

Standard Operating Procedures		
SOP #511.2 Revision 2	TITLE: Compliance with Applicable Laws and Regulations	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature 	Date 3/1/2019
Approved By: IRB Chair	Signature 	Date 3/1/2019

PURPOSE

This purpose of this policy is to provide a summary of local laws, state statutes, and international regulations that may be applicable to human research.

REVISIONS FROM PREVIOUS VERSION

Clarification for international research and administrative corrections

POLICY

All researchers must know and comply with relevant laws in the localities where they conduct research on human participants, including U.S. tribal, territorial and foreign localities, regardless of funding source. In the case of variances between U.S. federal laws and state or local laws, or between U.S. and foreign laws and regulations, the more protective standard typically takes precedence. UNM researchers should contact the UNM Office of University Counsel for additional guidance.

RESPONSIBILITIES

Execution of SOP: Researchers, IRB.

PROCEDURE

Informed Consent to Participate in Research

1. Age of majority: For purposes of consenting to participate in research, the age of majority is determined by the locality in which the participant is physically located. For example, in 47 US states and the US Virgin Islands the age of majority is 18 years. In Nebraska and Alabama it is 19 years and in Mississippi and Puerto Rico it is 21 years. Researchers are expected to know the age of majority in the locality they intend to use, should laws change, this policy does not replace state law.
2. Internet surveys and interviews: For internet based survey research for purposes of providing independent consent to participate, the minimum age is 18 years. Surveys and internet-based interviews involving persons under the age of 18 require either documented parental/guardian permission, or a waiver from the IRB.

New Mexico Laws Pertaining to Research on Human Participants

Research activity concerning fetuses, infants or pregnant women:

N.M. Stat. Ann. § 24-9A-5 - Establishes limits for research activity involving fetuses, live-born infants or pregnant women. No inducements, monetary or otherwise, are allowed. Valid consent by the pregnant woman or the parent or guardian of the infant is required. Elements of the valid consent include explanation of the procedures and their purpose, disclosure of all experimental procedures, descriptions of discomforts, risks, benefits expected, alternative procedures, availability for follow-up questions, and an explanation of voluntary withdrawal option.

Genetic Information Privacy Act:

N.M. Stat. Ann. § 24-21-1 et seq. - Genetic analysis without informed consent is prohibited. Listed exceptions include DNA testing for the purpose of medical or scientific research and education so long as such DNA testing is for retention of gene products, genetic information or genetic analysis involved in research and if the identity of the individual or the individual's family members is not disclosed. See § 24-21-3.

Human Immunodeficiency Virus Test Act:

N.M. Stat. Ann. § 24-2B-1 et seq. - No person shall perform a test designed to identify the human immunodeficiency virus or its antigen or antibody without first obtaining the informed consent of the person upon whom the test is performed. The act sets out requirements for informed consent. However, under § 24-2B-5, informed consent for testing is not required for the purpose of research if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher or the performance of a test done in a setting where the identity of the test subject is not known, such as in public health testing programs and sexually transmitted disease clinics.

Research on Participants in a Foreign Country or Involving Non-U.S. Institutions

1. To identify relevant foreign laws pertaining to research regulations see the OHRP guidance [International Compilation of Human Research Protections](#).
2. UNM researchers who conduct research activities at or collaborate with non-U.S. institutions in human research must meet the requirements of U.S. Federal laws pertaining to human research, as specified in the UNM policies and procedures, as well as any laws that govern research that is conducted in the foreign locality.
3. If the proposed research is conducted on tribal land, appropriate authorizations must be obtained such as Navajo Nation IRB and/or tribal council approval.
4. UNM researchers who conduct transnational research activities must provide verification of knowledge of cultural context for the locations under study in the protocol.
5. Researchers also must provide, as appropriate, evidence of approval(s) from foreign institution(s) before the research may commence.
6. Formal review and approval by the IRB is required, including for research that is determined by the IRB to be exempt from the federal regulations. OIRB staff screen the protocol to determine whether documentation has been provided regarding the qualifications of the researchers for conducting research in that country. OIRB staff will also determine whether additional expertise outside of the IRB is necessary to conduct the review. If so, OIRB staff may ask an ad hoc or cultural consultant who has appropriate expertise and knowledge of the countries, populations or locations to participate in the review.
7. The IRB will conduct initial, continuing, modifications review and post-approval monitoring according to standard operating procedures. The IRB will also coordinate and communicate with local IRBs, when appropriate, to understand consent process/document and other language issues, resolve complaints, noncompliance and unanticipated problems involving risk to participants or others.

Additional NM Laws, Administrative Codes and Statutes

Adult Abuse:

N.M. Stat. Ann. § 27-7-30 - This statute requires any person having reasonable cause to believe that an incapacitated adult is being abused, neglected or exploited to immediately report that information to NM Adult Protective Services.

Child Abuse and Required Reporting:

N.M. Stat. Ann. § 32A-4-1, et seq. - Every person who knows or has a reasonable suspicion that a child is an abused or a neglected child must report the matter immediately to a local law enforcement agency, a department such as New Mexico Children, Youth and Families Department (CYFD), or a tribal law enforcement or social services agency for any Indian child residing in Indian country. Examples of abuse encompass physical, emotional or psychological abuse, sexual abuse, exploitation, abandonment, or neglect, torture, confinement, and cruel punishment. Reporting obligation applies to everyone, including school officials whose communications would ordinarily be protected by privilege such as, but not limited to, a physician, medical resident, an intern, a nurse, police officer, school official, or member of the clergy. These laws also apply to information gained as a researcher.

Mental Health:

N.M. Code R. § 16.27.18.17 - This administrative code states that mental health counselors, therapists, and alcohol and drug counselors may not disclose confidential information pertaining to a client without written consent with the exception of reporting the abuse of children and vulnerable adults.

N.M. Code R. § 7.1.20.11 - Research organizations, state agencies, and federal agencies may be granted access to the data and information contained in the NM Health Information System (HIS) with specific confidentiality requirements. All data that is used for research and analytic purposes must protect the confidentiality of the individual's identity, providers, and third party payers.

Public Health:

N.M. Stat. Ann. § 24-1-20 - This statute is intended to protect and promote the public health. Information shared with the Department of Health in connection with medical research studies is confidential and shall be used only for the purposes of medical research. The information shall not be admissible as evidence in any action of any kind in any court or before any administrative proceeding or other action.

Status of Minors:

N.M. Stat. Ann. § 32A-21-1, et seq. - Minors are defined as persons less than 18 years old. This statute also establishes criteria and procedures that lead to the emancipation of a minor who is 16 years or older. Among other things, a formally emancipated minor has the right to consent to medical, dental or psychiatric care or capacity to enter into a binding contract. See **§ 32A-21.5**.

Additional Guidance on Minor's Consent to Medical Care:

N.M. Stat. Ann. § 24-10-1 - Consent to Medical Treatment if married or emancipated: an emancipated minor or any minor that is legally married may consent to hospital, medical and surgical care. Subsequent judgment of annulment of the marriage or judgment of divorce shall not deprive the minor of his or her adult status once attained.

Age of Majority Act of 1978:

N.M. Stat. Ann. § 28-6-1 - Except as otherwise specifically provided by existing law, any person who has reached his or her eighteenth birthday shall be considered to have reached his or her majority and is an adult for all purposes the same as if he or she had reached his or her twenty-first birthday.

Patient Care Monitoring Act and Legal Representative:

N.M. Stat. Ann. § 28-6-1 A legally authorized representative (LAR) is authorized to consent on behalf of someone to participate in procedure(s) involved in health care. Under New Mexico statutes, the closest definition of LAR is of a "surrogate" under the Patient Care Monitoring Act, which addresses use of monitoring devices for patients receiving medical care. Surrogate is defined as a legal guardian or a legally appointed substitute decision-maker who is authorized to act on behalf of a patient.

Blood Donation; minors:

N.M. Stat. Ann. § 24-10-6 - A minor who is at least seventeen years of age may donate blood to a licensed, accredited or approved blood bank, storage facility or hospital without parental consent. No monetary payment is allowed.

REFERENCES

45 CFR 46.111(a)(3)

21 CFR 56.111(a)(3)

<http://www.nmcompcomm.us/>