Requirements for other Federal Agencies

Department of Defense (DOD)
When Human Research is conducted or funded by the Department of Defense (DOD), the University of Arizona commits to apply DOD Directive 3216.02.

1. When appropriate, research protocols must be reviewed and approved by the IRB prior to Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.
2. Department of Defense employees (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participated in research and should check with their supervisor before accepting such payments.
3. Department of Defense components might have stricter requirements for research-related injury than the DHHS regulations.
4. There may be specific Department of Defense educational requirements or certification required.

Department of Navy (DON)
When Human Research is conducted or funded by the Department of the Navy, the University of Arizona commits to apply SECNAVINST 3900.39D.

1. All research personnel conducting Department of Navy research must complete DON Human Subjects training through CITI. Once logged in, affiliate with the Department of Navy and choose the affiliation: “DON-supported Extramural Performers Group.”
2. Surveys usually require Department of Navy review and approval. See SECNAVINST 5300.8B for more information.
3. When conducting research with the Navy, a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities. The agreement should briefly describe the research, specific roles and responsibilities of each institution, responsibility for scientific and IRB review, recruitment of subjects, and procedures for obtaining informed consent. The agreement also should describe provisions for oversight and ongoing monitoring, reporting requirements, documentation retention, and compliance for the entire research project. See SECNAVINST 3900.39D section 6f for more information.
4. The Office of the Assistant Secretary of Defense for Health Affairs (OSAD(HA)) TRICARE Management Activity (TMA) has provided a guide for Department of Defense (DoD) researchers who plan to request Military Health System (MHS) data for research purposes, in particular, for database research. This guide provides an overview of the MHS as well as guidance regarding the types of research data available within the MHS, reviews specific to the protection of human subjects, and requirements of the TRICARE Management Activity (TMA) Privacy and Civil Liberties Office (Privacy Office) for requesting MHS data. Although this document is not comprehensive, it seeks to provide useful information for DoD researchers about MHS data and required reviews.

The principal audience for this guide is investigators within the DoD; however, external...
investigators may find the information helpful. Investigators from outside the DoD need to be aware that there are requirements beyond those listed in this Guide, and they should seek additional guidance from the TMA Privacy Office and the TMA Human Research Protection Program (HRPP) regarding specific requirements. You can find the "Guide for DoD Researchers on Using MHS Data" here.

**Department of Energy (DOE)**

When Human Research is conducted or funded by the Department of Energy (DOE), the University of Arizona commits to applying DOE O 443.1A and to use “Checklist for Researchers Conducting Human Subjects Research with/at DOE Sites, with DOE Funding, or Using DOE Data.”

1. Protocols must address DOE requirements regarding personally identifiable information (PII).
2. The investigator must report the following within ten business days to the Department of Energy human subject research program manager
   a. Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken.
   b. Any suspension or termination of IRB approval of research.
   c. Any significant non-compliance with HSPP procedures or other requirements.
3. The investigator must report the following within three business days to the Department of Energy human subject research program manager any compromise of personally identifiable information.

**Department of Education (ED)**

When Human Research is conducted or funded by the Department of Education (ED), the University of Arizona commits to applying 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).
2. Provide a copy of all surveys and instructional material used in the research. Upon request parents of children involved in the research must be able to inspect these materials.
3. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.

**Department of Justice (DOJ)**

When Human Research is conducted or funded by the Department of Justice (DOJ), the University of Arizona commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the University of Arizona relies on the Bureau Research Review Board to ensure compliance with 28 CFR §512.
Environmental Protection Agency (EPA)
When Human Research is conducted or funded by, or when the results of research are intended to be submitted to the Environmental Protection Agency (EPA), the University of Arizona commits to applying 40 CFR §26.