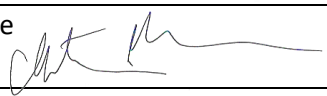


| Standard Operating Procedures          |                                                                                                |                             |
|----------------------------------------|------------------------------------------------------------------------------------------------|-----------------------------|
| <b>SOP #301.5</b><br><b>Revision 5</b> | <b>TITLE: Determination of Activities that Require IRB Review</b>                              | Effective Date:<br>5/8/2022 |
| Approved By:<br>OIRB Director          | Signature<br> | Date<br>5/8/2022            |
| Approved By:<br>IRB Chair              | Signature<br> | Date<br>5/8/2022            |

## 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

Update references to electronic research administration (ERA) system

## 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 UNM 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 research project when its employees or agents for the purposes of the research project obtain: (1) data about the participants of the research through intervention or interaction with them; (2) identifiable private information about the participants of the research; or (3) the informed consent of participants for the research.

*Research:* A systematic investigation designed to develop or contribute to generalizable knowledge [45CFR 46.102(l)]. 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. The following activities are **not** research for the purpose of this policy: scholarly and journalistic activities (e.g. oral history, journalism, biography, legal research) and public health surveillance activities.

*Human subjects:* A living individual about whom a researcher conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies,

or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens [45 CFR 46.102(e)(1)].

*Intervention* includes both physical procedures by which information or biospecimens are gathered (for example, saliva collection) and manipulations of the participant or the participant's environment that are performed for research purposes [45 CFR 46.102(e)(2)].

*Interaction* includes communication or interpersonal contact between researcher and participant [45 CFR 46.102(e)(3)].

*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 participant is or may readily be ascertained by the researcher or associated with the information) in order for obtaining the information to constitute research involving human subjects [45 CFR 46.102(e)(4)].

#### Food and Drug Administration (FDA)

*Clinical investigation* means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies [21 CFR 56.102(c)]. 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*: 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 (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 [Dept of Justice Program Statement 1070.07].

### **RESPONSIBILITY**

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

### **PROCEDURES**

#### Human 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 participants or before conducting any clinical investigation.
2. The researcher is responsible for making a preliminary decision regarding whether their 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 project requires IRB review, the OIRB or the IRB may ask the researcher to send a memorandum to the IRB/OIRB by e-mail or submit documentation via the ERA system 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 OIRB staff make the final determination whether the activities meet the federal definitions using applicable policy/regulation.
5. The OIRB communicates the decision of the IRB or the OIRB to the researcher via e-mail or the ERA system.

### **REFERENCES**

[21 CFR 56.102](#)

[45 CFR 46.102](#)

[28 CFR 512.10](#)

[OHRP Guidance Engagement of Institutions in Human Subjects Research \(2008\)](#)