**Frequently Asked Questions: IRB-04 Department of Defense (DoD)**

There are unique considerations before beginning Department of Defense (DoD) - supported research. The items below represent a brief overview of some of them.

For more detail on these and other issues relating to DoD-supported research, please go to [Department of Defense Guide for Researchers at the University of Iowa](https://hso.research.uiowa.edu/department-defense-guide-researchers-university-iowa)**,**referenced below asUI DoD Guide***.*** Also, ‘DoD Instruction’ refers to DoD Instruction 3216.02, April 15, 2020, and specifically to Section 3 thereof unless otherwise noted.

1. [Is My Study DoD Research?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ1)
2. [Do I Need Training in Human Subjects Research Beyond the CITI Course?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ2)
3. [What Is an ‘Experimental Subject’?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ3)
4. [Does My Research Qualify for A Waiver of Informed Consent?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ4)
5. [Will My Study Need Scientific Review?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ5)
6. [What if My Study is International in Scope?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ6)
7. [What if I Will Collaborate with Other Institutions?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ7)
8. [Is There Research that is Prohibited?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ8)
9. [What Is a Research Monitor and When Do I Need One?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ9)
10. [What If My Study Involves a Survey?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ9)
11. [What If There Are Medical Expenses Related to the Research?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ11)
12. [What Are the Rules for Compensating Subjects in DoD Research?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ12)
13. [Are There Special Concerns for Military and DoD Civilian Personnel Subjects?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ13)
14. [What do I Need to Know About the Inclusion of Diverse Subject Populations?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ14)
15. [What Do I Do after the IRB Approves My Application?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ15)
16. [What do I Need to Report to the HRPO during the Study?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ16)
17. [Are There Special Rules for Recordkeeping?](https://hso.research.uiowa.edu/frequently-asked-questions-irb-04-department-defense-dod#FAQ17)

1. Is My Study DoD Research?

The answer is yes if….

* The research is funded by a DoD Component, *or*
* The research involves cooperation, collaboration, or other type of agreement with a DoD Component, *or*
* The research uses DoD resources, including its equipment, property, facilities, assets, or identifiable data or specimens from living individuals, *or*
* The subject population will ***intentionally include*** personnel (military and/or civilian) from a DoD Component.

2. Do I Need Training in Human Subjects Research Beyond the CITI Course?

* The Navy requires that you take additional certification modules. These are offered in the CITI program course, which you may have already taken in order to do research at the University of Iowa. For directions on taking the new modules, see Training Requirements on this page **\*\*Chris please link to ‘DoD web text update’ saved in 2.2.4\*\***.
* Check with your DoD representative to determine if you need other DoD research-related training.
* If you have taken DoD-related training in the past, check with your DoD representative to see if it needs to be renewed.

3. What Is an ‘Experimental Subject’?

The DoD uses the term ‘experimental subject’ to describe people (human subjects) engaged in an “activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.” [*(DoD Instruction, Glossary)*](https://search.yahoo.com/yhs/search?p=DOD%20INSTRUCTION%203216.02&hspart=fc&hsimp=yhs-3971&type=fc_AC5AE6A96A2_s69_g_e_d_n0002_c999&param1=7&param2=eJwti8sKgzAQRX9llhYkzhijDW77Bd2Ki1RTDYlGfGDp13eEMot77rnM4Pqmbp8PQpSVLpq0nbkjYs54TRwdh9aayS2MlN9FrpQgSYJYDjayPTbGwzBN8etCMJkSCMnp5j6eG8w7EAqsgUVZ1PApixuYZQn2tC%2Fv9kzJSsgSEj%2FuU0ghOG9hsJ2PN%2BjGNU42I6oEXgebeZvV%2FV9%2B%2BRE51Q%3D%3D)

4. Does My Research Qualify for A Waiver of Informed Consent?

* A waiver of informed consent for Research Involving a Human Being as an Experimental Subject is prohibited unless the waiver is obtained from the Under Secretary of Defense for Research and Engineering USD (R&E) or a delegated head of DoD component. This waiver must be attached to the HawkIRB application. See [UI DoD Guide](https://hso.research.uiowa.edu/department-defense-guide-researchers-university-iowa) for details on when a waiver may be obtained. [*(DoD Instruction, 11. Unique Limitations on Waiver of Informed Consent)*](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf)
* Consent may be obtained by the subject’s legal representative if the research will be of benefit to the individual subject. The IRB determines whether there is a benefit to the subject.

5. Will My Study Need Scientific Review?

The Army and Navy require independent scientific review and approval of nonexempt research prior to IRB review of new applications and substantive modifications. The review may be conducted by the funding agency (including DoD), through the use of an established internal review mechanism in the PI’s school or department, or via an ad hoc scientific review by the researcher’s chair or dean. At the University of Iowa, the requirement for scientific review is met by the DEO’s signature on the Assurances submitted by the PI in conjunction with the form documenting scientific review. For details, see [UI DoD Guide](https://hso.research.uiowa.edu/department-defense-guide-researchers-university-iowa).

6. What if My Study is International in Scope?

* Documentation must be included in HawkIRB indicating that local IRB/ethics committee approval and permission of the host country has been obtained and that the laws, customs, and practices of the host country will be followed.
* DoN-sponsored international research requires permission of the host country and an ethics review and approval by the host country, or the Naval IRB with host country representation. [*(SECNAVINST 3900.39D (6)(i). International Research.)*](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/irp.fas.org/doddir/navy/secnavinst/3900_39d.pdf)

7. What If I Will Collaborate with Other Institutions?

Collaborating institutions in multi-site research must have a federalwide assurance (FWA). Investigators must provide documentation of IRB approval or an IRB Authorization Agreement **\*\*\*NEED UPDATED LINK\*\*\*** for collaborators. The roles and responsibilities of each institution must be specified, along with a statement that the parties agree to comply with any special DoD requirements.

8. Is There Research that is Prohibited?

* The UI, by policy, prohibits ‘secret’ research on human subjects. This is defined by the UI as “research for which the nature, purpose, and non-proprietary results are not freely communicable” and “activities designated as ‘classified’ by the federal government.” Maintaining the confidentiality of proprietary information does not constitute secret research. ([*UI Operations Manual*, *27.2b*](http://opsmanual.uiowa.edu/community-policies/research/principles-governing-access-research-information)*)*
* Research with detainees (prisoners of war) and testing chemical or biological warfare agents is also restricted. See the [UI DoD Guide](https://hso.research.uiowa.edu/department-defense-guide-researchers-university-iowa) for details.

9. What Is a Research Monitor and When Do I Need One?

Research with greater than minimal risk requires a research monitor, approved by the IRB. The research monitor is the subject/patient advocate and is independent of the investigative team. They/ S/he has the authority to stop the research in progress, remove a subject from the study, take the necessary steps to protect the safety and well-being of human subjects until the IRB can assess the monitor’s report, and report observations and findings to the IRB or other designated official. The PI must identify the monitor by name and provide the IRB with a written summary of the monitors’ duties, authorities and responsibilities. See the [UI DoD Guide](https://hso.research.uiowa.edu/department-defense-guide-researchers-university-iowa) for details about choosing a research monitor and required documentation. [*(DoD Instruction, 8. Research Monitor)*](http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf)

10. What If My Study Involves a Survey?

Research involving surveys or interviews with DoD military or civilian personnel, or their families may require DoD approval. Check with the DoD contact for details on additional requirements.

11. What If There Are Medical Expenses Related to the Research?

If the research is greater than minimal risk, provisions for emergency treatment and necessary follow-up care of any research-related injury is required.

12. What Are the Rules for Compensating Subjects in DoD Research?

The ability to compensate a subject, and the amount of compensation available, depends both upon status in the military or as a DoD civilian employee and the procedure. See [UI DoD Guide](https://hso.research.uiowa.edu/department-defense-guide-researchers-university-iowa) for details. [(*DoD Instruction, 9.f.(7) Compensation to Human Subjects for Participation in Research)*](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf)

13. Are There Special Concerns for Military and DoD Civilian Personnel Subjects?

* Two concerns for working with the above populations involve permission to participate in research and coercion:
  + Active duty personnel must follow their command policies regarding obtaining permission to participate in human subjects research while on or off duty. The IRB will require proof of command approval in the form of a letter of agreement (submitted as an attachment in HawkIRB), indicating that the PI has permission to conduct the research at the location*.*
  + Officers and senior-non-commissioned officers should not be present when subordinates are recruited.
* DoD civilian personnel have the same protections as military personnel[*. (DoD Instruction, 7. Additional Protections for Human Subjects, 9.f.. DoD Personnel as Subjects)*](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf)

14. What Do I Need to Know About the Inclusion of Diverse Subject Populations?

Selection of human subjects for clinical research shall comply with [Public Law 103-160, Section 252 – Inclusion of Women and Minorities in Clinical Research Projects](https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/html/USCODE-2011-title10-subtitleA-partIV-chap139-sec2358.htm). This requirement may be waived by the Secretary of Defense if the project is 1) inappropriate with respect to the health of the subjects, 2) is inappropriate with respect to the purpose of the research, or 3) is inappropriate under such other circumstances as the Secretary of Defense may designate.

15. What Do I Do after the IRB Approves My Application?

Submit the approved application to the HRPO for the sponsoring component. You may not begin activities with human subjects until the HRPO performs an administrative review of the research.

16. What do I Need to Report to the HRPO during the Study?

Certain events, such as noncompliance, substantive changes, and continuing reviews must be reported to the HRPO, just as they are reported to the IRB. Report them within 30 days of the event. *([DoD Instruction, 3.16.a. Research Involving Human Subjects Conducted by a Non-DoD Institution, Non-DoD Institutional Responsibilities](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf" \t "_blank)*[)](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf" \t "_blank)

17. Are There Special Rules for Recordkeeping?

There may be special requirements for HSR documents, therefore it is best to determine the recordkeeping requirements of the relevant DoD component as they may differ from IRB requirements[*. (DoD Instruction, 15. Recordkeeping)*](http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf)