TEXAS A&M UNIVERSITY-SAN ANTONIO

IRB IN-OFFICE STANDARD OPERATING PROCEDURE (SOP)

SOP #: 1	Version: 1.0	Effective Date: August 14, 2020
Title: Definitions		
Approved by: Dr. Vijay Golla, Vice Provost		
Signature: Vijay Golla		**Date: August 14, 2020**

1. Purpose

The purpose of this SOP is to establish the definitions followed by the Human Research Protection Program.

2. SOP Statement

2.1. 2018 Requirements: The term "2018 Requirements" refers to the Common Rule as published in the July 19, 2018 edition of the e-Code of Federal Regulations. The 2018 Requirements were original published on January 19, 2017 and further amended on January 22, 2018 and June 19, 2018 Requirements may also be referred to as the "revised Common Rule."

2.2. Pre: 2018 Requirements: The term "pre-2018 Requirements" refers to subpart A of 45 CFR part 46 (i.e., the Common Rule) as published in the 2016 edition of the Code of Federal Regulations. The pre-2018 Requirements were originally promulgated in 1991, and subsequently amended in 2005. The pre-2018 Requirements may also be referred to as the "pre-2018 Common Rule."

2.3. Adverse Event: It can be any unfavorable and unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. It does not necessarily have to have a causal relationship with the research.

2.4. Allegation of Non-Compliance: As yet unproved assertion of Non-Compliance.

2.5. Conflicting Interest: Refer to Texas A&M System Regulation 15.01.03 Financial Conflicts of Interest in Sponsored Research.

2.6. Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews. The terms Designated Reviewer and Expedited Reviewer may be used interchangeably.

2.7. Experienced Reviewer: An IRB member is considered experienced if the IRB chair considers the IRB member to have demonstrated sufficient experience in and knowledge of conducting IRB reviews.

2.8. Expiration Date/Lapsed Date: The first date that the IRB study is no longer approved. The date after the end date of the approval period. The terms expiration date and lapsed date are interchangeably.

2.9. Human Research: Any activity that either:

2.9.1. Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or
2.9.2. Is Research as Defined by USFDA and involves Human Subjects as Defined by USFDA.

2.10. Human Research Protection Program: A collaborative effort between all who develop, conduct, review, approve and facilitate Human Research. It includes institutional leaders, the Institutional Review Board (IRB), researchers, faculty, staff, students and the community.

2.11. Human Subject:

2.10.1 As defined by the Pre-2018 Requirements: A living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or
(2) Information that is both Private Information and Identifiable Information

2.11 Identifiable Information as defined by the Pre-2018 Requirements: Information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associate with the information).

2.12 Intervention:

- As defined by the Pre-2018 Requirements: Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

2.13 Interaction: includes communication or interpersonal contact between investigator and subject.

2.14 IRB Approval: means the determination of the IRB that the research has been reviewed and may conducted at an institution within the constraints set forth by the IRB and by other institutional and regulatory requirements.

2.15 Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2.16 Non-Compliance: The failure to follow the regulations governing human research, the requirements and determinations of the IRB, or the HRPP, University of System Polices rules or procedures.

2.17 Organization/Institutional Official: The Texas A&M University-San Antonio Vice Provost of Research and Graduate Studies.

2.18 Principal Investigator: the individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract or other sponsored project.

2.19 Private Information as defined by the Pre-2018 Requirements: Information about behavior that occurs in 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).

2.20 Protected Health Information: The HIPAA Privacy Rule protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information (PHI)."

2.21 Quorum is defined as one half of the number of regular members plus one. A quorum must be present to approve or disapprove a study.

2.22 Reportable New Information: Information that becomes known during the course of a research study that will need to be reported to the IRB in a timely, meaningful way so that research participants can be protected from avoidable harms. This information may be Unanticipated Problems Involving Risk to Subjects or Others, Non-compliance or other reportable events.

2.23 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

2.24 Standard Operating Procedure (SOP): Instructions and Methods established or prescribed by the Institution to be followed for the performance of designated operations and designated situations.

2.25 Unanticipated Problem Involving Risks to Subjects or Others: Any information, including any incident, experience, or outcome that meets ALL three of the following conditions:

1) Is unexpected (in terms of nature, severity or frequency) given the procedures described in the research protocol documents (e.g., the IRB approved research protocol and informed consent document) and the characteristics of the human subject population being studied;
2) Is related or possibly related to participation in the research (in this instruction, possibly related meant that it is more likely than not, the incident, experience, or outcome was caused by the procedures involved in the research); and
3) Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized, ern if no harm has actually occurred.

3. References

Texas A&M University. Institutional Review Board. Standard Operating Procedures SOP: Definitions. Retrieved August 3, 2020 from:

https://rcb.tamu.edu/humansubjects/forms/HRP001SOPDefinitions.pdf