

**SOP: 406**  
**DETERMINATION OF HUMAN RESEARCH**

**1. POLICY**

The IRB shall evaluate research projects initiated by key personnel to determine whether they involve the use of human participants (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 and submit it to the IRB for determination regarding these matters. The IRB Chair or designee shall make the determination regarding whether human participants are involved and/or whether the project constitutes research when a Determination of Human Research Worksheet is submitted to the IRB.

**Specific Policies**

**1.1 Human Participant Research Determination**

If it is determined that the project involves human participants, 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 research project is then reviewed for HIPAA compliance per SOP 1001, HIPAA Privacy Rule. If the research project is HIPAA compliant, the Investigator may initiate the research project without further involvement of the IRB. The usual types of activities that may be initiated without submitting to 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 beyond the University.

**1.3 Research vs. Non-Research Determination**

The Investigator shall complete the Research Determination Worksheet and submit it IRB for a determination of whether the project constitutes research. Projects that meet the definition of research are submitted per SOP 301, Research Submission Requirements, to the IRB and prospectively reviewed by the IRB per applicable SOP 401, Research Exempt from IRB Review, 402, Expedited Review; or 403, Initial Review – Criteria for Approval;

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 reports involving no more than two (2) separate cases, provided that the case reports 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 deemed not-human participant or non-research shall be re-reviewed to determine whether the change alters the original determination of not-human participant or non-research.

## **2. SCOPE**

This policy and procedure applies to all on-going and future human participant research projects at this institution.

## **3. RESPONSIBILITY**

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 Research Determination Worksheet or by contacting the IRB.

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.

The IRB Administrator is responsible for entering research projects into the IRB database, forwarding the research project to the IRB Chair or designee for review, and drafting a determination letter to the Investigator.

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

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46

21 CFR 50.603

## **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
- SOP 403, Initial Review – Criteria for IRB Approval.

**6. ATTACHMENTS**

- 406-A Determination of Human Research Worksheet (HSC includes FDA and DHHS regulations)
  
- 406-A-1 Determination of Human Research Worksheet (Norman Campus includes DHHS regulations but excludes FDA regulations)

**7. PROCESS OVERVIEW**

- 7.1 The Investigator completes the Research Determination Worksheet and submits it to the IRB to seek IRB determination regarding whether human participants are involved in a proposed research project and/or whether the project meets the definition of research.

The Research Determination Worksheet is directed to an appropriate IRB Chair or designee for determination.

The IRB Chair reviews the worksheet and indicates his/her determination on the worksheet.

The IRB Administrator communicates the IRB Chair’s determination to the Investigator via letter or email.

Documentation of the submission and determination is kept on file in the IRB Office (see SOP 304, Documentation, Document and Data Management, for details).

- 7.2 If the Research Determination Worksheet indicates that the project does not involve human participants and is not considered research, the IRB will notify the investigator that the project may be initiated without IRB review.

If the Research Determination Worksheet indicates that the project involves humans as participants and/or if the definition of research is met, the investigator completes an Application for New Research and submits the application and applicable supporting documents to the IRB for review and approval per SOP 301, Research Submission Requirements.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** MAY 2012