	SOP: Definitions	
	Section I: Administrative Management	
	Number	Effective Date
	IRB I-001	9/13/2025

1. PURPOSE

1.1. This SOP outlines the definitions followed by the Texas A&M University-Kingsville Institutional Review Board.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. *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 originally published on January 19, 2017, and further amended on January 22, 2018, and again on June 19, 2018, with an institutional compliance date of January 21, 2019. The 2018 Requirements are also referred to as the "revised Common Rule." Further/future amendments may be applicable under this definition.

3.2. *Pre: 2018 Requirements*: The term "pre-2018 Requirements" refers to subpart A of 45 CFR 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 are also referred to as the "pre-2018 Common Rule." The pre-2018 *Common Rule* applies to all studies approve before January 21, 2019.

3.3. *Administrative Reviewer*: Administrative reviewers are designated by the IRB Chair for the following processes:

3.3.1. Verify study closures

3.3.2. Confirmation that modifications are made on protocols given a determination of 'Modifications Required to Secure Approval' by the IRB.

3.4. *Adverse Event*: Any untoward or unfavorable medical occurrence, including any abnormal sign (e.g., abnormal physical exam result or laboratory finding), symptom, or disease, occurring in the same timeframe as the human subject's participation in research, whether or not related to the research. An adverse event may be considered a Serious Adverse Event, described in 3.57.

3.5. *Affiliated IRB Member*: An IRB member who is associated with TAMUK in some way such as being an employee, student, consultant or immediate family member to a person who is affiliated with TAMUK.

3.6. *Allegation of Non-Compliance*: An unproved assertion of Non-Compliance, as defined in 3.42.

3.7. *Alternate IRB Member*: The Department of Health and Human Services (HHS) regulations at 45 CFR 46 do not address the designation of alternate IRB members. However, for many years, the OHRP has permitted organizations submitting IRB registrations to OHRP to identify alternate members for primary members. When reviewing rosters that include alternate members, OHRP assumes that each alternate IRB member has experience, expertise, background, professional competence, and knowledge

comparable to that of the primary IRB member whom the alternate would replace during a convened review.

3.8. *Assurance of Compliance*: (Human Subjects) or *Federalwide Assurance (FWA)*: A written commitment to protect human research subjects and comply with the requirements of the Common Rule submitted to the Office for Human Research Protections (OHRP) within the Department of Health and Human Services (HHS) via their electronic submission system and renewed every five years.

3.9. *Authorization Agreement*: Also known as a Reliance Agreement, is documentation outlining the respective authority, roles, responsibilities, and communication between an institution or organization providing IRB/ethical review and another institution or investigator relying on that review.

3.10. *Certificate of Confidentiality* (COC): A COC is a document issued by a component of HHS pursuant to The Public Health Service Act Section 301(d), 42 U.S.C. 241(d) amended by Section 2012 of the 21st Century Cures Act, Public Law 114-255, meant to protect the privacy of individuals who are subjects of certain specified research activities by authorizing investigators to withhold from all persons not connected with the conduct of such research, the names or other identifying characteristics of such subjects. Persons authorized to protect the privacy of such individuals may not disclose information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

3.11. *Certification*: The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance commitment.

3.12. *Clinical Trial*: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3.13. *Collaborative Study*: A study in which two or more institutions coordinate, with each institution completing a portion(s) of the research activities outlined in a specific protocol. See also 3.59 Single IRB (sIRB).

3.14. *Conflict of Interest/Conflicting Interest*: Refer to TAMUK SOP: Member Review Expectations (IRB SOP II-003).

3.15. *Continuing Non-Compliance*: A pattern of Non-Compliance, as defined in 3.42, that suggests the likelihood that, without intervention, instances of Non-Compliance will recur, a repeated unwillingness to comply, or apparent persistent lack of knowledge of how to comply.

3.16. *Designated Reviewer*: The IRB Chair or an experienced IRB Member designated by the IRB Chair to conduct Non-Committee Reviews, as defined in 3.41. The terms Designated Reviewer and Exempt/Expedited Reviewer (3.17) may be used interchangeably.

3.17. *Exempt/Expedited Reviewer*: The IRB Chair or an experienced IRB Member designated by the IRB Chair to conduct Non-Committee Reviews, as defined in 3.41. The terms Exempt/Expedited Reviewer and Designated Reviewer (3.16) may be used interchangeably.

3.18. *Experienced IRB Member*: An IRB member is considered experienced if they have demonstrated sufficient experience and an understanding of the process of IRB review, as determined by the IRB Chair.

3.19. *Expiration Date/Lapsed Date*: The date after the end date of the approval period. The terms expiration date and lapsed date are used interchangeably.

3.20. *Finding of Non-Compliance*: Non-Compliance confirmation upon examination and verification of evidence. A "finding of non-compliance" can be asserted by a compliance officer, internal auditor, regulatory agency inspector, or any individual authorized to conduct compliance reviews within an organization, who identifies instances where practices or procedures do not adhere to established rules, regulations, or company policies

3.21. *Harm*: Any harm experienced by a subject or other individual, which in the opinion of the investigator is unexpected and probably related to the research procedures. See also: Adverse event (3.4), Serious adverse event (3.57) or an unanticipated problem (3.64).

3.22. *Human Research*: Any activity that either: [1]

3.22.1. Is research as defined by Department of Health and Human Services (HHS) and involves human subjects as Defined by HHS; or

3.22.2. Is research as defined by US Food and Drug Administration (USFDA) and involves human subjects as Defined by USFDA.

3.23. *Human Subject*: A living individual about whom an investigator (whether professional or student) is conducting research and:

3.23.1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

3.23.2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

3.23.3. For the purposes of this definition:

3.23.3.1. *Human Subject as Defined by FDA*: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose person a medical device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

3.24. *Hybrid Policy Requirements*: Includes requirements from both the 2018 (revised) Common Rule and the pre-2018 Common Rule to allow institutional oversight flexibility on certain minimal risk research. Hybrid policy requirements may not be applied to FDA regulated research, federally funded or supported research, or any research determined to be greater than minimal risk. The 2018 Common Rule new elements of informed consent apply to federally funded research.

3.25. *Identifiable Private information:* Information for which the identity of the human subject is or may be readily ascertained by the investigator or associated with the information.

3.26. *Identifiable biospecimen*: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator.

3.27. *Interaction*: Includes communication or interpersonal contact between investigator and subject.

3.28. *Immediate Family*: Spouse, domestic partner, and dependent children of a human research participant.

3.29. *Informed Consent:* A voluntary agreement by a participant to take part in a study after receiving complete and understandable information about the study's purpose, procedures, potential risks and benefits, and their right to withdraw at any time, ensuring they can make an informed decision about participation without coercion or undue influence.

3.30. *Institutional Official*: The individual at Texas A&M University-Kingsville responsible for ensuring the institution complies with all regulations regarding human subject research, including overseeing the Institutional Review Board (IRB), guaranteeing proper ethical conduct of studies, and acting as the primary point of contact for regulatory agencies regarding research activities within the institution.

3.31. *Institutional Profile*: A record of information an institution keeps about another collaborating institution/organization for one or more Collaborative Studies or Multi-Site Studies.

3.32. *Institutional Review Board*: The regulatory body specifically created to review human research studies to ensure that they protect the rights and welfare of human research participants.

3.33. *Intervention*: Includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

3.34. *Investigation*: A searching inquiry for facts; detailed or careful examination of evidence.

3.35. *IRB Chair*: This individual at Texas A&M University-Kingsville that presides over the Institutional Review Board. This individual leads meetings, oversees reviews, and ensures that research projects are approved in compliance with regulations and ethical principles.

3.36. *IRB Approval*: The determination of the IRB after review that the study may be conducted at an institution within the constraints set forth by the IRB and by other institutional and regulatory requirements.

3.37. *Legally Authorized Representative (LAR)*: An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

3.37.1. If there is no applicable law addressing this issue, Legally Authorized Representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject regarding the subject's participation in the procedure(s) involved in the research.

3.38. *Minimal Risk*: The probability and magnitude of harm or discomfort anticipated in the research 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], as determined by the IRB Chair, board member(s), or designees.

3.38.1. For research involving prisoners, minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of healthy persons.

3.38.2. When following the US Department of Defense regulations, the definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall not be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, when conducting

research involving human participants from a special population, the risks should not be assessed based upon the inherent risks of their occupation (e.g., emergency responders, pilots, soldiers in combat) or medical condition (frequent medical testing or chronic pain).

3.39. *Multi-Site Study*: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol (see also 3.59).

3.40. *Non-Affiliated IRB Member*: Is a person who is not associated with TAMUK and who is not an immediate family member to a person who is affiliated with TAMUK.

3.41. *Non-Committee Review*: A review completed by a member of the Office of Research and Innovation assigned by the IRB Chair, to include any of the following:

3.41.1. Determination of whether an activity is Human Research.

3.41.2. Determination of whether Human Research is exempt from regulation.

3.41.3. Limited IRB review to make the determination as required by §46.111(a)(7).

3.41.4. Reviews of non-exempt research using the expedited procedure.

3.41.5. Determinations of which human subjects can continue in expired research.

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

3.42.1. In the case of research funded or conducted by the US Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with US Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements.

3.43. *Non-Scientist*: IRB members will be considered “non-scientists” when their training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline.

3.44. *Participating Site*: An institution that participates in a Single IRB study.

3.45. *Private Information*: Information about behavior that occurs in a 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 that the individual can reasonably expect will not be made public (e.g., a medical record).

3.46. *Prisoner*: Any individual involuntarily confined or detained. The term is intended to encompass individuals sentenced under a criminal or civil statute; individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; and individuals detained pending arraignment, trial, or sentencing.

3.46.1. For US Department of Defense (DOD) research, the term includes military personnel in either civilian or military custody.

3.47. *Protocol Exception*: A one-time, intentional action or process that deviates from the approved protocol. Protocol Exceptions are generally for a single subject in the context of medical research (e.g., the subject does not meet eligibility criteria or is allergic to one of the medications provided as supportive care). IRB approval of the Protocol Exception is required prior to implementation by the study team. Approval of a Protocol Exception does not affect the Approval Date or Expiration Date of the protocol.

3.48. *Protected Health Information*: The HIPAA Privacy Rule[3] 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)." Individually identifiable health information is information, including demographic data, that relates to:

3.48.1. The individual's past, present or future physical or mental health or condition,

3.48.2. The provision of health care to the individual, or

3.48.3. The past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. Individually identifiable health information includes the following:

3.48.3.1. Names

3.48.3.2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes. Except for the initial three digits of the ZIP code, according to the current publicly available data from the Bureau of the Census, if:

3.48.3.2.1. The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and

3.48.3.2.2. The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000

3.48.3.3. All elements of dates (except year) that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

3.48.3.4. Telephone numbers

3.48.3.5. Fax numbers

3.48.3.6. Email addresses

3.48.3.7. Social security numbers

3.48.3.8. Medical record numbers

3.48.3.9. Health plan beneficiary numbers

3.48.3.10. Account numbers

3.48.3.11. Certificate/license numbers

3.48.3.12. Vehicle identifiers and serial numbers, including license plate numbers

3.48.3.13. Device identifiers and serial numbers

3.48.3.14. Web Universal Resource Locators (URLs)

3.48.3.15. Internet Protocol (IP) addresses

3.48.3.16. Biometric identifiers, including finger and voice prints

3.48.3.17. Full-face photographs and any comparable images

3.48.3.18. Any other unique identifying number, characteristic, or code, except as permitted by paragraph (3.48.3.3) of this section.

3.49. *Public Health Authority*: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, which is responsible for public health matters as part of its official mandate.

3.50. *Related to the Research*: A financial interest is Related to the Research when the interest is in:

3.50.1. A sponsor of the research;

3.50.2. A competitor of the sponsor of the research;

3.50.3. A product or service being tested; or

3.50.4. A competitor of the product or service being tested.

3.51. *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 (3.64), Allegation of Non-compliance (3.6), or other reportable events.

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

3.52.1. DOJ regulations state that implementation of Bureau of Prisons programmatic or operational initiatives made through pilot projects do not meet this definition.

3.52.2. The following activities are not considered Research as Defined by HHS:

3.52.2.1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

3.52.2.2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3.52.2.3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

3.52.2.4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

3.52.2.5. Secondary research involving non-identifiable newborn screening blood spots.

3.53. *Research as Defined by FDA*: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:

3.53.1. Must meet the requirements for prior submission to the US Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;

3.53.2. Must meet the requirements for prior submission to the US Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR

3.53.3. Any activity the results of which are intended to be later submitted to, or held for inspection by, the US Food and Drug Administration as part of an application for a research or marketing permit.

3.54. *Restricted*: Applies to investigators who are delinquent in meeting IRB requirements and are subject to restrictions on processing new applications until all IRB requirements are met.

3.55. *Risk*: Information that indicates a new or increased risk or a new safety issue. For example: safety monitoring report, drug or device changes, interim analysis, or investigator finding.

3.56. *Scientist*: IRB members will be considered "scientists" when their training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline.

3.57. *Serious Adverse Event*: Any adverse event that: (1) Results in death, (2) Is life threatening, or places the participant at immediate risk of death from the event as it occurred, (3) Requires or prolongs hospitalization, (4) Causes persistent or significant disability or incapacity, (5) Results in congenital anomalies or birth defects, or (6) Is another condition which investigators judge to represent significant hazards.

3.58. *Serious Non-Compliance*: Non-Compliance such that the failure to comply could adversely affect the rights, safety, or welfare of a subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

3.58.1. For US Department of Defense (DOD) research, Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with US Department of Defense (DOD) Instruction 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

3.59. *Single IRB (sIRB) Study*: A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution's/organization's IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the participating sites.

3.60. *Standard Operating Procedure (SOP)*: Instructions and methods established or prescribed by the institution to be followed for the performance of designated operations or designated situations.

3.61. *Suspension of IRB Approval*: An action of the IRB, IRB Designee, Institutional Official, or designee of the Institutional Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval (3.63). Suspended studies are subject to continuing review.

3.62. *Systematic*: Having or involving a system, method, or plan.

3.63. *Termination of IRB Approval*: An action of the IRB, IRB Designee, Institutional Official, or designee of the Institutional Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

3.64. *Unanticipated Problem Involving Risks to Subjects or Others*: Any information that is (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm.

3.65. For Department of Defense (DOD) research, the term *Unanticipated Problem Involving Risks to Subjects or Others* includes any incident, experience, or outcome that meets ALL three of the following conditions:

3.65.1. 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; is related or possibly related to participation in the research (in this instruction, possibly related means that it is more likely than not, the incident, experience, or outcome was caused by the procedures involved in the research); and 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, even if no harm has actually occurred.

3.66. *Un-reviewed Change*: Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.

3.67. *Written, or in writing*: refers to writing on a tangible medium (e.g., paper) or in an electronic format.

4. RESPONSIBILITIES

4.1. Individuals using policies and procedures are to consult this SOP for the definitions of underlined and related terms.

5. PROCEDURES

5.1. None

6. REFERENCES

6.1. 45 CFR §46.102

6.2. 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3

7. FOOTNOTES

7.1. The terms “Human Subject Research,” “Research Involving Human Subjects,” “Clinical Research,” “Clinical Investigation,” “Clinical Study” and similar phrases are considered to be synonyms for the term Human Research.

7.2. The phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” should not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks

encountered in their environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

7.3. The term “HIPAA Privacy Rule” establishes national standards to protect individuals' medical records and other individually identifiable health information (collectively defined as “protected health information”) and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The “HIPPA Privacy Rule requires appropriate safeguards to protect the privacy of protected health information and sets limits and conditions on the uses and disclosures that may be made of such information without an individual’s authorization. The HIPAA Privacy Rule is located at 45 CFR Part 160 and Subparts A and E of Part 164.

Approved by: 

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