DoD-wide survey study steps

Information current in 2019

1. Become familiar with regulations.
	1. DODM 8910.01-V1, “DoD Information Collections Manual: Procedures for DoD Internal Information Collections”
		1. Do not mistake this with DODM 8910.01-V2, “DoD Information Collections Manual: Procedures for DoD Public Information Collections” (\*This is for PUBLIC surveys\*)
		2. Section 3c. “DoD internal information collections, where information across multiple OSD or DoD Components is collected, must be approved and licensed with an RCS.”
		3. In Enclosure 3, Section 1.b.(14), this manual excludes from survey regulation research involving human subjects as defined in DoD Instruction 3216.02
		4. *This manual refers to the DoD instruction below (DODI 3216.02)*
	2. DODI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research”
		1. Purpose: “…To establish policy and assign responsibilities for the protection of human subjects in DoD-supported programs to implement part 219 of title 32, Code of Federal Regulations (CFR) (also known and hereinafter referred to as ‘the Common Rule’.”
		2. *This instruction refers to the DoD regulation below (32 CFR 219)*
	3. Title 32 CFR, Part 219, Department of Defense Protection of Human Subjects
		1. 219.101: “Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A–D.” “Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS).”
		2. *This regulation refers to the HHS regulation below (45 CFR 46)*
	4. Title 45 CFR, Part 46, Health and Human Services “Public Welfare”
		1. 45 CFR 46, Subpart A = Federal Policy for the Protection of Human Subjects (or “the Common Rule”)
	5. In case you are unfamiliar with “research involving human subjects” – read on. This phrase means something very specific which carries with it federal regulations. “The Common Rule” is subpart A of 45 CFR 46 (a HHS regulation), which is the basis for instruction in 32 CFR 219 (a DoD regulation) – they are all talking about the same thing when they discuss research involving human subjects. The Common Rule describes the federal policy for regulating research on humans. The Common Rule generally covers any research that comes into contact with humans except some types of education methods and market research. All other research, including survey research, falls under research involving human subjects and must abide by federal regulation. From there, the research is either subjected to, or exempted from, further specific regulation, depending on policy-regulated examination of the study methods. This examination is conducted by an Institutional Review Board (IRB), which follows the Common Rule regulations. The DoD generally follows these government-wide policies (with noted exceptions to some regulations for children and prisoners). In addition, all institutions working with, or receiving funding from, the federal government must follow these policies. Thus, almost every institution in the United States follows these Common Rule regulations.
2. Obtain an IRB protocol approval while the survey approval is in pending status.
	1. In order to qualify for survey exemption, your study needs to be “research involving human subjects.” An IRB approval letter confirms that the research does involve human subjects.
		1. Even an “exempt” protocol is research involving human subjects. Having an IRB protocol implies that it *IS* research involving human subjects, and it must be regulated as such (like having the protocol on file with the IRB). “Exempt” means that it is excused from further regulations (such as having a research monitor) intended to provide even more safety to human subjects (see chart “2016-chart-01.png”). If your study was not research involving human subjects, it would not have an IRB protocol at all.
	2. Seek IRB administrative reviews/human research protection office reviews from each component you intend to survey outside of your component.
		1. Your institutional IRB will generally cover you for all of the research involving personnel within your component (Navy, Army, Air Force)
			1. There are some special cases and institutions which will require an additional administrative review even if they are within your component/branch (example: the academies, some training commands, and the Marine Corps)
		2. At the Administrative Review level, you often do not need to have a formal collaboration or IAIR in-place. Though, you may need to name an institutional POC. Just ask the office in question. There are exceptions which will require a full, formal inter-institutional collaboration involving an amendment to your protocol to add an additional research site (such as the Air Force Academy).
		3. The Marine Corps may request that you seek Research Regulatory Oversight Office administrative review approval of your protocol in order to collect data
3. Inform, inform, inform, part one (about intention to get exemption).
	1. Contact the Information Management Control Officer (IMCO) within your component and communicate your intention to seek an exemption from WHS.
		1. 8910.01-V1 reads, “The Component IMCO: (1) Serves as the Component advisor on information collections. (2) Reviews, approves, and maintains an inventory of Component internal information collections,” among other roles.
	2. Your component IMCO may communicate with the DoD Survey Manager on your behalf. If they do not, you may want to reach out yourself.
4. Request survey exemption by email to Washington Headquarters Services.
	1. Mention:
		1. DoDM 8910.01-V1, June 30, 2014, Enclosure 3 – Procedures

1. DoD Internal Information Collections

b. Items not considered DoD internal information collections and therefore are not subject to the licensing or approval requirements in this volume include:

(14) Facts or opinions from individuals (including individuals in control groups) under treatment, clinical examination, or in connection with research involving human subjects as defined in Reference (t).

Reference (t) = DoDI 3216.02

* + 1. Your study has an IRB approval letter indicating that it is research involving human subjects as defined by DoDI 3216.02
	1. Attach your protocol, approval letter, and IRB-stamped collection instrument
	2. Save the exemption email as a PDF as this is the only document they will return to you.
1. Inform, inform, inform, part two (about having obtained survey exemption).
	1. Once you receive WHS exemption, you will want to go back and forward that to everyone you have communicated with thus far, including your own IRB.
	2. You may want to inform IMCOs and/or Survey Managers from other Components so that they find out from you at the beginning, rather than from someone else later on when you are collecting data.
		1. This is also an opportunity to learn if you need to do anything further with each individual component or institution.

Note: Procedures may change as staff turns over in these offices, and some steps may have to be repeated with new personnel. Patience and humility are important components to the process.

POCs

1. Institutional Review/Human Subjects Protection Offices

	1. DoD Research Regulatory Oversight Office (R2O2)
		1. Main email inbox: dha.ncr.reg‐support.mbx.r2o2@mail.mil
		2. One person at the office:
		Sidrah Malik, MHA MPH

Research Regulatory Oversight Office

Contractor to Defense Health Agency

Defense Health Headquarters

7700 Arlington Boulevard, 3M190D

Falls Church, VA 22042

sidrah.malik.ctr@mail.mil

* + 1. Another person at the office:
		James E. McNerney, JD CIP RAC

Research Regulatory Oversight Office

Booz | Allen | Hamilton

Contractor to Defense Health Agency

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(OUSD(P&R))

Defense Health Headquarters (DHHQ)

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Falls Church, VA 22042

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USMC Human Research Protection Official

Chair, USMC Institutional Review Board

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2. Survey Managers

	1. DoD
		1. Mike DiNicolantonio

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		1. Maj Kerry Hogan
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		Manpower Studies and Analysis Branch
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1. Washington Headquarters Services

	1. General email inbox: WHS MC-ALEX ESD Mailbox DD DoD Information Collections whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil
	2. One person at the office:
	Kira Starks

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