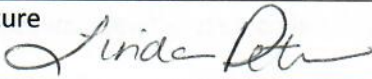





Standard Operating Procedures		
SOP #301.2 Revision 2	TITLE: Determination of Activities that Require IRB Review	Effective Date: 7/7/2016
Approved By: OIRB Director	Signature 	Date 8/31/2016
Approved By: IRB Chair	Signature 	Date 8/11/16

PURPOSE

To describe policies and procedures for determining the types of activities that qualify as human research or clinical investigations and therefore require prior Institutional Review Board (IRB) review and approval.

REVISIONS FROM PREVIOUS VERSION

Addition of clarification regarding engagement in human subject research

POLICY

In accordance with federal and institutional regulations and prior to project implementation, the IRB must approve any undertaking in which a UNM employee or agent engages in human research. This policy outlines what types of activities are human subject research or clinical investigations and therefore require IRB review and approval.

Definitions

Department of Health and Human Services (DHHS)/Common Rule

Employees or Agents: Individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include faculty, staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Engaged: In general, an institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

Research: A systematic investigation designed to develop or contribute to generalizable knowledge [45CFR 46.102(d)]. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Some research development or testing and evaluation may also meet this definition.

Human subjects (DHHS): A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.



Intervention includes both physical procedures by which data are gathered (for example, saliva collection) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Food and Drug Administration (FDA)

Clinical investigation involves use of a test article (i.e. drug, device, food substance, or biologic), one or more human subjects, meets requirements for prior submission to the FDA (involves drugs or medical devices other than the use of FDA approved drugs or medical devices in the course of medical practice), or results are intended to be part of an application for research or a marketing permit.

If the activities involve use of an FDA regulated test article (i.e. drug, device, food substance, or biologic under the purview of the FDA), UNM applies the FDA definitions of "human subjects."

Human subjects (FDA): An individual who is or becomes a participant in research either as a recipient of a test article or as a control or as an individual on whose specimen a device is used. A subject may be either a healthy individual or a patient [21 CFR 56.102(e)] (Drug, Food, Biologic).

Human subjects (FDA for medical devices): A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease [21 CFR 812.3(p)] (Medical Devices). This definition includes the use of tissue specimens even if they are unidentified.

If the research involves any of the following, FDA regulations 21 CFR 50 & 56 apply and require IRB approval prior to implementation:

- Any use of a drug in research other than the use of an FDA approved drug in the course of medical practice;
- Any use of a medical device in studies where the purpose is to determine the safety or effectiveness of the device; or
- Data will be submitted to or held for inspection by FDA as part of a marketing permit.

Department of Justice

For research conducted within the Bureau of Prisons, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.



RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Study Personnel, OIRB Staff, IRB Members, IRB Chair.

PROCEDURES

Human Subject Research Determinations

1. It is the responsibility of the Principal Investigator to seek IRB review and approval prior to engaging in any research involving human subjects or before conducting any clinical investigation.
2. The researcher is responsible for making a preliminary decision regarding whether his/her activities meet either (a) the Department of Health and Human Services (DHHS) definitions of “engaged”, “research” and “human subjects” and/or (b) the FDA definitions of both “clinical investigations” and “human subjects.”
3. The researcher may contact OIRB staff, the IRB Chair/Vice Chair, or IRB members for advice on the applicability of the federal regulations and UNM policy.
4. In cases where it is not clear whether the study requires IRB review, the OIRB or the IRB may ask the researcher to send a memorandum to the IRB/OIRB by e-mail or through IRBNet detailing the proposed research. In complicated cases, the OIRB or the IRB may ask the researcher to complete and submit an application to the IRB for a decision. The Director or IRB Chair or their designees make the final determination whether the activities meet the federal definitions using applicable federal policy/regulation.
5. The OIRB communicates the decision of the IRB or the OIRB to the researcher via e-mail or IRBNet.

REFERENCES

21 CFR 56.102

45 CFR 46.102

28 CFR 512.10