TITLE:	**Applicability of Regulations and Laws**
PURPOSE:	Outline the regulations under which the University of Arizona conducts Human Research
RESPONSIBILTIES:	HSPP staff and Administrative/Designated Reviewer

PROCEDURES

It is the policy of The University of Arizona to apply the regulations found under 45 CFR §46 Subpart A, federal law, state law, local law, and if applicable, 45 CFR §46 Subpart D, to all Human Research, regardless of funding source.

- The Common Rule and all applicable subparts (B Pregnant Women, Fetuses and Neonates and C Prisoners) will be applied to Human Research that is conducted, supported or otherwise subject to regulation by any federal department or agency which has adopted the Common Rule, with the exception of:
    - Human Research involving **pregnant women** that is deemed no more than minimal risk, as defined in 45 CFR §46.110, is not required to meet the criteria under 45 CFR §46 Subpart B as long as participation in the research does not affect the medical status of the pregnant woman or the fetus.
    - Human Research involving **prisoners** that is deemed no more than minimal risk, as defined in 45 CFR §46.110, is not required to be reviewed by the convened IRB; however for these projects a written consultation from a prisoner representative will be obtained for the Non-Committee Review.
- Other required regulations regarding Human Research that is conducted, supported or otherwise subject to regulation by a federal department that has adopted the Common Rule will be applied.
- Human Research that is not conducted, supported or otherwise subject to regulation by any federal department or agency which has adopted the Common Rule must have equal protections in regards to vulnerable populations. If such Human Research becomes subject to those regulations the Human Research will be re-evaluated under all applicable subparts.
- All Human Research that is **not exempt** as described in 45 CFR §46.101(b) must meet the criteria found in 45 CFR §46.111 in order to be approved.

Ethical Requirements

The University of Arizona (including its investigators, research staff, students involved with the conduct of Human Research, IRB members and chairs, IRB staff, the organizational official, employees, and students) follows the ethical principles outlined in the April 18, 1979, report of **The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled** "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," known as "The Belmont Report" in the conduct of all Human Research:

1. **Respect for Persons** -- Respect for persons incorporates at least two ethical convictions:

first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

2. **Beneficence** -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often
understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

3. **Justice** -- All are eligible to receive the benefits of research and bear its burdens. This is a principle of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

Legal Requirements

The University of Arizona commits to apply its ethical standards to all Human Research regardless of funding. All non-exempt Human Research must undergo review by an organizationally designated IRB. It is against Federal regulations to conduct research involving human subjects without prior IRB approval. If an activity is determined to not be Human Research and, therefore, does not require IRB review, such determination **cannot for any reason** be reversed or revoked at a later date for **any** part of the project. Further, data derived from this project may not in any way be presented as research.

When the University of Arizona is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulatory oversight by a federal department or agency that is a signatory of the Common Rule (45 CFR §46 Subpart A), the organization commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When the University of Arizona is engaged in FDA Human Research, the organization commits to apply the FDA-regulations relevant to the protection of Human Subjects.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the HSPP for discussion.

Other Requirements

All policies and processes that are applied to Human Research that is conducted domestically are applied to Human Research conducted in other countries.

The IRB will consider the Community-Based Research Principles (CBRP) outlined by the University of Washington when reviewing research that involves community-based research.

For Clinical Human Research, the University of Arizona commits to apply the International Council on Harmonisation – Good Clinical Practice E6, to the extent that it corresponds with FDA regulations.

Other federal entities that have adopted the Common Rule may have additional requirements in order to conduct Human Research that is funded or supported by the entity.

Additional Requirements for Common Rule 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. When Human Research is conducted or funded by the Department of the Navy, the University of Arizona commits to apply SECNAVINST 3900.39D.

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 participate 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)

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
   a. 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[1] involved in the research[2] must be able to inspect these materials.

[1] Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

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.

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A-4: 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.

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A-5: 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.

MATERIALS:

- None

REFERENCES:

- None

REVIEW/REVISIONS: From 10/01/2010 version: Renumbered from P&P-002.

From 03/24/15 version addition of ethical and legal requirments.