TITLE: Applicability of Regulations and Laws

PURPOSE: Outline the regulations under which the University of Arizona conducts Human Research

RESPONSIBILITIES: 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.

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 requirements.