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1 PURPOSE


1.1 This SOP establishes the definitions followed by the human research protection program.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from 5/30/2017 version
- 2.2 Revised from the 6/30/2019 version
- 2.3


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 June 19, 2018. The 2018 Requirements may also be referred to as the "revised Common Rule."
- 3.2 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."
- 3.3 Administrative Reviewer: Experienced HRPP personnel designated by the HRPP Director to make Non-Human Subjects Determinations, Exemption Determinations, Not Engaged Determinations and perform other administrative reviews. Administrative reviewers are also designated the by the IRB Chair to verify study closures and responsive materials on protocols given a determination of 'Modifications Required to Secure Approval' by the IRB.
- 3.4 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.
- 3.5 Allegation of Non-Compliance: An unproved assertion of Non-Compliance.
- 3.6 Assurance of Compliance (Human Subjects) or Federalwide Assurance (FWA): An assurance is written commitment to protect human research subjects and comply with the requirements of the Common Rule.
- 3.7 Authorization Agreement: Also called a Reliance Agreement, is the agreement that documents respective authorities, roles and responsibilities, and communication between one institution/organization providing the IRB/ethical review and another institution or investigator that is relying on the IRB/ethical review.
- 3.8 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, 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 so 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.
- 3.9 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.
- 3.10 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.
- 3.11 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.
- 3.12 Conflicting Interest: Refer to Texas A&M System Regulation 15.01.03 Financial Conflicts of Interest in Sponsored Research and University Rule 15.01.01.M1.

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- 3.13 Continuing Non-Compliance: A pattern of Non-Compliance that suggests the likelihood that without intervention, the instances of Non-Compliance will recur, a repeated unwillingness to comply, or an apparent persistent lack of knowledge of how to comply.
- 3.14 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.
- 3.15 Expedited Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews. The terms Expedited Reviewer and Designated Reviewer may be used interchangeably.
- 3.16 Experienced IRB Member: An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.
- 3.17 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 used interchangeably.
- 3.18 Finding of Non-Compliance: Non-Compliance in fact.
- 3.19 Human Research: Any activity that either:¹
- 3.19.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or
 - 3.19.2 Is Research as Defined by FDA and involves Human Subjects as Defined by USFDA.
- 3.20 Human Subject:
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.
- 3.20.1 as defined by the 2018 Requirements or Hybrid Policy: A living individual about whom an investigator (whether professional or student) conducting research:
- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purposes of this definition:
- 3.20.2 Intervention:
 - 3.20.3 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.
 - 3.20.4 as defined by the 2018 Requirements or Hybrid Policy: 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.
 - 3.20.5 Interaction: includes communication or interpersonal contact between investigator and subject.
 - 3.20.6 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 (for example, a medical record).
 - 3.20.7 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 associated with the information).

¹ The terms "Human Subject Research," "Research Involving Human Subjects," "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.

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3.20.8 Identifiable Private information as defined by the 2018 Requirements or Hybrid Policy: Information for which the identity of the human subject is or may be readily ascertained by the investigator or associated with the information.

3.20.9 Identifiable biospecimen: a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

3.21 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 specimen 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.

3.22 Hybrid Policy Requirements: Includes requirements from both the 2018 (revised) Common Rule and the pre-2018 Common Rule to allow institutional oversight flexibility on unregulated minimal risk research. This policy excludes FDA regulated research, federally funded or supported research and any research determined to be greater than minimal risk. The 2018 Common Rule new elements of informed consent apply to federally funded research, only. Each HRPP standard operating procedure addresses the hybrid policy as applicable.

3.23 Immediate Family: The immediate family of a Faculty member or Staff member includes spouse, domestic partner, and dependent children.

3.24 Institutional Official / Organizational Official (IO/OO): The Texas A&M University Vice President for Research. The terms Institution and Organization are used interchangeably.

3.24.1 The Institutional Official (IO): Term utilized by DHHS.

3.24.1.1 The Institutional Official (IO) is the individual authorized to act for the university and to assume on behalf of the university, obligates the institution to the Terms of the Assurance and is named on the Federalwide Assurance (FWA)². The IO is responsible for ensuring the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects.

3.24.2 Organizational Official (OO): Term utilized by AAHRPP.

3.24.2.1 An identified, knowledgeable leader of the HRPP who is responsible for the program and has the authority to implement the program. This individual may rely on others for the interpretation of laws, regulations, codes, and guidance and the day-to-day operations of the HRPP, and should have a basic understanding of the relevant laws, codes, regulations and guidance that govern research involving human participants, the responsibilities of an organizational official, and the responsibilities of the IRB or EC and researchers and research staff in protecting research participants. This individual should be directly involved in the allocation of resources to the HRPP. In some circumstances, more than one individual serves in this capacity³.

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


3.26 Investigation: A searching inquiry for facts; detailed or careful examination.

3.27 Legally Authorized Representative (LAR): An individual or 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.

3.27.1 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-

² <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/index.html>

³ AAHRPP Evaluation Instrument (2018-10-15); <http://www.aahrpp.org/apply/web-document-library/domain-i-organization>

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research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

3.27.2 See HRP-013 - SOP - Legally Authorized Representatives, Children, and Guardians for who may serve as a Legally Authorized Representative at this institution.

3.28 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.⁴

3.28.1 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.

3.28.2 When following 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, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

3.29 Multi-Site Study: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.

3.30 Non-Committee Review: Any of the following:

- 3.30.1 Determination of whether an activity is Human Research.
- 3.30.2 Determination of whether Human Research is exempt from regulation.
- 3.30.3 Limited IRB review to make the determination required by §46.111(a)(7).
- 3.30.4 Reviews of non-exempt research using the expedited procedure.
- 3.30.5 Determinations of which subjects can continue in expired research.
- 3.30.6

3.31 Non-Compliance: Failure to follow the regulations governing human research, the requirements and determinations of the IRB, or the HRPP, University or System Policies rules or procedures.

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


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

3.33 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.


3.33.1 For Department of Defense (USDOD) research the term includes military personnel in either civilian or military custody.

3.34 Protocol Exception: a one-time, intentional action or process that departs 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.

⁴ 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).


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- 3.35 Related to the Research: A financial interest is Related to the Research when the interest is in:
- 3.35.1 A sponsor of the research;
 - 3.35.2 A competitor of the sponsor of the research;
 - 3.35.3 A product or service being tested; or
 - 3.35.4 A competitor of the product or service being tested.
- 3.36 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)." Individually identifiable health information is information, including demographic data, that relates to:
- o the individual's past, present or future physical or mental health or condition,
 - o the provision of health care to the individual, or
 - o 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:
- (A) Names
 - (B) 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 if, according to the current publicly available data from the Bureau of the Census:
 - (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
 - (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
 - (C) All elements of dates (except year) for dates 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
 - (D) Telephone numbers
 - (E) Fax numbers
 - (F) Email addresses
 - (G) Social security numbers
 - (H) Medical record numbers
 - (I) Health plan beneficiary numbers
 - (J) Account numbers
 - (K) Certificate/license numbers
 - (L) Vehicle identifiers and serial numbers, including license plate numbers
 - (
 - M) Device identifiers and serial numbers
 - (N) Web Universal Resource Locators (URLs)
 - (O) Internet Protocol (IP) addresses
 - (P) Biometric identifiers, including finger and voice prints
 - (Q) Full-face photographs and any comparable images
 - (R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section [Paragraph (c) is presented below in the section "Re-identification"]; and
- 3.37 Public Health Authority: means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or 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, that is responsible for public health matters as part of its official mandate.

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- 3.38 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.
- 3.39 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- 3.39.1 DOJ regulations state that implementation of Bureau of Prisons programmatic or operational initiative made through pilot projects do not meet this definition.⁵
- 3.39.2 The following activities are not considered Research as Defined by DHHS:
- (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.
 - (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) 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.
 - (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
 - (5) Secondary research involving non-identifiable newborn screening blood spots.
- 3.40 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:
- 3.40.1 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;
 - 3.40.2 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
 - 3.40.3 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.
- 3.41 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..
- 3.42 Serious Non-Compliance: Non-Compliance such that the failure to comply could adversely affects 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.
- 3.42.1 For Department of Defense (USDOD) research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (USDOD) 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

⁵ https://www.bop.gov/policy/progstat/1070_007.pdf

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human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

- 3.43 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.
- 3.44 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.
- 3.45 Suspension of IRB Approval: An action of the IRB, IRB Designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.
- 3.46 Systematic: Having or involving a system, method, or plan.
- 3.47 Termination of IRB Approval: An action of the IRB, IRB Designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.
- 3.48 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.
- 3.49
- 3.50 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:
 - 3.50.1 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.
- 3.51 Written, or in writing: refers to writing on a tangible medium (e.g., paper) or in an electronic format.

4 RESPONSIBILITIES

- 4.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.
- 4.2 Individuals using policies and procedures are to consult this SOP for the definitions of double underlined terms.

5 PROCEDURE

- 5.1 None.

6 MATERIALS

- 6.1 HRP-013 - SOP - LARs, Children, and Guardians

7 REFERENCES

- 7.1 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)
- 7.2 45 CFR §46.102.
- 7.3 AAHRPP elements I.1.A, I.1.E, I.5.D, I.6.B, I.7.C, I-9, II.1.D, II.2.A, II.2.B, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.4.A, III.1.B, III.2.D



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