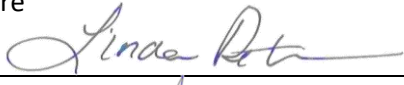
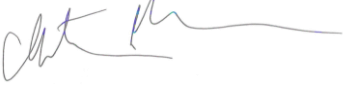


Standard Operating Procedures		
SOP #209.0 Revision 0	TITLE: UNM Policy on Engagement in Human Research	Effective Date: 3/6/2018
Approved By: OIRB Director	Signature 	Date 3/6/2018
Approved By: IRB Chair	Signature 	Date 3/6/2018

PURPOSE

To describe the policy for determining whether UNM main and branch campus employees or agents are engaged in human research that requires oversight by the UNM IRB.

REVISIONS FROM PREVIOUS VERSION

None

POLICY

In accordance with institutional policy and UNM’s federalwide assurance, the UNM IRB has oversight of human research in which UNM main or branch campus employees or agents are engaged. Many institutions and individuals (e.g., the principal investigator, statistical centers, community members, educators, data repositories) may work together on various aspects of a human research project; however, not all participating institutions and individuals are *engaged* in the project as defined below. This policy provides the definition of engagement in research and examples of situations when UNM employees/agents are and are not engaged in activities covered by the federal regulations and/or UNM policy.

DEFINITIONS

Employees or Agents: Individuals who: **(1) act on behalf of UNM main or branch campuses; (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. Individuals are not considered employees/agents of UNM if engaging in research activities as volunteers, private consultants or in other capacities not for the University.

Engaged: In general, UNM is *engaged* in a particular human research project when its employees/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.**

PROCEDURE

When UNM employees/agents are engaged in the research project, UNM IRB must either review and approve the project, or defer oversight to an appropriate, qualified IRB. Principal Investigators should contact the OIRB for assistance with determining when UNM is engaged and thus UNM IRB review or deferral is required.

Generally, UNM is engaged in a research project when employees/agents of UNM (as defined in this policy):

1. Receive an award through a grant, contract, or cooperative agreement directly from HHS (i.e. UNM is prime awardee), even where all human research activities are carried out by employees/agents of another institution.
2. Intervene with participants for research purposes by performing procedures or manipulating the environment.
3. Interact with participants for research purposes.
4. Obtain identifiable private information or identifiable biological specimens from any source for research.

UNM is **NOT engaged** in a research project if the involvement of employees/agents are limited to one or more of the following:

1. Performing commercial or other services for external researchers provided that all of the following conditions also are met:
 - a. the services performed do not merit professional recognition or publication privileges (e.g., transcription, radiation technician, coding, etc.);
 - b. the services performed are typically performed by those institutions for non-research purposes; and
 - c. employees/agents do not administer any research intervention being tested or evaluated.
2. Permitting use of UNM facilities for intervention or interaction with participants by researchers from another institution.
3. Releasing to researchers at another institution identifiable private information or identifiable biological specimens (e.g. schools that release identifiable student test scores to outside researchers, medical centers that release identifiable human biological specimens). Note that in some cases the institution releasing identifiable private information or identifiable biological specimens may have institutional requirements that would need to be satisfied before the information or specimens may be released, and/or may need to comply with other applicable regulations or laws (e.g. HIPAA).
4. Obtaining coded private information or coded biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or social security number); and UNM researchers are unable to readily ascertain the identity of the participants to whom the coded information or specimens pertain because, for example:
 - a. UNM researchers and the holder of the link enter into an agreement prohibiting the release of the link to UNM under any circumstances;
 - b. the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the link under any circumstances; or
 - c. there are other legal requirements prohibiting the release of the link.
5. Authoring a paper, journal article, or presentation describing a human research project (with no access to identifiers).

The criteria noted above can be used to evaluate whether other institutions are engaged in research.

REFERENCES

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