TEXAS A&M UNIVERSITY-SAN ANTONIO

INSTITUTIONAL REVIEW BOARD (IRB) STANDARD OPERATING PROCEDURE (SOP)

SOP #: 8	**Version:** 2.0	**Effective Date:** 11/17/2023
Title: Not Human Subjects Research (NHSR)		
Approved by: Dr. Vijay Golla, PhD Vice Provost for Research and Health Sciences		**Date:** 11/17/2023

1. **Purpose**

1.1 This SOP covers the process for reviewing submitted information to determine if research is classified as Not Human Subjects Research (NHSR) as defined by federal guidelines.

2. **Scope**

2.1 Federal, System and University policy are all formed and enforced for the ultimate purpose of human subjects' protection. The IRB review process is subject to 45 CFR Part 46 Subpart A.

3. **Responsibilities**

3.1. Principal Investigators (PIs) are responsible for:

3.1.1. Submitting all information and required supporting documents to the IRB Office for NHSR determination.

3.2. Director of Research Compliance (DRC) is responsible for:

3.2.1. Receiving all submitted information and required supporting documentation from the PI.

3.2.2. Determining if the submitted information and supporting documentation is classified as NHSR as defined by federal guidelines.

3.3. Research Compliance Administrator (RCA) is responsible for:

3.3.1. Receiving all submitted information and required supporting documents from the DRC and PI (when applicable).

3.3.2. Drafting and signing (for DRC) the Memorandum of NHSR Determination.

3.3.3. Sending the Memorandum of NHSR Determination to the PI.

3.3.4. Updating the IRB Log Spreadsheet.

3.3.5. Filing all documents and correspondence in the protocol folder.

4. **Procedure**

4.1. Regulatory Review

4.1.1. The Regulatory Review will be conducted by the Director of Research Compliance (DRC) within three business days of receipt of submitted information and required supporting documents from the PI.

4.1.2. The DRC will consult the Human Subjects Regulations Decision Charts to determine if the research falls under the IRB purview.

4.1.3. The DRC will determine the research as Not Human Subjects Research.

4.1.4. After the research has been determined as Not Human Subjects Research, the DRC will send all relevant documents to the RCA to prepare the Memorandum of NHSR Determination.

4.1.5. The RCA will draft, sign (for the DRC) and send the Memorandum of NHSR Determination to the PI.

4.1.6. The RCA will update the IRB Log Spreadsheet.

4.1.7. The RCA will file all documents and correspondence in the protocol folder.

5. **Revision History**

5.1 March 2019, October 2023