SOP 406: Determination of Human Research and Protocol Development

1. POLICY

The IRB shall evaluate research projects initiated by Key Study Personnel to determine whether the projects involve the use of human participants or “Experimental Subjects” (as defined in the Glossary) and/or qualify as research (as defined in the Glossary). The Investigator shall complete the Determination of Human Research Worksheet (DHRW) and submit it to the IRB for determination regarding these matters. The IRB Chair or IRB designee shall make the determination regarding whether human participants are involved and/or whether the project constitutes research when a DHRW is submitted to the IRB.

Specific Policies

1.1 Human Participant Research Determination

If it is determined that the project involves human participants and the investigator desires to proceed, the research project shall be submitted per SOP 301: Research Submission Requirements, and reviewed per applicable SOP 401: Research Exempt from IRB Review; 402: Expedited Review; or 403: Initial Review – Criteria for IRB Approval.

The project shall be concurrently reviewed for compliance with the Health Insurance Portability and Accountability Act (HIPAA) per SOP 1001: HIPAA Privacy Rule.

1.2 Not-Human Participant Research Determination

If it is determined human participant research is not proposed, the IRB, acting as the Privacy Board, shall review the research project for HIPAA compliance, per SOP 1001: HIPAA Privacy Rule. If the project is HIPAA-compliant, the Investigator may initiate the project without further involvement of the IRB. The usual types of activities that may be initiated without prior involvement of the IRB include:

A. Classroom evaluation activities when assessment involves regular classroom activities and the results of the evaluation process are intended to be used for the sole purpose of enhancing teaching practices of the instructor.

B. Quality improvement activities designed to enhance functionality of a department or campus program provided that results are not intended to be shared outside of the University.

C. Program evaluations.

D. Public health practice surveillance activities.

1.3 Research vs. Non-Research Determination

The Investigator shall complete the DHRW and submit it to the IRB for a determination of whether the project constitutes human research. Projects that meet the definition of human research are submitted, per SOP 301: Research Submission Requirements, to the IRB and prospectively reviewed by the IRB per
There are limited types of non-research that may be initiated without prior submission to the IRB. These activities include:

A. Requirements of a course that are being conducted only for the purpose of learning research skills.

B. Case studies involving no more than two (2) separate cases, provided that the case studies are void of private identifiable information. This activity is **not** to be confused with thesis or dissertation projects, which do require prospective IRB review and approval.

C. Training exercises wherein humans are taught job/position-related responsibilities.

### 1.4 Other Applicable Standards for Not-Human Participant or Non-Research Projects

All projects conducted at the University shall be subject to other standards of review as determined by University policy and/or procedure.

All projects conducted at the University shall be subject to the same ethical standards as IRB-approved projects.

Any change to a research project that was initially deemed not-human participant or non-research shall be resubmitted to the IRB for review to determine whether the change alters the original determination of not-human participant or non-research.

### 1.5 Protocol Development (Norman Campus Only)

Investigators may have received external grants that include funding for the development of the research protocol and data collection instruments. In order to receive these funds from the Office of Research Services, the investigator needs to complete and submit the Norman Campus Protocol Development form in the IRB’s electronic information system and upload relevant supporting documents.

In these instances, protocols are to be submitted to the IRB with as much information as is available. The protocols must include assurances that additional information will be submitted when developed and, in the case of training grants, that all trainees will submit individual protocols if human participants are to be used. Grant Proposals lacking definite plans for research participant involvement may include the following:

- Research training programs or grants in which the activities involving human participants remain to be selected or designed.
- Research, pilot or developmental projects in which the involvement of human participants depends on such factors as the completion of instruments or prior studies.
The IRB will issue a protocol development letter that can be given to the Investigator in order to have external funding released from ORS for research activities. After the protocol has been developed and the investigator is ready to begin human research activities, the investigator must submit an application for a new research project using the IRB’s electronic information system (See SOP 403: Initial Review – Criteria for IRB Approval).

2. SCOPE

This SOP applies to all on-going and planned human participant research projects at the University.

3. RESPONSIBILITY

3.1 The Investigator is responsible for seeking IRB determination as to whether new research projects involve humans as participants and meet the definition of research, either by utilizing the DHRW or by contacting the IRB.

3.2 The Investigator is responsible for seeking IRB determination as to whether any changes to on-going not-human participant or non-research projects alter the need for additional IRB review.

3.3 The IRB Administrator is responsible for processing submissions in the IRB’s electronic information system, forwarding the submission to the IRB Chair or IRB designee for review, and drafting and sending a determination letter to the Investigator.

3.4 The IRB Chair or IRB designee is responsible for determining whether the research project involves humans as participants and whether the project is considered research.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50.603
DoD Directive 3216.02

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 1001: Health Insurance Portability and Accountability Act (HIPAA Privacy Rule)
SOP 301: Research Submission Requirements
SOP 304: Documentation and Document Management
SOP 401: Research Exempt from IRB Review
SOP 402: Expedited Review

6. ATTACHMENTS

406-A Determination of Human Research Worksheet
7. PROCESS OVERVIEW

7.1 The Investigator completes the DHRW for the appropriate campus and submits it to the IRB to seek IRB determination regarding whether the proposed research project involves human participants and/or whether the project meets the definition of research.

If applicable, the Investigator shall complete the Protocol Development Form and submits it to the IRB for approval. The IRB Administrator shall communicate the IRB Chair’s determination to the Investigator via the IRB’s electronic information system. The investigator provides the IRB protocol development approval letter to the ORS.

The DHRW is directed to an appropriate IRB Chair or IRB designee for determination.

The IRB Chair reviews the submission and indicates his/her determination on the reviewer checklist.

The IRB Administrator communicates the IRB Chair’s determination to the Investigator via the IRB’s electronic information system.

Documentation of the submission and determination is maintained in the IRB’s electronic information system (see SOP 304: Documentation, Document and Data Management, for details).

7.2 If the IRB Chair or IRB designee indicates that the project does not involve human participants and is not considered research, the IRB Administrator notifies the investigator that the project may be initiated without IRB review.

If the IRB Chair or IRB designee indicates that the project involves humans as participants and that the definition of research is met, the IRB Administrator notifies the investigator of this determination and instructs the Investigator to complete and submit a Study Application along with applicable supporting documents to the IRB for approval, per SOP 301: Research Submission Requirements.

APPROVED BY: ____________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016