Department of Defense generally requires that the researcher or investigator obtain your informed consent if you are going to participate in a medical research study. This means that prior to participating in the study, you should have a confidential discussion with the military physician who is performing the research about known or expected risks, any anticipated therapeutic benefits and treatment options. There are times when the Department of Defense may obtain a waiver of the informed consent requirement from the secretary of defense, which means that your informed consent will not be sought or obtained. This may occur for a number of reasons, such as emergency research or

if the research study will advance the development of a medical product that is needed by the armed forces. While service members should be aware of this possibility, these instances are limited and are not covered in this guidebook. The informed consent process also involves a document known as the informed consent form, which summarizes the research study, explains the study's purpose, provides the treatment procedures and schedule, lists the potential risks and benefits of participating in the study and provides alternative treatments. The form should also provide an explanation of your rights as a medical research participant, such as your right to confidentiality and access to a resource hotline for questions or concerns

that you might have about the study. You should keep a copy of the informed consent form so that you can refer back to it when necessary. The informed consent process, including any discussions you have with the medical research team, and the informed consent form should not include language that makes you or your representative waive, or appear to waive, any legal rights. The informed consent process and form should also not include language that releases, or appears to release, the study's investigator(s), its sponsor(s), the military treatment facility or its agents from liability due to negligence.

Review and oversight of military medical research

To help ensure that adequate informed consent is provided and to help prevent against undue influence, military medical research studies are subject to multiple levels of review and oversight by various governmental agencies and regulatory bodies. Before a service member can be recruited into a Department of Defense study, the study will be reviewed for compliance with all applicable federal rules, regulations and administrative guidance. An institutional review board and/or a human use committee (depending on the service branch) will review, approve and oversee the study. An ombudsman may also be appointed by the institutional review board in any study that involves more than minimal risk (and sometimes





The entire informed consent process should provide you with adequate information so that you can make an informed decision about whether you want to participate in a medical research study.

in studies involving only minimal risk) to oversee the recruitment process. The ombudsman is an advocate for potential volunteers who ensures that the voluntary nature of participation is stressed and that the information provided during recruitment is clear, accurate and adequate so the potential volunteer can decide if he or she wants to participate in the study. The ombudsman ensures that no one who is in a position to influence a decision, such as a superior or a commanding officer, is involved with or observes the recruitment process. In addition, the institutional review board may appoint a research monitor to oversee the entire study, including the recruitment and

informed consent process, to report back to the board.

Additional protection and oversight applies to studies involving vulnerable populations, such as pregnant women, fetuses, neonates, prisoners and children, whether or not the studies are funded or conducted by the Department of Defense. These protections are set forth in regulations by the Department of Defense and the U.S. Department of Health and Human Services. The protections afforded to minors do not apply, however, to those who are underage but serving as active-duty service members. Reserve Component members in a federal-duty status who are underage are also deemed to be adults for purposes of having the legal capacity to consent. Students at service academies also fall into this category and, as a result, institutional review boards should carefully scrutinize the recruitment process as they consider if these underage individuals should be allowed to participate in medical research. Additionally, individual service branches may have policies restricting participation of those who are younger than 18, so that their participation is limited to studies involving only limited risk.

Can a service member refuse to participate in research?

No military member may be forced to participate in any Department of Defense-funded or conducted medical research study. The Department of Defense has clear requirements that are similar to the requirements that govern medical research for the civilian population.





Payments to research subjects

Volunteers may be paid for participating in military medical research. The institutional review board generally reviews the payment amount, payment schedule and proposed method of payment to ensure they do not present undue influence. While full payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable. Any credit for payment should accrue as the study progresses. If the volunteer withdraws from a study, payment may be delayed until the study has been completed by all the remaining participants. The Department of Defense and service branch rules and regulations may restrict the payment amount to active-duty volunteers depending on the nature of the study. This is an exception to the rule that prohibits payment to federal personnel from any source outside their regular salaries while on duty. The rules regarding payment to off-duty personnel vary depending on whether the medical research is Department of Defense-funded or not.

Resources

Each military branch conducts or sponsors medical research. If a service member has specific questions about a study, each of the military branches has offices that can help answer those questions.

Conclusion

We hope this guidebook will assist active-duty service members and Reserve Component members who need help deciding whether to participate in a military medical research study that is conducted or funded by the Department of Defense. Understanding your rights about the informed consent process is the first step in that decision-making process. As this guidebook indicates, there are special and unique requirements for Department of Defense research that you, the active-duty service member, should understand to ensure that your informed consent is given appropriately and voluntarily.





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