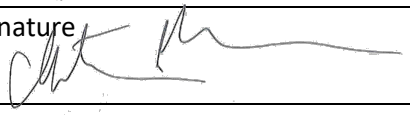
OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #202.3 Revision 3	**TITLE: Ethical and Legal Standards and Practices for Human Subject Research**	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature 	Date 3/1/2019
Approved By: IRB Chair	Signature 	Date 3/1/2019

PURPOSE
To describe the ethical and legal standards for the conduct of human research at the University of New Mexico (UNM).

REVISIONS FROM PREVIOUS VERSION
Addition of DOD and other administrative changes

POLICY
UNM has the following written policies for working with research participants, sponsors, researchers, and the Human Research Protections Program (HRPP) to uphold legal and ethical standards and practices in research involving human participants. IRB policies and procedures are available to sponsors, researchers, participants, reviewers and other interested parties via the OIRB website and internal documents, as appropriate.

Ethical Principles
The primary ethical principles applied to research covered by the HRPP, including protocols that are exempt from the federal regulations pertaining to human subject research, are those set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Belmont Report). The three main principles are:

1. **Respect for persons** (demonstrated by obtaining informed consent, respecting privacy and confidentiality, and adding protections for vulnerable populations)
2. **Beneficence** (demonstrated by balancing risks and benefits)
3. **Justice** (demonstrated by equitable participant selection & distribution of risks and benefits)

In addition, all researchers (including UNM faculty, employees, and students) are expected to adhere to the principles of expertise (competent to do the work) and integrity (uphold professional principles and standards). Additional ethical principles may be applied when appropriate. Examples include but are not limited to the following:

1. International Council on Harmonization Good Clinical Practice principle on restricted use of placebo-controlled projects;
2. Research data management and security;
3. Native language or other accommodations for illiterate or non-English speaking participants.

Training on the ethical principles and researcher responsibilities are covered in the CITI training . IRB members are trained through various mechanisms (see the IRB Member and Staff Training SOP).

Legal Principles

The basic legal principles governing research involving human participants are:

1. DHHS regulations for Protection of Human Subjects (Common Rule) in 45 CFR Part 46
2. FDA regulations for the Protection of Human Subjects in 21 CFR Parts 50 and 56
3. DOJ regulations for the Protection of Human Subjects in 28 CFR 512
4. DOD regulations for the Protection of Human Subjects in 32 CFR 219 and DoD Directive 3216.02
5. Privacy Rule regulations of Individually Identifiable Health Information (HIPAA Privacy Rule) in 45 CFR Parts 160 and 164
6. Applicable New Mexico and local law

RESPONSIBILITIES

Execution of SOP: OIRB Staff, IRB, Researchers