Human Research Protection Program
&
Institutional Review Board
Handbook

Human Research Protection Program & Institutional Review Board HANDBOOK

Approval and Document Control

Approval

This Human Research Protection Program and Institutional Review Board Handbook establishes the institutional policies, written procedures, responsibilities, and operational requirements governing the protection of human research participants at The University of Texas Rio Grande Valley. Approval of this handbook by the Institutional Official authorizes its implementation as the governing handbook for the UTRGV Human Research Protection Program and Institutional Review Board.

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PART I. HRPP FOUNDATION

Human Research Protection Program & Institutional Review Board HANDBOOK

Section 1. Overview

This handbook describes the internal policies and procedures and operational framework governing the **Institutional Review Board (IRB)** and Human Research Protection Program (HRPP) at The University of Texas Rio Grande Valley (UTRGV). The handbook applies to all **human subjects research (HSR)** conducted under the auspices of The University of Texas Rio Grande Valley (UTRGV), regardless of funding source, location, or investigator status, and includes **research** conducted by faculty, staff, students, and affiliated personnel. All such research must comply with applicable federal and state laws and regulations, as well as institutional policy, including but not limited to *HOP ADM-07-104, Human Subjects Research*.

The HRPP maintains the written procedures as required by U.S. Department of Health and Human Services (DHHS) 46 CFR 46.108(a)(3)-(4), and **U.S. Food and Drug Administration (FDA)** 21 CFR 56.108(a).

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Section 2. Abbreviations

AE – Adverse Event(s)
CDC – Centers for Disease Control and Prevention
CFR – Code of Federal Regulations
CIP – Certified IRB Professional
CITI – Collaborative Institutional Training Initiative
CoC – Certificate of Confidentiality
COI – Conflict of Interest
CR – Continuing Review
ED – U.S. Department of Education
DHHS – U.S. Department of Health and Human Services
DOW – U.S. Department of War
DSMB – Data and Safety Monitoring Board
DSMP – Data and Safety Monitoring Plan
DTUA – Data Transfer and Use Agreement
EHSRM – Environmental Health, Safety & Risk Management
FDA – Food and Drug Administration
FERPA – Family Educational Rights and Privacy Act
FWA – Federalwide Assurance
GCP – Good Clinical Practice
HIPAA – Health Insurance Portability and Accountability Act
HPA – Human Protections Administrator
HOP - Handbook of Operating Procedures
HRPP – Human Research Protection Program
HSR – Human Subjects Research
HUD – Humanitarian Use Device
IBC – Institutional Biosafety Committee
IDE – Investigational Device Exemption
IND – Investigational New Drug Application
IO – Institutional Official
IRB – Institutional Review Board
LAR – Legally Authorized Representative
LDS – Limited Data Set
LSGD – Large Scale Genomic Data
MTA – Material Transfer Agreement
NHSR – Non-Human Subjects Research

NIH – National Institutes of Health
OHRP – Office for Human Research Protections
OCR – Office of Clinical Research
ORC – Office of Research Compliance
PAM – Post Approval Monitoring
PHI – Protected Health Information
PHS – U.S. Public Health Service
PI – Principal Investigator
PII – Personally Identifiable Information
PPRA – Protection of Pupil Rights Amendment
RCIA – Office of Research Contracts and Industry Agreements
RCR – Responsible Conduct of Research
RIO – Research Integrity Officer
SAE – Serious Adverse Event
SOP – Standard Operating Procedures
UP – Unanticipated Problems
UTRGV – The University of Texas Rio Grande Valley
UTS – University of Texas System

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Section 3. Glossary

Accrual – see "enrollment."

Adverse Event (AE) – any untoward or unfavorable medical occurrence in a research participant, including abnormal signs, symptoms, or diseases, regardless of attribution to the research.

Alternate Member – an IRB member designated to substitute for a specific primary IRB member when the primary member is unavailable or recused. The alternate member should have comparable expertise and may vote only when serving in place of the designated member.

Ancillary Review – review conducted by institutional units other than the Institutional Review Board (IRB) to assess specific regulatory, safety, or administrative aspects of a study (e.g., biosafety, conflict of interest, data privacy, contracts).

Anonymous – the inability to readily ascertain the identity of a subject, either directly or through information.

Anonymous Data – information that is collected or that an individual has disclosed in a study that has no identifiers linked to the participants and therefore cannot in any way be traced to the participant. An example would be survey research that does not ask for participants' names or any other form of personal identification.

Approved – a study that has been approved by the Institutional Review Board (IRB) when all components of the criteria for approval are met, in addition to any IRB requirements.

Assent – a child's affirmative, active agreement to participate in research or clinical investigation. Silence, lack of resistance, or a mere failure to object may not be construed as assent.

Biologics – products such as vaccines, blood, and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues.

Code of Federal Regulations (CFR) – the Code of Federal Regulations (CFR) is the official codification of federal rules published by federal government agencies, including but not limited to those used in order to protect human research subjects.

Child/Children – persons who have not attained the legal age for consent to treatments or procedures involved in research or clinical investigations. In Texas, where federal regulations and state law both apply, individuals under the age of 18 are considered to meet

the definition of children. For research conducted outside Texas, children are defined under the applicable law of the jurisdiction in which the research or clinical investigations will occur.

Clinical Investigation – as defined by the Food and Drug Administration (FDA) any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies (FDA, CFR - Code of Federal Regulations Title 21, n.d.).

Clinical Trials – a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (NIH, n.d.).

Coercion – an overt or implicit threat of harm that is intentionally presented by one person to another in order to obtain compliance.

Common Rule – refers to the general rule from the Department of Health & Human Services (DHHS), on the protection of human subjects in research, codified at 45 CFR Part 46, Subpart A.

Confidentiality – regarding research, confidentiality is the agreement that information related to human subjects is protected and not disclosed to others without a need to know for research purposes or to the extent required by law.

Conflict of Interest – any situation in which financial or personal obligations may compromise, or present the appearance of compromising an individual or group's professional judgement in conducting, reviewing, or reporting research.

Convened IRB Meeting – a meeting of the Institutional Review Board (IRB) at which a quorum of voting members is present, including at least one member whose primary concerns are in nonscientific areas, for the purpose of conducting initial or continuing review of research and other business requiring review by the full board.

Covered Family Member – includes: (1) a spouse; (2) a dependent child or stepchild or other dependent, for purpose of determining federal income tax liability during the period covered by the disclosure statement; and (3) a related or non-related, unmarried adult who resides in the same household as the researcher and with whom the researcher is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investment. If the researcher is in doubt whether an individual is a family member, the researcher should resolve the doubt in favor of disclosure. In disclosing

financial interest, the interest of any legal entity, including a foundation or a trust, that is controlled or directed by the researcher or by the researcher and a covered family member, is considered to be the interest of the researcher or family member as if the separate legal entity did not exist.

Data and Safety Monitoring Board (DSMB) - an independent committee responsible for reviewing accumulated research data to ensure the safety of participants, the validity and integrity of study data, and the ethical conduct of the research. The DSMB may recommend that a study continue as planned, be modified, temporarily suspended, or terminated based on its assessment of safety, efficacy, or other study-related concerns.

Data and Safety Monitoring Plan (DSMP) – a document that describes procedures for monitoring participant safety and the integrity of research data during a study.

De-Identified – information or data where direct identifiers such as name, address, and other identifying information have been removed. In common use, the term refers to data where it may still be possible to identify individuals by inference or through codes held by the investigator or third party. Therefore, data that is de-identified may not be anonymous because it may still permit at least probabilistic identification when analyzed in conjunction with other datasets.

Deception – in the context of research, deception means intentionally providing false information or misleading research subjects to establish false beliefs about a key aspect of the study. Giving incomplete disclosures or intentionally withholding aspects of the study are also forms of deception.

Designated Reviewer – an Institutional Review Board (IRB) voting member designated by the Office of Research Compliance on behalf of the IRB chair to review expedited studies, exempt limited reviews, or reviewer assignments for convened IRB reviews based on the member's qualifications, experience, and relevant expertise.

Disapproved – an Institutional Review Board (IRB) determination that a research study does not meet the regulatory criteria for approval.

Emergency Research Exception - An exception from informed consent for emergency research permits enrollment into certain emergency research studies without prospective informed consent when subjects have life-threatening conditions, available treatments are unproven or unsatisfactory, obtaining consent is not feasible because of the participant's medical condition and limited therapeutic window, and all additional regulatory requirements are satisfied.

Emergency Use - the use of an investigational test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available and there is insufficient time to obtain IRB approval before treatment must begin. Under FDA regulations, emergency use is generally limited to a single use and must be reported to the IRB as soon as possible.

Engaged in human subjects' research – refers to when individuals are involved in research in such a way that their involvement impacts the outcome and conduct of the research. This is further defined by the Office of Human Research Protection (OHRP) in their "Engagement of Institutions in Human Subjects Research" guidance document.

Enrollment – in the context of research, enrollment includes all subjects intended to be included in a study, including screen failures and withdrawals. (Example: The investigator has a target enrollment of 100 and expects 75 to be screen failures, so the study will accrue 25.)

- **Accrual** – refers to the number of subjects who have completed or are actively in the process of completing a research study.
- **Withdrawal –** with regard to a participant who has been enrolled, means a state in which research activity and/or data collection is suspended or lost with regard to that specific participant. The participant can withdraw their consent willingly when no longer able or wanting to participate in the research for any reason. An investigator can also withdraw a participant for ongoing non-compliance or if continuing the research would expose the participant to an unacceptable level of risk.
- **Screen Failure** – refers to any individual who undergoes screening procedures for eligibility but is not enrolled because they do not meet one or more protocol-specified eligibility criteria or other enrollment requirements.

Exempt Study (ies) – research activities in which the only involvement of human subjects will be in one or more of the exempt categories defined by the federal regulation as per 45 CFR 46.104. Exempt studies are exempt from some sections of the federal regulations but are still subject to UTRGV policies and procedures.

Exempt Limited Review Study (ies) – Research that qualifies for an exemption under 45 CFR 46.104(d) and requires a limited IRB review of specified privacy and confidentiality protections before the exemption determination can be granted.

Expanded Access (Compassionate Use) - the use of an investigational drug, biologic, or medical device outside of a clinical trial to diagnose, monitor, or treat a patient with a serious or immediately life-threatening disease or condition when no comparable or satisfactory alternative therapy is available.

Expedited Study (ies) – research activities that involve minimal risk to participants but do not fulfill the criteria for Exemption study categories. To be an expedited study, the research must meet one of the expedited criteria as defined by the Office for Human Research Protections (OHRP; 45 CFR 46.110) or the Food and Drug Administration (FDA; 21 CFR 56.110).

Food and Drug Administration (FDA) - the Food and Drug Administration (FDA) is a federal agency that is responsible for protecting public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products, and

medical devices.

Family Education Rights and Privacy Act (FERPA) - a federal law that ensures the privacy of student education records.

Federalwide Assurance (FWA) – a formal declaration of an institution's commitment to the U.S. government that it will comply with Federal regulations for the protection of human subjects participating in research. This assurance is required for any institution that engages in human subjects research conducted or supported by the Department of Health Human Services (DHHS) or other federal agencies that have adopted the common rule.

Full Board Review – research activities that place human subjects at more than minimal risk or research studies that are deferred to the full board by an expedited reviewer.

Health Insurance Portability and Accountability Act (HIPAA) - a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge (45 CFR Part 160 and Subparts A and E of Part 164).

Human Subject (also known as research study participant) – see *HOP ADM-07-104, Human Subjects Research*.

Human Subjects Research – see *HOP ADM-07-104, Human Subjects Research*.

Informed Consent – the voluntary agreement of an informed and competent individual, or their legally authorized representative (LAR), to participate in a study. The informed consent process is generally documented through an IRB-approved informed consent form unless otherwise approved by the IRB.

Informed Consent Process - the ongoing exchange of information between the investigator and the prospective participant (or legally authorized representative) that begins before enrollment and continues throughout participation. Its purpose is to facilitate the individual's understanding of the research and allow a voluntary decision about participation

Investigational Device Exemption (IDE) – is a regulatory submission to the Food and Drug Administration (FDA) that allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data.

Investigational New Drug Application (IND) – is a request to the Food and Drug Administration (FDA) authorization to administer an investigational drug to humans.

Investigator - see *HOP ADM-07-104, Human Subjects Research*.

Institutional Official (IO) – see *HOP ADM-07-104, Human Subjects Research*.

Institutional Review Board (IRB) – an independent committee that protects the rights of human subjects who participate in research studies by reviewing and approving all research studies to ensure they fall within ethical guidelines, federal regulation requirements, and UTRGV policies and procedures.

Minimal Risk – refers to the probability and magnitude of harm or discomfort anticipated in the research that is no greater than in and of themselves those ordinarily encountered in daily life or during the performance of a routine physical or psychological examination or test.

Minutes - a written record of the events, responses, and decisions that occurred during a convened Institutional Review Board (IRB) meeting.

Non-Compliance – lack of adherence to applicable law, regulation, policies, procedures, requirements, or Institutional Review Board (IRB) determinations for conducting human subjects research, including but not limited to approved IRB protocols. Noncompliance can be classified as serious, continuing, and nonserious. Serious typically involves risks to participants, continuing is ongoing noncompliance of any magnitude, and nonserious is inconsistent with policy or procedure, but little to no risk to participants.

Legally Authorized Representative (LAR) – under the Department of Health and Human Services (DHHS) regulations, the term Legally Authorized Representative means 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 procedures involved in the research study.

Limited Data Set (LDS) - protected health information (PHI) from which specified direct identifiers of the individual and relatives, employers, or household members have been removed, but which may retain certain elements such as dates and some geographic information. It may be used or disclosed for research, public health, or health care operations under a Data Transfer and Use Agreement (DTUA) or similar agreement.

Personally Identifiable Information (PII) - HHS defines personally identifiable information as information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual.

Protected Health Information (PHI) – individually identifiable health information held or transmitted by a HIPAA-covered entity in any form, electronic, paper, or oral.

Post Approval Monitoring (PAM) – institutional oversight activities conducted after Institutional Review Board (IRB) approval to assess compliance with approved study, regulatory requirements, IRB determinations, and institutional requirements.

Primary Reviewer – an Institutional Review Board (IRB) member responsible for presenting a study for discussion at the Institutional Review Board convened meeting.

Principal Investigator (PI) – an individual who is affiliated with The University of Texas Rio Grande Valley (UTRGV) through employment, a contract, or a subcontract, and who serves as the responsible leader of the research team, with primary responsibility for the overall design, conduct, integrity, and regulatory compliance of a research study involving human subjects. The PI is ultimately accountable for ensuring that all research activities are conducted in accordance with applicable laws, regulations, institutional policies, and Institutional Review Board (IRB)

approved study. For research led by trainees, a Faculty Advisor PI must be designated to provide oversight and guidance. The Faculty Advisor PI retains responsibility for assuring the proper conduct of the study and compliance with all regulatory and institutional requirements.

Prompt reporting - reporting as soon as sufficient information is available to permit assessment of the event and typically no later than five (5) business days after identification of the event unless another regulatory timeframe applies.

Protection of Pupil Rights Amendment (PPRA) – federal law that grants parents the right to review research activities involving sensitive topics such as political affiliations, mental/psychological problems, sexual behavior, illegal/self-incriminating behavior, or religious practices prior to granting permission to their children's participation in research. PPRA applies to schools that receive funding from the Department of Education (ED) or research funded in whole or in part by ED. Human subjects research where PPRA applies cannot require waiver of parental permission.

Protocol Deviation – an excursion from the approved protocol.

Quality Assurance (QA) – planned and systematic activities within the HRPP to ensure that processes and research oversight comply with regulatory requirements, institutional policies, and ethical standards.

Quorum – the minimum number of Institutional Review Board (IRB) voting members who must be present at an IRB meeting to legally conduct business. To constitute a quorum, more than half of the IRB voting members must be present, with at least one member whose primary concern is non-scientific.

Reportable Event – any incident, experience, or outcome that must be reported to the IRB or other oversight entities in accordance with applicable regulations (e.g., 45 CFR 46; 21 CFR 56), institutional policy, or sponsor requirements. Reportable events include, but are not limited to, unanticipated problems, serious or continuing noncompliance, certain protocol deviations, and IRB actions such as suspension or termination.

Research - see *HOP ADM-07-104, Human Subjects Research*.

Research Site – a location where research is being conducted.

Screen Failure - see “enrollment.”

Secondary Reviewer – An Institutional Review Board (IRB) member assigned to review the study materials in support of the primary reviewer. The secondary reviewer provides an additional perspective, identifies questions or concerns, and contributes to the convened IRB’s discussion and evaluation of the study.

Serious Adverse Event (SAE) – An adverse event that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or

significant disability or incapacity, causes a congenital anomaly or birth defect, or requires intervention to prevent one of these outcomes.

Short Form (Informed Consent Document) – An IRB-approved consent document stating that the required elements of informed consent have been presented orally to a prospective participant or legally authorized representative in a language understandable to them. The short form consent process requires a witness, an IRB-approved written summary of the information presented, and provision of signed copies to the participant. This process is distinct from simplified consent materials or information sheets used in exempt research.

Sponsor – person or entity that funds a study.

Unaffiliated IRB Member – an Institutional Review Board (IRB) member who has no affiliation with UTRGV, other than with the IRB, and whose immediate family members are not affiliated with UTRGV. Immediate family includes a spouse or dependent children. Retirees from UTRGV are eligible to serve as unaffiliated members.

Unanticipated problem - an incident, experience, or outcome that is unexpected, related or possibly related to participation in the research, and suggests that the research places participants or others at a greater risk of harm than previously known or recognized, consistent with 45 CFR 46 and 21 CFR 56.

Unforeseen Events or Emergency Situations – events beyond UTRGV's control, such as natural disasters, civil unrest, public health emergencies, or institutional closures, that may disrupt IRB operations or affect the conduct, oversight, or continuation of human subjects research

Withdrawal – see "enrollment".

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Section 4. Ethical Principles and Regulatory Framework

The University of Texas Rio Grande Valley (UTRGV) Human Research Protection Program (HRPP) and **Institutional Review Board (IRB)** operate under the ethical principles outlined in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Nuremberg Code, and Declaration of Helsinki. The UTRGV HRPP also follows all applicable U.S. Department of Health and Human Services (DHHS) regulations and other requirements described below.

4.1 Ethical Principles

a) The Belmont Report

The Belmont Report identified three basic ethical principles related to **human subjects research (HSR)**: respect for persons, beneficence, and justice. These principles remain as the foundation for the ethical conduct of **research** involving **human subjects**.

- Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. This principle underlies the need to obtain **informed consent**.
- Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle supports the need to engage in a risk/benefit analysis and to minimize risks.
- Justice requires that the benefits and burdens of research be distributed fairly. This principle guides the equitable selection of research participants.

b) The Nuremberg Code and Declaration of Helsinki

The Nuremberg Code and the Declaration of Helsinki are foundational ethical frameworks that guide the conduct of research involving human participants. These documents established key principles, including voluntary informed consent, minimization of risk, protection of participant rights and welfare, and independent ethical review of research. Their principles continue to inform contemporary human research protections, **Institutional Review Board (IRB)** oversight, and international ethical standards.

4.2 Federal, State, and Local Laws

UTRGV complies with all applicable federal, state, and local laws, regulations, and guidance governing the conduct of **research** involving human participants. Applicable requirements

include, but are not limited to, the following provisions of the Code of Federal Regulations (CFR):

- Department of Health and Human Services
  - 45 CFR 46 – Protection of Human Subjects
- Food and Drug Administration (FDA)
  - 21 CFR 50 - Protection of Human Subjects
  - 21 CFR 56 – Institutional Review Board (IRB)
  - 21 CFR 312 – Investigational New Drug Application (IND)
  - 21 CFR 812 – Investigational Device Exemptions(IDE)
- Additional Requirements, as applicable, including but not limited to:
  - Health Insurance Portability and Accountability Act (HIPAA) - 45 CFR 160, 162, and 164
  - Family Educational Rights and Privacy Act (FERPA) – 34 CFR 99
  - Protection of Pupil Rights Amendment (PPRA) – 34 CFR 98
  - All applicable Texas law(s) and other relevant regulations and guidelines.

4.3 Federal-Wide Assurance (FWA)

As a recipient of Federal Public Health Service (PHS) funding, UTRGV maintains an active FederalWide Assurance (FWA) with the U.S. Department of Health and Human Services (DHHS) (See Appendix 1, Historical Federalwide Assurance (FWA) Record).

A FWA is a binding agreement between UTRGV and the DHHS Office for Human Research Protections (OHRP). Through the FWA, UTRGV commits to upholding the ethical principles of the Belmont Report and complying with 45 CFR 46 for all human subjects research. The FWA outlines the responsibilities of the Institution, the Institutional Official (IO), and Investigators. All UTRGV Investigators are expected to conduct research in accordance with the FWA, *HOP ADM-07-104, Human Subjects Research*, and to protect the rights and welfare of human subjects.

4.4 IRB Written Procedures (Regulatory Framework and Authority)

In accordance with federal regulations, UTRGV, HRPP, and Institutional Review Board (IRB) maintain written procedures governing IRB operations and oversight of human subjects research.

These written procedures are established to ensure compliance with:

- 45 CFR 46.108(a)(3)-(4)

- 21 CFR 56.108(a)–(b)

At a minimum, IRB written procedures address the following required operational areas:

1. Conduct of initial and continuing review of **research**, including reporting of IRB findings and actions;
2. Determination of which research requires review more often than annually and when verification from sources other than the **investigator** is required;
3. Review and approval of proposed changes in research prior to implementation, except when necessary to eliminate immediate hazards to subjects;
4. **Prompt reporting** of:
   - **Unanticipated Problems (UP)** involving risks to subjects or others,
   - Serious or continuing **non-compliance**,
   - Suspension or termination of IRB approval.

These procedures are operationalized throughout this handbook and corresponding standard operating procedures (SOPs) and are designed to ensure the protection of the rights, welfare, and safety of human research participants.

All **reportable events** and associated determinations are documented in IRB records, reflected in IRB meeting **minutes**, when reviewed by the convened IRB, and maintained[1].

4.5 Development and Implementation of IRB Policies and Procedures

As per *HOP ADM-07-104, Human Subjects Research*, the authority to create, change, and implement institutional **human subjects** protection policies resides with the **Institutional Official (IO)**. The IO, through this handbook, has delegated this responsibility in part to the Human Protections Administrator (HPA) for review and recommendations. New policies or modifications may be presented to the **Institutional Review Board (IRB)** for input. At the discretion of the IO or the IRB, the HPA may seek input from other stakeholders who would be affected by the policy. The HPA is responsible for reporting any policy or procedure that interferes with the ability of the IRB to effectively protect human subjects or to function as an independent body to the IO.

At a minimum, the HPA and the Office of Research Compliance (ORC) will conduct a comprehensive review of institutional policies contained in this handbook every three (3) years or before if there are substantiated changes to federal regulations or if related institutional policy is made. The review will include an assessment of the accuracy and relevancy of the policies, a determination as to whether IRB policies are in line with current UTRGV policies, and whether there is a need for new policies to be developed. HPA will lead the review process with input from the IRB, ORC, and other HRPP stakeholders and will then

[1] 45 CFR 46.115 and 21 CFR 56.115

submit to the IO for approval.

PART II. REGULATORY FRAMEWORK

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Section 5. Administrative Structure of the Human Research Protection Program

5.1 Organizational Structure Overview

The Human Research Protection Program (HRPP) at The University of Texas Rio Grande Valley (UTRGV) operates under the Division of Research led by a designated **Institutional Official (IO)**. The HRPP functions as an integrated institutional system comprising multiple organizational units and stakeholders with shared responsibility for the protection of **human subjects**. This coordinated framework includes the IO, the Human Protections Administrator (HPA), the Office of Research Compliance (ORC), and the **Institutional Review Board (IRB)**. This coordinated oversight applies to all **human subjects research** conducted under institutional authority, regardless of funding source, location, or **investigator** status.

Additional stakeholders of the UTRGV HRPP structure include, but are not limited to, Research Administration, Legal Counsel, the Office of Clinical Research (OCR), Privacy Officer, the Institutional Biosafety Committee (IBC), Compliance Officers, and Administrative Units responsible for areas such as **Conflict of Interest (COI)**, Research Security, Export Control, and the Office of Research Contracts & Industry Agreements (RCIA), and scientific and scholarly review.

Through this integrated structure, the HRPP ensures that all components of human subjects research, including policy development, education and training, application review, **Post Approval Monitoring (PAM)**, and compliance oversight, are conducted in accordance with ethical principles, applicable regulations, and institutional requirements.

5.2 Institutional Official (IO)

The **Institutional Official (IO)** is responsible for ensuring that the HRPP at UTRGV functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to **research** involving **human subjects** (45 CFR 46.103). The IO represents UTRGV in the **Federalwide Assurance (FWA)**. The IO ensures that the **Institutional Review Board (IRB)** is able to carry out its responsibilities independently and without undue influence.

The Assistant Vice President for Research Integrity, or another designated official, serves as UTRGV's IO. The authority and responsibilities of the IO are described in UTRGV *HOP ADM 07-104, Human Subjects Research*.

5.3 Human Protections Administrator (HPA)

The Human Protections Administrator (HPA) serves as a central resource for **investigators**, **Institutional Review Board (IRB)** members, and institutional leadership on matters related to **human subjects** protection and HRPP operations, and acts as the primary institutional contact with regulatory agencies on matters pertaining to the **Federalwide Assurance (FWA)**. The HPA provides operational leadership and ensures coordination among HRPP components. The **Institutional Official (IO)** appoints the HPA. The Director of the Office of Research Compliance currently serves as the HPA.

Administrative Obligations of the HPA:

- Supports the protection of IRB independence and facilitates appropriate escalation of concerns related to undue influence.
- Conducts periodic evaluation of the performance of the IRB members.
- Serves as the primary contact for correspondence with the Office for Human Research Protections (OHRP), **Food and Drug Administration (FDA)**, and other agencies regarding **human subjects research**.
- Oversees the review and conduct of human **research** under the jurisdiction of the HRPP.
- Reviews this handbook in coordination with relevant stakeholders to ensure it is effective and suggests changes as necessary.
- Facilitates regular and effective educational training programs for IRB members, ORC staff, and investigators.
- Ensures that the IRB Chair(s) and members have direct access to the IO if they experience undue influence or if they have concerns about the function of the IRB.
- Investigates allegations of **non-compliance** involving human research.
- Oversees qualitative assurance and quality improvement procedures within the ORC.
- Investigates and remediates identified systemic problem areas and, where necessary, recommends changes.
- Ensures that the IRB composition is appropriate for the volume and types of human subjects research to be reviewed, supporting timely, thorough, and competent review.
- Provides recommendations of candidates for IRB members to the IO.
- Maintaining an updated roster of all members serving on the IRB.
- Reporting changes in IRB membership to the OHRP as required.
- Maintains FWA and IRB registration(s).

5.4 The Office of Research Compliance (ORC)

The Office of Research Compliance (ORC) is responsible for supporting the **Institutional Review Board (IRB)** by providing educational activities, expert analysis of applicable

regulations, administrative and professional support, and liaising with researchers. The ORC serves as the operational hub of the HRPP. The ORC maintains and manages administrative procedures to ensure that the IRB members have adequate time to thoroughly assess proposed studies for compliance with regulatory requirements and institutional policies and procedures.

The ORC staff conducts initial reviews for all **research** study applications involving **human subjects** to determine if it falls within the scope of the IRB review and refers their findings and recommendations to the UTRGV IRB, as applicable.

Responsibilities of the supporting staff at the ORC:

- Managing IRB operations and regulatory review. This includes, but is not limited to:
  - Conducting pre-reviews of all applications to ensure completeness, consistency, and sufficient information for regulatory decision-making.
  - Coordinating IRB meetings by preparing agendas, administratively assigning reviewers on behalf of the chairperson, distributing meeting materials, and ensuring **quorum** is met and maintained.
  - Drafting and recording approval of IRB meeting **minutes**.
  - Recording and communicating on IRB decisions.
  - Managing reviews of research involving reliance on non-UTRGV IRBs.
  - Maintaining all HRPP and IRB records in accordance with federal regulations and institutional policy.
- Providing professional support and expert guidance to IRB members and researchers.
- Participating in the review and updating of standard operating procedures for the IRB and HRPP to reflect regulatory or institutional changes.
- Assist with annual performance evaluations of IRB members, Chairs, and Vice Chairs.

5.5 The Institutional Review Board (IRB)

The **Institutional Review Board (IRB)** is an administrative body that exercises independent decision-making authority in the review and oversight of **human subjects research** conducted under the auspices of UTRGV. The IRB has a direct line of communication to the **Institutional Official (IO)**, who holds ultimate responsibility for UTRGV's commitments under its FWA. The authority and responsibilities of the IRB are described in UTRGV *HOP ADM 07-104, Human Subjects Research*, and applicable federal regulations.

UTRGV is committed to ensuring the independence of the IRB in the conduct of its responsibilities. The IRB operates free from undue influence and has the authority to make

determinations regarding the approval, modification, or disapproval of human subjects research in accordance with applicable regulatory and ethical requirements.

The IRB is responsible for reviewing, prior to initiation, all **research** involving human participants, regardless of funding source. The primary mission of the IRB is safeguarding the welfare, rights, and privacy of participants. In carrying out this responsibility, the IRB has the authority to approve, require modifications to secure approval, disapprove, and conduct ongoing oversight of research activities within its jurisdiction. This authority includes the ability to suspend or terminate IRB approval when warranted, in accordance with federal and state laws and regulations, and UTRGV policies and procedures.

Research projects **approved** by the IRB may be subject to further review by other administrative **institutional officials**. Administrative institutional officials may determine that an IRB-approved study cannot be conducted for administrative reasons (such as budget constraints or lack of compliance with **Post Approval Monitoring (PAM)** requirements. However, no administrative official, including the IO, may approve human subjects research that the IRB has not approved.

The responsibilities below supplement the IRB authority, jurisdiction, and oversight functions described in UTRG *HOP ADM-07-104, Human Subjects Research*, and outline additional operational duties required for compliance with **human subjects** protection standards.

- Ensuring that information provided to participants as part of **informed consent** is in accordance with applicable laws, regulations, and international standards. The IRB may require that additional information be given to the participants when, according to the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants;
- Determining when written documentation of informed consent is required or when a waiver of documentation is appropriate
- Conducting continuing review of research covered by these policies at intervals appropriate to the level of risk, but not less than once per year, (unless the research qualifies for an Exemption or has been approved as Expedited). The IRB has the authority to require continuing reviews on all approved research activities as deemed necessary. The IRB has the authority to observe or have a third party observe the **informed consent process** and the research;
- Serving as the Privacy Board when reviewing requests to waive or alter **Health Insurance Portability and Accountability Act (HIPAA)** Authorization requirements for the use or disclosure of **Protected Health Information (PHI)** in research under the HIPAA Privacy Rule;
- Suspending or terminating approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.

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Section 6. HRPP Mission, Program Assessment, and Continuous Improvement

6.1 Mission Statement

The Human Research Protection Program (HRPP) at The University of Texas Rio Grande Valley (UTRGV) is committed to upholding the highest ethical standards in the conduct of **human subjects research** and to ensuring the protection of the rights, welfare, and privacy of **research** participants.

This commitment is grounded in the ethical principles of the Belmont Report, respect for persons, beneficence, and justice, and in compliance with applicable federal regulations, including 45 CFR 46, and, when applicable, **Food and Drug Administration (FDA)** regulations under 21 CFR Parts 50 and 56.

The HRPP supports the responsible conduct of research through an integrated system of oversight that includes education, policy development, application review, and **Post Approval Monitoring (PAM)**. UTRGV affirms its institutional responsibility to provide the leadership, resources, and infrastructure necessary to maintain an effective HRPP and to promote a culture of ethical research and accountability.

6.2 Program Assessment

The Human Research Protection Program (HRPP) maintains a systematic program assessment process to evaluate the effectiveness of its policies, procedures, oversight activities, and institutional safeguards for protecting the rights and welfare of **research** participants.

As part of the HRPP's quality framework, assessment activities incorporate information obtained through **Post Approval Monitoring (PAM)** oversight activities, which support the HRPP's commitment to compliance, education, and continuous quality improvement. PAM findings are evaluated in aggregate to identify trends, assess program effectiveness, inform educational initiatives, and support the development of corrective or preventive actions when appropriate.

The HRPP handbook is also subject to periodic review to ensure continued alignment with applicable regulations, guidance, accreditation standards, and institutional practices. This review may include:

- Evaluation of consistency between written procedures and actual HRPP and **Institutional Review Board (IRB)** operations;
- Assessment of regulatory compliance in IRB determinations and documentation;

- Review of aggregate findings from PAM activities, audits, and investigations; and
- Identification of procedural gaps, emerging risks, or areas requiring clarification.

Updates to policies, procedures, guidance documents, and educational resources are implemented as necessary to reflect regulatory changes, institutional needs, assessment findings, and best practices. These activities support continuous improvement, audit readiness, and the effective protection of **human subjects**.

6.3 Reporting and Oversight

The Human Protections Administrator (HPA) prepares periodic reports, including an annual summary of program activities, for review by the **Institutional Official (IO)** or designee. These reports may include aggregated data related to **Institutional Review Board (IRB)** activity, compliance oversight, program performance, and resource needs. Assessment findings inform institutional resource planning to ensure adequate support for HRPP operations.

The IO is responsible for reviewing program assessment outcomes and ensuring that appropriate institutional support, resources, and corrective actions are implemented as necessary to maintain compliance with 45 CFR 46 and, when applicable, 21 CFR Parts 50 and 56.

6.4 Continuous Improvement

The Office of Research Compliance (ORC) is committed to continuous improvement of the Human Research Protection Program (HRPP) through the ongoing evaluation of program performance and the implementation of enhancements to policies, procedures, and practices.

The ORC program assessment activities are coordinated with the HRPP Program and other oversight mechanisms to support data-driven decision-making, strengthen compliance, and improve the overall effectiveness of the HRPP.

Findings from assessment and oversight activities are used to inform the **Institutional Official (IO)** and Human Protections Administrator (HPA) of updates to institutional policies, enhance education and training initiatives, and promote consistency and accountability across all components of the HRPP.

6.5 HRPP Communication and Regulatory Updates

The Office of Research Compliance (ORC), in coordination with the **Institutional Review Board (IRB)** and **Institutional Official (IO)**, provides institutional communication to

investigators, research personnel, IRB members, and other stakeholders regarding applicable federal regulations, institutional policies, and emerging issues in human subjects protections.

Communication activities may include guidance documents, training materials, website updates, announcements, and other appropriate mechanisms to support awareness, consistency, and compliance across the HRPP.

These efforts are intended to ensure that individuals involved in human subjects research remain informed about their responsibilities and can conduct research in accordance with applicable ethical and regulatory requirements.

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Section 7. Institutional Coordination

The Human Research Protection Program (HRPP) operates through coordination among multiple institutional units that contribute to the protection of **human subjects** and the conduct of compliant **research**.

Depending on the nature of the research, **investigators** may be required to obtain review and approval from relevant institutional committees or offices, including but not limited to:

- Institutional Biosafety Committee (IBC)
- Office of Research Integrity and Export Control
- Office of Sponsored Programs
- Office of Grants and Contracts
- Environmental Health, Safety & Risk Management (EHSRM)
- Office of Clinical Research (OCR)
- Office of Research Contract and Industry Agreements (RCIA)
- Administrative Units

Coordination among these units ensures that all applicable regulatory, safety, and institutional requirements are addressed prior to the initiation of research. The HRPP, through the Office of Research Compliance (ORC), facilitates communication and coordination among institutional stakeholders to support consistent and comprehensive oversight of **human subjects research**.

Institutional reviews may occur concurrently or sequentially depending on the regulatory and risk considerations associated with the research. In general:

- Required **ancillary reviews** should be initiated prior to or in parallel with **Institutional Review Board (IRB)** review, as appropriate;
- IRB approval may be contingent upon receipt and confirmation of required ancillary approvals; and
- Research activities may not begin until all applicable institutional and IRB approvals have been obtained.

Investigators are responsible for identifying applicable ancillary reviews and ensuring that required approvals are obtained. The ORC, in coordination with the IRB and relevant institutional units, facilitates communication and verification of required approvals to support comprehensive oversight.

Institutional units share responsibility for ensuring that regulatory, safety, and compliance

requirements within their respective areas are addressed. The IRB relies on the expertise and determinations of these units, as applicable, while retaining final authority for the approval of human subjects research.

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Section 8. Training Requirements

The Human Research Protection Program (HRPP) maintains a comprehensive education and training program to ensure that **investigators**, **research** personnel, **Institutional Review Board (IRB)** members, and administrative staff are knowledgeable about ethical principles, regulatory requirements, and institutional policies governing **human subjects research**.

All individuals involved in human subjects research are required to complete initial and continuing education in **human subjects** protections, as applicable to their roles and responsibilities.

The HRPP ensures that training completion is documented and maintained in accordance with institutional requirements. Ongoing education activities are provided to address regulatory updates, emerging issues, and identified areas for improvement.

8.1 IRB Members

Prior to beginning **Institutional Review Board (IRB)** service, all members must complete onboarding that includes a new member orientation conducted by the Human Protections Administrator (HPA) or Office of Research Compliance (ORC) staff and the required Collaborative Institutional Training Initiative (CITI) training. IRB members may receive additional training through attendance at **convened IRB meetings**, attending training conferences and courses, and professional membership. Ongoing education for IRB members includes the distribution, review, and discussion of relevant publications, as well as an annual member retreat provided by the ORC.

8.2 The Office of Research Compliance

The Office of Research Compliance (ORC) staff members must be familiar with pertinent federal regulations and **Institutional Review Board (IRB)** policies and procedures, including but not limited to those contained in this handbook. The ORC staff are also required to obtain/maintain professional certifications (e.g., Certified IRB Professional (CIP) designation) consistent with their role as described in this handbook.

8.3 Principal Investigator and Research Personnel

Principal Investigator and the **research** team members, including collaborators from other institutions, must complete **human subjects research** training before submitting an **Institutional Review Board (IRB)** application.

The UTRGV IRB uses the CITI training as the primary program for human subjects research training. Instructions for registering to complete training through the CITI program, or for adding or changing the affiliated institution, are available on the IRB webpage. CITI courses must be completed with a passing score of at least 80% and renewed every four (4) years. Training must remain current for the entire duration of the study.

Other training may be accepted in lieu of CITI on a case-by-case basis.

All individuals engaged in the conduct of human subjects research are required to complete one **Human Subjects** Protection Basic Course, selecting the appropriate to their type of research area:

- Social/Behavioral Research **Investigators** and Key Personnel track
- Biomedical Research Investigators and Key Personnel track

In addition, individuals must complete training on the Responsible Conduct of Research (RCR) by choosing one from the following options (based on the nature of their research):

- Social and Behavioral RCR
- Biomedical RCR
- Physical Science RCR
- Humanities RCR

If the study involves clinical research or **clinical trials**, as defined by *HOP ADM 07-104, Human Subjects Research,* individuals also complete training in Good Clinical Practice (GCP) as applicable to the study:

- Social and Behavioral Research Best Practices for Clinical Research
- **Clinical Investigations** of Devices
- Clinical Trials with Investigational Drugs and **Biologics**
- Clinical Trials with Investigational Drugs and Medical Devices (U.S. **Food and Drug Administration (FDA)** Focus) Refresher Training

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PART III. IRB STRUCTURE AND OPERATIONS

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Section 9. IRB Membership, Composition, and Governance

The University of Texas Rio Grande Valley (UTRGV) may have multiple **Institutional Review Boards (IRB)** as the **Institutional Official (IO)** deems necessary to adequately provide oversight and protect the rights of **human subjects**. The requirements of this policy apply to all IRBs registered under UTRGV **Federalwide Assurance** (FWA00000805).

9.1 IRB Composition

The composition of the **Institutional Review Boards (IRB)** conforms to the requirements described in federal regulations (U.S. Department of Health and Human Services (DHHS): Office for Human Research Protections (OHRP), 45 CFR 46.107, and the U.S. **Food and Drug Administration (FDA)**, 21 CFR 56.107).

Each IRB shall be composed of at least five (5) voting members who possess varying backgrounds (experience, professional expertise, racial, cultural, and gender). These must include at least one scientific member, one member whose primary concerns are in nonscientific areas, one member who is not otherwise affiliated with UTRGV and who is not a **covered family member** of a person who is affiliated with UTRGV, and one member who represents the perspective of **research** participants. The role of a nonscientist and the person representing the perspectives of research participants may be fulfilled by a single member. Scientific members of the IRB generally will demonstrate experience in research involving **human subjects** and will be recruited from among active UTRGV researchers. Nonscientific members will often be recruited from the faculty and staff, and will reflect relevant professional expertise in a non-scientific area, such as law, ethics, human or patient rights, etc. Consideration is given to ensuring representation from colleges or units within UTRGV **engaged in human subjects research**. Additional members with specific expertise or experience relevant to the population under review (e.g., prisoner representative) may be appointed as needed. The Human Protections Administrator (HPA) is responsible for verifying non-affiliation and confirming appropriate expertise to serve on the board.

Alternate members may be appointed and engaged in IRB-related activities in the same manner as the primary IRB members. The alternate's expertise must be comparable to that of the primary member for whom the alternate member is substituting. The role of the alternate member is to serve as a voting member of the IRB only when the voting member(s) they are representing is unable to attend a **convened IRB meeting**. Alternate members must recuse themselves from voting when the voting member is present at the meeting. When an

alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The alternate member will not be counted as a voting member unless they are acting in a voting member capacity. The IRB **minutes** will document when an alternate member acts as a voting member.

The **Institutional Official (IO)** may appoint administrative staff or faculty (e.g., administrative support) at UTRGV to serve as non-voting members of the IRB if the IO, the IRB Chair(s), or the HPA decides that such persons would be of assistance to the IRB in conducting its duties. Non-voting members can include individuals within the Office of Research Compliance (ORC), whose expertise supports the review process but who do not participate as voting members. A non-voting member cannot be counted in the **quorum** and cannot vote, but can participate in discussions.

Externally funded studies may have additional IRB membership requirements dictated by the funding agency. These requirements often reflect the nature of the populations involved or the specific expertise needed to evaluate the ethical dimensions of a project. For example, a **sponsor** may require that the IRB include at least one member with expertise relevant to a particular participant group, condition, or methodology when reviewing studies it supports. In situations where the IRB does not have the necessary expertise within its membership, it may also rely on ad hoc consultants or reviewers with specialized knowledge to ensure an adequate and informed review.

9.2 IRB Independence

The **Institutional Review Boards (IRB)** functions as an independent review body authorized by the institution to review, approve, require modifications, disapprove, suspend, or terminate **human subjects research** within its jurisdiction. In carrying out these responsibilities, the IRB must be free from undue influence by **Institutional Officials (IO)**, **investigators**, **sponsors**, or other parties.

9.3 IRB Members Selection

The Human Protections Administrator (HPA) identifies potential board members through consultation with the Office of Research Compliance (ORC) staff, **Institutional Review Boards (IRB)** Chairs, Vice-Chairs, current IRB members, the Associate Dean for Research, School Directors, Department Chairs, and Deans. After evaluating their Curriculum Vitae (CV) and ascertaining their willingness to serve, the HPA submits the names of potential candidates along with their CV to the **Institutional Official (IO)** for review and approval.

Upon approval, an appointment letter is issued indicating the representative capacity of the member (e.g., scientist, non-scientist, **unaffiliated IRB member**), voting role right (e.g., voting, non-voting), whether the member is serving in an alternate role, and term of service.

For purposes of quorum, an appointment is considered effective as of the date written on the appointment letter.

9.4 IRB Member Duties

Institutional Review Boards (IRB) members' duties include, but are not limited to:

- Reviewing all applications to be discussed in a convened IRB meeting;
- Reviewing assigned study applications
- Serving as primary reviewer for research studies within their area of expertise and leading the discussion during the convened IRB meeting;
- Serving as secondary reviewer for research studies outside of their area of expertise and leading the IRB discussion in the absence of the primary reviewer;
- Attending and participating in board meetings;
- Voting on proposed human subject research (HSR) activities at the board meetings;
- Maintaining a working knowledge of applicable regulations and relevant UTRGV policies;
- Attending training and conferences related to IRB activities;
- Requesting consultants when needed;
- Interacting with Principal Investigators (PI), research teams, and external experts when necessary.

9.5 IRB Chairs and Vice Chairs Selection

The Institutional Review Boards (IRB) chair and vice chair will be full-time employees at UTRGV. The Human Protections Administrator (HPA) identifies possible candidates from current IRB members at the time. If none of the voting members affiliated with UTRGV are willing to take on the role, the HPA requests input from the academic colleges, Office of Research Compliance (ORC) staff, and current IRB members to identify potential candidates to serve as the IRB chairperson based on expertise and experience. Candidates submit their CVs to the HPA for review. The HPA will send a recommendation to the Institutional Official (IO) for approval. The HPA will then assess candidates' availability and willingness to serve, as well as support from the School Director or Department Chair and Dean.

9.6 IRB Chairs and Vice Chairs' Duties

Institutional Review Boards (IRB) chairs and vice-chairs' duties include, but are not limited to:

- Leading board meetings to ensure the review of the research studies is consistent with all applicable ethical and regulatory requirements
- Approving and signing documents relevant to the review and approval of human

subjects research activities on behalf of the IRB;
- Assessing Conflicts of Interest (COI) and ensuring that members who have conflicts of interest are not present during deliberation and voting;
- Managing time during meetings to guarantee enough discussion time for each topic on the agenda;
- Ensuring a decision is made for each action item on the agenda;
- Engaging in IRB policy development and discussions;
- Reviewing and acting upon reports of Adverse Events (AE), reports of non-compliance allegations, and protocol deviations;
- Assisting in the planning and implementation of continuing education for the board.
- Providing feedback to the Human Protections Administrator (HPA) and the Institutional Official (IO) regarding the quality and adequacy of staff support;
- Providing input for training the board members;
- Representing the board to outside agencies and organizations, when required.

9.7 Determining Whether Prospective Members are "Unaffiliated"

Unaffiliated IRB members may not be current UTRGV employees, students, or vendors. An individual with no affiliation with UTRGV other than as a member of the Institutional Review Boards (IRB) or whose only association with UTRGV is that of a healthcare patient or research participant may be considered unaffiliated.

A former UTRGV employee or alumnus who is not employed by or enrolled as a student at UTRGV may be considered unaffiliated. Retirees may serve as unaffiliated IRB members after separation. Family members who are not considered covered family members of a person affiliated with UTRGV may serve as affiliated members. For purposes of IRB membership, covered family members include a spouse or domestic partner and dependent children of an individual affiliated with UTRGV. Individuals who are covered family members of a UTRGV-affiliated person are considered affiliated with the institution and therefore do not qualify as unaffiliated IRB members.

Paying an unaffiliated IRB member reasonable market value for the costs associated with participation as a member of the IRB (e.g., transportation and parking costs, internet access, IRB-required training, etc.) shall not affect the member's status as unaffiliated.

9.8 Scientist versus Non-Scientist

UTRGV considers individuals whose training, background, and occupation position them to evaluate scientific activities from within a behavioral or biomedical research discipline to be scientists. In contrast, those whose perspective comes from outside a biomedical or behavioral scientific discipline are considered non-scientists. With regard to scientists,

UTRGV includes members with adequate knowledge of the scientific disciplines relevant to the research it reviews.

The Food and Drug Administration (FDA) further explains that Physicians and Doctor of Philosophy (PhD)-level physical or biological scientists meet the requirement for at least one scientific member. Nurses, pharmacists, and other biomedical health professionals should not be considered non-scientists simply because their roles are not physician-based. Instead, examples of members whose primary concerns are in non-scientific areas include lawyers, clergy, and ethicists.

UTRGV also recognizes that some individuals may have training in both scientific and non-scientific fields, such as a J.D. and R.N. Although these members can provide valuable perspectives, the IRB should still appoint other members whose primary concerns are clearly non-scientific in order to satisfy the regulatory requirement.

Finally, this requirement applies not only to overall IRB composition but also to convened meeting quorum. At least one member whose primary concerns are in non-scientific areas must be present for quorum at a convened IRB meeting.

9.9 Length of Term

Institutional Review Boards (IRB) Members, Chairs, and Vice-Chairs are appointed to one (1) to three (3) year terms that can be renewed at the discretion of the Institutional Official (IO), with an initial two-year term. Members may resign at any time by submitting a letter of resignation to the IO. The IO may remove members from the board if the member is unable to complete their responsibilities as an IRB member. The IRB Chair(s) and Vice Chair(s) are expected to hold the positions for three (3) years, while general members will be appointed for two (2) year terms. The IO will consider annual evaluations of IRB members and institutional standing when deciding on renewal of terms.

9.10 Evaluation of Members

The Human Protections Administrator (HPA), with input from Office of Research Compliance (ORC), will conduct annual Institutional Review Boards (IRB) Chair and Vice Chair evaluations of their performance. The HPA will forward the member evaluation along with the recommendation to the Institutional Official (IO) for consideration if the member team is up for renewal.

9.11 IRB Roster

The Office of Research Compliance (ORC), through the Human Protections Administrator (HPA), maintains an updated roster of all members serving on the Institutional Review

Boards (IRB). Current rosters are accessible on the UTRGV IRB website.

The IRB Roster shall include, at a minimum, the following:

1. Name of the IRB Panel, if more than one IRB
2. Name of member
3. Gender
4. Earned degree(s)
5. Role (e.g., scientific, nonscientific, community representative)
6. Primary area of expertise or specialty
7. Affiliation status with the University
8. Alternate status and which member(s) or class of primary members the alternate may replace.

9.12 Registering and Maintaining IRB Registration

The UTRGV **Institutional Review Boards (IRB)** is registered electronically by the Human Protections Administrator (HPA) or designee through the Office for Human Research Protections (OHRP) portal. Registration becomes effective for three (3) years after it is reviewed and accepted by OHRP. Registration is updated within 90 days after changes occur regarding the **Institutional Official (IO)** or the HPA. The changes must be communicated to OHRP in accordance with 45 CFR 46.504. Upon approval of a change, the end date of the registration period is extended.

UTRGV's decision to inactivate a registered IRB that it is operating must also be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of PHS-supported **research**. Official IRB roster records for all panels and their respective members are maintained for a minimum of three (3) years, in accordance with applicable record retention requirements and federal regulations.

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Section 10. IRB Meetings and Operations

10.1 IRB Convened Meetings

A **convened IRB meeting** may be held in person, virtually, or in a hybrid format, as determined by the **Institutional Review Board (IRB)** Chair and the Office of Research Compliance (ORC). The IRB meeting schedule is available at the IRB website. **Investigators** may also contact the ORC for the dates of the monthly meetings.

The IRB may not convene to conduct official business until a **quorum** is established. The ORC support staff is responsible for informing the IRB Chair when quorum has been established or is lost. ORC staff is also responsible for monitoring the meeting for late arrivals and departures of members during the meeting.

Consultants and visitors who are granted access to meeting materials must sign a UTRGV IRB Confidentiality Statement before receiving meeting materials. The confidentiality statement will be provided by the ORC staff. These agreements will be maintained by the ORC.

The ORC staff prepares the meeting agenda and distributes it to the IRB members prior to each meeting. All members will have access to the meeting materials, including the agenda, at least a week before the meeting to allow enough time to perform a substantive review. Members participating remotely through videoconference or other **approved** communication methods must be able to actively participate in deliberations and voting throughout the meeting.

Meeting materials received by the IRB are considered confidential and are distributed electronically only to meeting participants (voting members, non-voting members, consultants, and administrative staff) for the purpose of review. If hard copies are distributed during the convened IRB meeting, these must be collected by ORC staff after the meeting adjourns.

10.2 Quorum

The **Institutional Review Board (IRB)** may conduct official business only when a **quorum** is present and maintained throughout the deliberation and voting process. Quorum is defined as more than half of the voting members (rounded up to the nearest whole number), including at least one non-scientist voting member present. Member recusal affects quorum. Quorum must be maintained during the entire meeting.

If quorum is lost due to member departure, recusal because of a **Conflict of Interest (COI)**, technical difficulties, or other circumstances, the IRB shall suspend all actions requiring a

vote until quorum is restored. Discussion of research studies or administrative matters may continue; however, no determinations, approvals, modifications, requests for disapprovals, suspensions, or terminations may occur in the absence of quorum.

The IRB meeting minutes shall document any loss of quorum, the time at which quorum was lost and restored, the studies or agenda items affected, and any actions deferred until quorum was reestablished.

10.3 IRB Unforeseen or Emergency Situations

In case of emergency events or unforeseen situations that prevent the Institutional Review Board (IRB) from operating as usual, the IRB may:

- Convene a meeting through alternate means of communication (e.g., video conference)
- Call for emergency meetings outside of regularly scheduled meetings;
- Recommend to the Institutional Official (IO) the issuance of institutional interim policies supporting the IRB operations during the emergency.

Emergency situations and unforeseen events must be documented in the meeting minutes. If meetings are conducted through alternative means of communication, attendance must describe the means used by each member. If institutional interim policies are issued by the IO, such policies will be published on the IRB website.

10.4 Ad Hoc Consultants

The Institutional Review Board (IRB) may request consultants to assist with a review that is beyond the members' scope of expertise[2]. Consultant(s) shall not be appointed as designated reviewers and may only provide subject matter expertise related to a scientific, scholarly, or population-specific issue. Consultants may also be used during the initial review, review of modifications, or continuing review of a study. Consultants, however, may not vote during IRB deliberations, and their attendance cannot be used to establish quorum. If a consultant submits a written report, copies of such report will be distributed to all IRB members prior to the meeting. Consultants may also attend a convened IRB meeting and provide a verbal report to the IRB. The report and recommendations, if any, will be documented in the IRB minutes for the meeting.

Identifying a consultant:

- A recommendation may be made to seek assistance from a consultant by any IRB members (voting and non-voting). Upon request of a consultant, the IRB will review the basis for the request and approve the use of an ad hoc consultant.

[2] 45 CFR 46.107(e); 21 CFR 56.107(f)

- Consultants may be internal or external to UTRGV.
- Consultants must not have a **conflict of Interest (COI)** and must be willing to abide by **confidentiality** rules.
- Ex officio consultants (e.g., Radiation Safety Officer) internal to UTRGV will be appointed by the **Institutional Official (IO)** to be consulted as experts to the IRB on the topics in which they possess expertise.

10.5 Conflicts of Interest for IRB Members, Chairs & Vice-Chairs, and Investigators

a) IRB Members – Convened Meeting

Institutional Review Board (IRB) members must not participate in the review of any **research** study in which they have a **Conflict of Interest (COI)**. A COI includes any direct or indirect financial interest, conflict of commitment, personal relationship, or appearance of a COI that could reasonably be perceived as affecting the member's objectivity, impartiality, or professional judgment.

IRB members should not review, be present for deliberation, or vote on any research study from which they have a COI. In cases where a board member is also engaged in the proposed research, the IRB may ask the member to be present to answer questions posed by the board related to the study.

IRB members with a COI must recuse themselves for IRB deliberations and voting. Recusals for COI must be documented in the IRB **minutes**.

IRB members are considered to have a COI if they:

- Are involved in the design, conduct, or reporting of the research study.
- Have a financial and/or ownership interest of any amount in or related to the research, including any compensation, financial arrangement, or ownership interest that may be affected by the outcome of the study, even if the value cannot be readily determined.
- Have received in the past year, currently are receiving, or will receive from the **sponsor** of the study, honoraria, payments, or compensation.
- Have a proprietary interest in the proposed or **approved** research, including but not limited to a patent, trademark, copyright, or licensing agreement.
- Serve as directors, board members, scientific advisors, or hold other decision-making positions in the entity sponsoring the research.
- Are not an **investigator**, co-investigator, or consultant on a study, but are closely associated with the investigators on the study being reviewed.
- Is a **covered family member** of the **Principal Investigator (PI)**, co-PI(s), or any personnel listed on the study.

- If the existence of bias prevents them from rendering an objective opinion concerning a study.

b) Conflicts of Interest for Investigators

All investigators and research personnel are required to disclose outside affiliations that have the potential or could be perceived as having the potential to interfere with their institutional responsibilities in accordance with The University of Texas System (UTS) and UTRGV policies and procedures[3][4].

COI can occur when a research investigator's outside interests are, or perceived to:

1. Influence the way the PI performs his/her institutional responsibilities, or if the interest has been offered with the intent to influence the PI's conduct of decisions.
2. Induce the Investigator to disclose confidential or proprietary information acquired through the performance of institutional responsibilities.
3. Influence the way the study is designed, and subjects are being recruited.

When an outside affiliation appears to create a conflict with a research study, the IRB may review the conflict and require study-specific modifications to protect participants. The IRB will assess the COI at the initial and continuing review to determine whether participants are adequately protected and risks are minimized.

The IRB will contribute to the COI management plan by determining if the rights and welfare of human research participants will be better protected by any items deemed necessary, including but not limited, to the following:

- Disclosure to subjects through the **informed consent process**.
- Modification of the safety monitoring plan.
- Monitoring of research by independent reviewers (**Post Approval Monitoring (PAM)**).
- Disqualification of the conflicted party from participation in all or a portion of the study.

In instances in which a COI has not been approved, the IRB will defer the initial application review until the review process is completed by the Office of Research Integrity and Export Control and the results made available to the IRB.

[3] UTS 175 Disclosure of Significant Financial Interests and Management and Reporting of Financial Conflicts of Interest in Research
[4] UTS 180 Conflicts of Interest, Conflicts of Commitment, and Outside Activities

10.6 IRB Meeting Minutes

Meeting **minutes** are documented in writing, retained, and may undergo **quality assurance** review. They must contain sufficient detail to enable an outside observer to reconstruct the **Institutional Review Board (IRB)** discussions and actions taken during a **convened IRB meeting**. IRB meeting minutes shall be sufficiently detailed to document attendance, **quorum**, actions taken by the IRB, the vote on each action (including the number of members voting for, against, and abstaining), the basis for requiring modifications to secure approval or for disapproving **research**, and a written summary of the discussion of controverted issues and their resolution. Minutes shall also document the recusal of members with conflicting interests and confirm that quorum was maintained when applicable.

The meeting minutes shall include:

- Attendance of members, **alternate members**, consultants, and guests, as applicable;
- Participation of members attending remotely, confirmation of their access to review materials and ability to participate in deliberations and voting.
- Documentation that quorum was established and maintained throughout the meeting;
- Documentation of any loss of quorum and corresponding actions taken;
- Identification of members who recused themselves because of a **Conflicts of Interest (COI)**;
- A list of **Exempt** and **Expedited studies approved** during the previous period;
- Actions taken by the IRB for each study reviewed;
- Voting results, including the number of members voting for, against, and abstaining from each action;
- The basis for requiring modifications to secure approval, deferring review, or disapproving research;
- A summary of controverted issues discussed and their resolution;
- Summaries of discussions and determinations related to **Unanticipated Problems (UP), non-compliance**, suspensions, or terminations, when applicable;
- Documentation of the basis for requiring continuing review at an interval more frequent than annually, when applicable.
- Documentation of any suspension or termination of IRB approval, including the reasons supporting the action;
- For **Food and Drug Administration (FDA)** regulated medical device studies,

documentation of the Significant Risk (SR) or Non-Significant Risk (NSR) determination and the rationale supporting that determination.

The Office of Research Compliance (ORC) staff is responsible for counting and recording all votes in the meeting minutes.

The IRB minutes serve as the central repository for IRB decisions on proposed research activities. Copies of the minutes and meeting materials are maintained by the ORC and will be retained for three (3) years after the end of the corresponding research study (Section 40.2, *Research Record Retention*).

The ORC staff is responsible for preparing an outline of meeting minutes prior to a convened IRB meeting. After the meeting takes place, the determination of quorum, determinations, stipulations, and discussions will be documented following the minutes template in Appendix 2, IRB Meeting Minutes Templates, of this handbook.

The ORC staff is responsible for preparing the draft minutes and submitting them to the IRB Chair and Vice-Chair for pre-review within 7 business days following the date of the convened meeting. The draft minutes are then presented to the IRB for review and approval at the subsequent convened IRB meeting. Once **approved** by the board, meeting minutes are filed electronically at the ORC for future reference.

10.7 Records Access, Location, and Retention

The Office of Research Compliance (ORC) maintains adequate documentation of all **Institutional Review Board (IRB)** activities[5] for at least three (3) years after the study closes (Section 40.2, *Research Record Retention*). These activities include:

1. Copies of **research** study applications reviewed by the IRB;
2. IRB meeting **minutes**;
3. Research studies that are under continuing review;
4. Copies of all communication between the IRB and research **Investigators**;
5. IRB roster[6];
6. Written procedures for the IRB (this handbook);
7. Documentation and statements of significant new findings provided to subjects.

IRB records are available and accessible for inspection and protected from unauthorized access. To ensure privacy while maintaining accessibility, electronic documents are placed in a secure shared drive that backs up daily in UTRGV Microsoft SharePoint and at the electronic routing system (IRB electronic management system)[7].

[5] 45 CFR 46.115
[6] 45 CFR 46.107 and 21 CFR 56.107
[7] 45 CFR 46.116 (b)(5)

10.8 Tracking of Approval Periods and Prevention of Lapses

The Office of Research Compliance (ORC) maintains a system for tracking approval periods, continuing review due dates, annual status check-ins, and study closure. Reminder notices will be issued to **investigators** before a deadline approaches.

If continuing review materials are not submitted sufficiently in advance of the expiration date to allow completion of the **Institutional Review Board (IRB)** review process, including resolution of any requested revisions, or if the IRB has not **approved** continuation before the expiration date, the IRB approval lapses and all **research** activities must stop, except as otherwise permitted when discontinuation would place participants at increased risk.

The ORC will document lapse status and communicate required restrictions and next steps to the investigator.

10.9 Access to Information and IRB Policies and Procedures

Institutional Review Board (IRB) records are confidential and safeguarded against unauthorized access but must be available for inspection and copying by authorized federal representatives at reasonable times and in a reasonable manner[8]. Any audit notice, inspection request, subpoena, or other external request for records must be reported promptly to the **Institutional Official (IO)** and the Office of Legal Affairs. Record production will be coordinated in consultation with the Office of Legal Affairs, unless direct access is required by law or federal authority.

[8] 45 CFR 46.115; 21 CFR 56.115

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PART IV. INVESTIGATOR AND RESEARCH PERSONNEL RESPONSIBILITIES

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Section 11. Principal Investigators

Principal Investigators (PIs), as listed in **Institutional Review Board (IRB)** applications, are responsible for complying with the **approved** IRB application, UTRGV policies, all applicable federal, state, and local regulations, any signed agreements or contracts, and this handbook.

Responsibilities of PIs are outlined in UTRGV *HOP ADM 07-104, Human Subjects Research*, with additional responsibilities provided here:

1. Ensure that all **research** personnel listed on the application, including the PI, have completed required Collaborative Institutional Training Initiative (CITI) **human subjects research** training (Section 8, *Training Requirements*) and any institutional Outside Activity Disclosure requirement(s).
2. Submit complete and accurate applications and supporting documentation to the IRB.
3. Submit all proposed study and consent form modifications for IRB review and approval prior to implementation, except when necessary to eliminate apparent immediate hazards to participants; in which case they will need to be submitted immediately afterwards.
4. Conduct research using a scientifically and methodologically sound design and ensure that appropriate scientific review has been completed prior to IRB submission, as applicable.
5. Register the study on ClinicalTrials.gov (if applicable).
6. Ensure that adequate time, personnel, and resources are available prior to initiating the research.
7. Share relevant portions of the IRB-approved protocol with research personnel responsible for the conduct of the study.
8. Maintain appropriate oversight of all research activities and personnel and ensure that study responsibilities are clearly communicated.
9. Obtain **informed consent** from participants prior to initiating research procedures, unless the requirement is waived or altered by the IRB.
10. Protect and uphold the rights, safety, and welfare of research participants at all times.
11. For studies requiring review beyond the initial approval period, submit requests for

continuing review in a timely manner.

12. Address participants' questions, concerns, complaints, and requests for information in a timely and appropriate manner.
13. Report **Adverse Events (AE)**, **Unanticipated Problems (UP)**, and **protocol deviations** to the IRB promptly, in accordance with institutional requirements.
14. Fulfill all commitments outlined in the approved study, including, when applicable, providing study results to participants and honoring participant compensation or reimbursement agreements.
15. Submit a Project Closure Report to the IRB upon completion or termination of the study.
16. Maintain complete and accurate research records, including informed consent documents, for at least three (3) years after study completion (Section 40.2, *Research Record Retention*).

Although the PI may delegate some of these tasks to other IRB-approved personnel in the study (e.g., notifying of AE), the PI still retains overall responsibility for all aspects of the study.

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Section 12. Research Personnel Responsibilities

The **Principal Investigator (PI)** is responsible for selecting qualified **research** personnel relevant to the study. At a minimum, the following should be included in the study application for the **Institutional Review Board (IRB)** to determine the adequate qualifications of each of the individuals listed as research personnel.

1. Role in the study (i.e., PI, Co-Investigator, Research Personnel, Faculty Advisor, etc.)
2. Responsibilities (i.e., project role details)
3. Training
4. Qualifications (i.e., research experience, experience with participant population in the study, experience with methodology and procedures in the study, applicable coursework, etc.)

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Section 13. Trainees / Student Principal Investigators

UTRGV students may be designated as **Principal Investigators (PIs)** under the supervision of a Faculty Advisor/PI with **human subjects research** experience. This applies to independent study projects conducted by students, senior theses, undergraduate **research** projects, and advanced degree research (e.g., theses and dissertations). In this case, the student PI must fulfill all PI responsibilities and must submit an **Institutional Review Board (IRB)** application. The Faculty Advisors/PI must review and approve the IRB application prior to submission and be included in all IRB communications with the trainee or student. Trainees or students are not eligible to serve as PIs in **clinical trials**.

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Section 14. Faculty Advisor/Principal Investigator

Faculty Advisor / Principal Investigator (PI) overseeing student/trainee-led human subjects research (HSR) must provide active oversight of the research and accept full responsibility for its conduct. Faculty Advisors/PI must be actively involved throughout the research process, from research design to data analysis and report preparation, and are responsible for protecting the human subjects involved in their trainees' or students' research in accordance with UTRGV policies, applicable federal, state, and local regulations, and this handbook. A Faculty Advisor/PI must be a UTRGV employee or affiliated faculty with research responsibilities in the appointment letter. The following is a list of Faculty Advisor/PI responsibilities:

- Advising the student/trainee in the selection of a research topic and guiding the development, content, and preparation of the research proposal. Demonstrate familiarity with the research hypothesis, objectives, and methodology, and provide ongoing mentorship throughout the project.
- Assisting the student/trainee in preparing the Institutional Review Board (IRB) application and reviewing and approving all materials within the electronic routing system prior to submission. Ensure that all required approvals (e.g., IRB, IBC) are obtained before initiating any research activities.
- Maintaining oversight of the IRB-approved study and assuming responsibility for the study if the student/trainee leaves the institution prior to completion.
- Ensuring that the student/trainee has access to and is informed of applicable UTRGV policies and procedures governing the conduct and administration of the study.
- Ensure that the student trainee understands and applies the ethical principles for HSR policies and procedures governing the conduct of human subjects research.
- Provide active oversight and ongoing guidance to ensure that the student/trainee conducts the study in accordance with the IRB-approved protocol, applicable regulations, and UTRGV policies and procedures.
- Ensure that all study records and data are properly maintained and archived at the conclusion of the study in accordance with the approved study and relevant agreement terms and conditions (e.g., Data Transfer/Use Agreement (DTUA)).
- Remain reasonably available to the student/trainee during the conduct of the study to provide guidance and oversight.

- • **Maintain communication with the IRB and respond in a timely manner to requests for** information, clarification, or corrective actions related to any study for which the Faculty Advisor is listed.

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PART V. IRB REVIEW PROCEDURES

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Section 15. Regulatory Criteria and IRB Review Requirements

15.1 Scope of IRB Review

The University of Texas Rio Grande Valley (UTRGV) **Institutional Review Board (IRB)** reviews and approves all **research** activities that meet the definitions of **human subjects research** in accordance with *HOP ADM 07-104, Human Subjects Research*. These requirements apply regardless of funding source, **research site**, or **investigator** status, and extend to all research conducted under the authority or auspices of UTRGV.

Investigators are responsible for obtaining IRB review and approval prior to initiating any human subjects research procedures, including data collection or participant recruitment.

When a proposed study involves living individuals or human data, the IRB will first determine whether the proposed activities meet the definition of human subjects research and, therefore, whether IRB approval is required. If there is uncertainty regarding whether an activity meets these definitions, investigators must consult the Office of Research Compliance (ORC) and/or submit a Request for Determination.

15.2 Non-Human Subjects Research (NHSR) Determinations

Federal regulations at 45 CFR 46 apply only to activities that meet the definitions of both **research** and **human subjects**. Certain activities involving data, information, or interactions with individuals may fall outside the scope of these regulations because they do not constitute research designed to develop or contribute to generalizable knowledge, do not involve human subjects as defined by federal regulations, or both.

Because the distinction between **human subjects research** and activities that fall outside IRB oversight is not always clear, **investigators** may request an institutional Non-Human Subjects Research (NHSR) determination, which is the formal review conducted by the Office of Research Compliance (ORC) on behalf of the **Institutional Review Board (IRB)** to ensure compliance with applicable regulatory and institutional requirements under *HOP 07-104*, Human Subjects Research.

When there is uncertainty regarding their regulatory status, Investigators are responsible for ensuring that proposed activities are appropriately evaluated before initiation.

a) Activities Requiring an NHSR Determination

Investigators must submit the proposed activity to the Office of Research Compliance (ORC) for review before initiation when a Non-Human Subjects Research (NHSR) determination is required under institutional policy or when there is uncertainty regarding whether the activity constitutes human subjects research (HSR). The ORC will issue written documentation of the determination upon completion of the review process. If an NHSR is required under this policy, the ORC cannot issue an NHSR determination retroactively.

Examples of activities that may qualify for an NHSR determination include:

- Projects conducted solely to assess or improve local performance, practices, or operational processes without an intent to contribute to generalizable knowledge;
- Internal program evaluations conducted for administrative, quality improvement, or operational purposes;
- Case reports or case series involving three or fewer individuals that do not constitute a systematic investigation designed to contribute to generalizable knowledge; and
- Secondary analyses involving data, records, specimens, or cell lines from deceased individuals, or anonymous data or completely de-identified and inaccessible to the investigator through a linking code or other means. Data that retain a code or can be linked to identifiers are not considered anonymous, even when the investigator does not possess the linking information.

Activities described in this section are not automatically excluded from Institutional Review Board (IRB) oversight. When the nature of the activity, the data involved, or the intended use of the findings raises questions regarding regulatory applicability, the ORC will determine whether the activity qualifies as NHSR or requires IRB review.

b) Activities Not Requiring Prior NHSR Determination

The following activities generally do not require submission of a Human Subjects Research (HSR) application or a Non-Human Subject Research (NHSR) determination prior to initiation, provided the activity is limited to the circumstances described below:

- Use of publicly available or de-identified datasets from an institutionally approved list maintained by the Office of Research Compliance (ORC);
- Literature reviews, systematic reviews, scoping reviews, meta-analyses, and similar scholarly activities that rely exclusively on published sources and do not involve the collection or use of information about living individuals; and
- Activities that focus only on processes, systems, methodologies, algorithms, statistical techniques, or aggregate phenomena where conclusions are not drawn about individuals.

- Activities limited to the **investigator's** own experiences, reflections, or personal records that do not involve interaction or intervention with other living individuals and do not include identifiable private information about other persons.

Investigators should consult with the ORC before initiating activities that are not expressly identified in this section and that may involve **human subjects**, identifiable private information, identifiable biospecimens, or other circumstances that could require IRB review.

For activities identified by institutional policy as not requiring a prior NHSR determination, investigators may request a written NHSR determination letter when documentation is required by a **sponsor**, funding agency, publisher, collaborator, or other external entity. The ORC will review the request and, when appropriate, issue documentation confirming that the activity does not constitute HSR and does not require IRB review.

Activities initiated without a required NHSR determination, or that fall outside the scope of this section, may be subject to review by the ORC and/or IRB. Such review will determine whether the activity qualifies for an NHSR determination, constitutes HSR requiring **Institutional Review Board (IRB)** review, or represents **non-compliance** with institutional policy or applicable regulatory requirements requiring further review and, when appropriate, corrective and preventive actions.

c) Special Considerations

(1) Case Reports

A single case report or a case series involving no more than three individuals is generally not considered **human subjects research (HSR)** when all of the following conditions are met:

- The information was originally collected solely for clinical (non-research) purposes;
- The activity does not involve a systematic investigation or hypothesis testing;
- The intent is to describe a clinical observation, condition, or outcome, rather than to contribute to generalizable knowledge; and
- The activity is limited to patients under the clinician's own care or practice.

All case reports and case series must comply with applicable privacy and **confidentiality** requirements, including the **Health Insurance Portability and Accountability Act (HIPAA)** Privacy Rule, as applicable.

(2) Classroom-Based Projects

Classroom-Based Projects may qualify as non-research when conducted solely for instructional purposes, are not intended for dissemination outside the classroom, do not involve vulnerable populations, and do not collect identifiable or sensitive data.

(a) Faculty Responsibilities for Classroom-Projects

For classroom-based projects conducted as part of a course or instructional setting, Faculty Advisors (course instructors) are responsible for ensuring that such activities are appropriately evaluated to determine whether they constitute **human subjects research (HSR)** requiring **Institutional Review Board (IRB)** review.

The course instructor must submit a Non-Human Subjects Research (NHSR) determination request (or equivalent request for determination) via the electronic management system for all classroom-based projects involving interaction with individuals or collection of data about individuals.

No classroom-based projects involving **human subjects** may begin until an official determination has been issued by the IRB.

In the context of classroom-based **research** projects, the course instructor must ensure that:

1. Activities are appropriately designed for an instructional setting, including consideration of scope, timeline, and feasibility within the academic term;
2. Students apply appropriate safeguards when interacting with participants, including the use of suitable consent or information procedures when applicable;
3. Recruitment and participation practices are structured to avoid undue influence, particularly in educational or hierarchical settings; and
4. Projects are planned to allow sufficient time for institutional determination and, if applicable, IRB review prior to data collection.

15.3 Criteria for IRB Approval of Research

Before approving a proposed study, the UTRGV **Institutional Review Board (IRB)** will determine that all of the following requirements have been satisfied:

1. Risks to subjects are minimized by using procedures consistent with sound **research** design and that do not unnecessarily expose subjects to risk;
2. Risks are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge expected to result;
3. Selection of subjects is equitable, taking into account the purpose of the research and the setting;

4. **Informed consent** will be sought from each prospective subject or the subject's **legally authorized representative (LAR)**[9];
5. Informed consent will be appropriately documented[10];
6. When appropriate, the research includes adequate provisions for monitoring data to ensure subject safety;
7. Adequate provisions are in place to protect privacy and maintain **confidentiality** of data; and
8. Additional safeguards as required to protect subjects vulnerable to **coercion** or undue influence[11].

The IRB documents these determinations in the review record or meeting **minutes**, as applicable.

15.4 Appeals

Only the **Principal Investigator (PI)** may appeal an **Institutional Review Board (IRB)** action. Appeals must include new or clarifying information that was not previously available to the IRB and that could materially affect its risk/benefit analysis[12]. IRB decisions on appeals are final.

The IRB will notify the PI in writing, through the IRB electronic management system, of its determination to approve, require modifications, or disapprove the **research**[13]. The notification will include the reasons for the action and identify any required changes. If the notification requires PI action and no response is received within three months, the IRB will administratively close the application.

The IRB will review any additional information provided and issue a final determination based on whether the regulatory criteria for approval are satisfied. Revised applications may be resubmitted as needed; however, **investigators** are expected to submit well-developed applications that adequately minimize risks and include appropriate protections for **human subjects**.

Submission of an application should not be used as a mechanism for obtaining preliminary study design feedback. Investigators are encouraged to seek guidance from the ORC prior to submission of an application.

[9] 45 CFR 46.116
[10] 45 CFR 46.117
[11] 45 CFR 46.111(b)
[12] 45 CFR 46.111 and where applicable 21 CFR 56.111
[13] 45 CFR 46.109(d)-(e) and 21 CFR 56.109(d)-(e)

15.5 Ancillary reviews

Research studies may be subject to review by one or more research regulatory bodies (e.g., Conflicts of Interest (COI) or Institutional Biosafety Committee (IBC)). If an ancillary review is needed as a condition for the IRB to conduct its review, the proposed study will not be approved until all applicable ancillary reviews have been conducted and reviewed by the Institutional Review Board (IRB).

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Section 16. Levels of Review

Research involving human subjects is reviewed by the UTRGV Institutional Review Board (IRB) at one of four levels: Exempt, Exempt with Limited IRB Review, Expedited, and Full Board Review.

All studies must be submitted through the IRB electronic management system, and determinations are made by the IRB or the Office of Research Compliance (ORC) on behalf of the IRB. Research activities must not begin until an IRB approval letter is issued.

All changes to approved research must be submitted for IRB review prior to implementation, except where necessary to eliminate immediate hazards[14]. If a PI believes a project does not meet the definition of human subjects research (HSR), a formal determination must be requested.

16.1 Exempt Level of Review

Research may be determined to be exempt from certain regulatory requirements if it satisfies one or more of the Exempt study categories[15] and involves no more than minimal risk[16]. Exempt study determinations must be made by the institution or an IRB designee, not by the investigator. Some categories require Limited Institutional Review Board (IRB) Review to confirm adequate privacy and confidentiality protections. Research may be determined to be Exempt when it meets the criteria for one or more of the following Exempt study categories.

1. **Educational Practices - Research** in established educational settings involving normal educational practices, such as teaching methods, curricula, or classroom management.
2. **Educational Tests, Surveys, Interviews, or Public Observation** - Research using tests, surveys, interviews, or public observation when the regulatory conditions for exemption are met. Some identifiable information may require Limited IRB Review. The IRB will consider whether information is recorded as anonymous data, identifiable data, or could reasonably place participants at risk if disclosed.

[14] 45 CFR 46.108(a)(3)(iii) and 21 CFR 56.108(a)(4)
[15] 45 CFR 46.104(d)
[16] 45 CFR 46.102(j)

3. **Benign Behavioral Interventions** – Brief in duration, harmless, painless, and noninvasive behavioral interventions with adults who agree to participate. Some identifiable information may require Limited IRB Review.
4. **Secondary Research Using Existing Information or Biospecimens** - Secondary research using identifiable private information or identifiable biospecimens when one of the exemption criteria is met.
5. **Federal Public Benefit or Service Program Research** - Federal research or demonstration projects designed to study, evaluate, improve, or examine public benefit or service programs.
6. **Taste and Food Quality Studies -** Research involving taste, food quality, or consumer acceptance when applicable food safety requirements are met.

UTRGV does not permit the use of broad informed consent forms. Therefore, exemption categories that require broad consent under federal regulations are not available at UTRGV.

Exemptions do not apply to:

- Research involving prisoners when subject to 45 CFR 46 Subpart C[17],
- Research that is **Food and Drug Administration (FDA)** regulated, as FDA regulations do not include Exempt study categories (provide narrow exceptions, not Common Rule exemptions[18]), or
- Research involving children, except as permitted under Exempt Category 1 and Exempt Category 2 only when investigators do not participate in the activities being observed.

All research determined to be an Exempt study must still adhere to ethical principles and institutional requirements, including training, applicable consent or information disclosure provisions, and privacy, confidentiality, and data protection standards. The UTRGV IRB retains the authority to require a higher level of review when warranted by risk.

The ORC, on behalf of the IRB, determines whether a study qualifies for exemption[19].

FDA regulations do not recognize **Common Rule** exemption categories; therefore, studies subject to FDA oversight must comply with 21 CFR Parts 50 and 56, unless they meet the limited exemptions under 21 CFR 56.104:

- **clinical investigations** that commenced before July 27, 1981, and were either previously subject to FDA IRB requirements or not otherwise subject to FDA IRB requirements at that time;

[17] 45 CFR 46.101(a), 45 CFR 46 Subpart C
[18] 21 CFR 56.104
[19] 45 CFR 46.104(b)

- emergency use of a test article, provided the emergency use is reported to the IRB within 5 working days, and any subsequent use at the institution undergoes IRB review;
- and taste and food quality evaluations or consumer acceptance studies meeting the conditions specified in 21 CFR 56.104(d).

16.2 Exempt with Limited IRB Level of Review

The Institutional Review Board (IRB) conducts a Limited IRB Review when the proposed research meets specific Exempt study categories involving identifiable private information or biospecimens[20]. Limited IRB Review is conducted to ensure compliance with the provisions for the protection of privacy and confidentiality[21].

The IRB Chair or a designated experienced IRB member shall determine that:

- The research meets the criteria for the applicable Exempt study category; and
- Adequate provisions are in place to protect the privacy of subjects and maintain the confidentiality of identifiable data.

The IRB, through a designated reviewer, may approve the research, require modifications to secure approval, or refer the research for expedited or Full Board review, as appropriate.

The reviewer shall not disapprove research under Limited IRB Review and shall follow procedures consistent with Expedited study review.

The PI must provide the IRB with sufficient information regarding data collection, identifiers, storage, and access controls. Studies approved under this level of review are not required to undergo annual IRB review unless specified by the IRB in the approval letter.

The institution retains the authority to suspend or terminate research if participant protections are found to be inadequate.

16.3 Expedited Level of Review

Research may be reviewed through Expedited study procedures if it involves no more than minimal risk and falls within one or more of the following categories[22]:

1. Clinical studies of drugs and medical devices only when one of the following is met: (a) research on drugs for which an Investigational New Drug (IND) application is not required; or (b) research on medical devices for which (i) an Investigational Device

[20] 45 CFR 46.104(d)(2) and (d)(3)
[21] 45 CFR 46.111(a)(7)
[22] 45 CFR 46.110 and 21 CFR 56.110

Exemption (IDE) application is not required, or (ii) the medical device is cleared or approved for marketing and the device is being used in accordance with its cleared or approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture, as permitted under the applicable Expedited study review limits.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving general anesthesia or sedation, and excluding x-rays or microwaves, unless otherwise permitted under the published categories.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes, such as medical treatment or diagnosis.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, when eligible for Expedited study review.
8. Continuing Review (CR) of research previously approved by the convened IRB may be conducted using the Expedited Study review procedure under Category 8 when the study is closed to enrollment, interventions have been completed, and only long-term follow-up remains, no participants have been enrolled, and no additional risks have been identified, or the remaining activities are limited to data analysis.
9. Continuing Review (CR) of research, not conducted under an IND or IDE, where categories two through eight do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

All research reviewed under Expedited procedures must satisfy the criteria for IRB approval described in *Section 15.3, Criteria for IRB Approval of Research*, of this handbook.

The designated reviewer may approve the research, require modifications to secure approval, or refer the research to the convened IRB for Full Board review. Expedited study reviewers shall not disapprove research[23].

Referral to Full Board review shall occur when:

- The research is determined to involve more than minimal risk;

[23] 45 CFR 46.110(b); 21 CFR 56.110(b)

- The criteria for approval under Expedited study review are not satisfied; or
- The application presents significant ethical or regulatory concerns, unique ethical questions, or sufficient complexity to warrant review and deliberation by the convened IRB.

Continuing Review (CR) shall not be required for eligible Expedited studies unless specifically required by the IRB[24].

a) Notification of Exempt and Expedited Approvals

Research studies, modifications, Continuing Reviews (CR), and reportable events reviewed under Exempt and Expedited procedures shall be reported to all Institutional Review Board (IRB) members. The Office of Research Compliance (ORC) will maintain a record of all expedited determinations and provide a summary of these actions to IRB members at convened meetings.

These notifications shall include sufficient information to permit board members to remain informed and ask questions regarding studies reviewed under delegated authority while preserving any confidential information as required by applicable laws and institutional policy.

16.4 Full Board Level of Review

Research that does not qualify for Exempt or Expedited study level of review shall be reviewed by the convened Institutional Review Board (IRB) at a meeting conducted in accordance with quorum requirements set forth in Section 10, *IRB Meetings and Operations*, of this handbook.

Full Board review is required for research that:

- Involves greater than minimal risk;
- Involves certain vulnerable populations[25],
- Presents complex ethical, scientific, or regulatory considerations.

Approval of research by the convened IRB requires that the criteria outlined in *Section 15.3, Criteria for IRB Approval of Research*, of this Handbook are satisfied.

The convened IRB shall review research in accordance with quorum and membership requirements established under *Section 10.2*, *Quorum*, in this Handbook. The IRB shall ensure that the meeting includes members with the appropriate expertise and perspectives necessary to conduct a thorough review of the proposed research. When additional

[24] (45 CFR 46.109(f))
[25] 45 CFR 46 Subparts B, C, and D

scientific or scholarly expertise is required, the IRB may obtain consultation from individuals with relevant competencies[26].

Primary and **secondary reviewers** shall conduct a comprehensive review of all submitted materials prior to the **convened IRB meeting**. During the meeting, the reviewers shall present a summary of the proposed research, including its objectives, design, procedures, and subject population, and evaluate risks, anticipated benefits, and ethical and regulatory considerations.

Assigned reviewers shall lead the discussion by identifying key issues, outlining required modifications, and providing recommendations regarding approvability. The reviewers shall facilitate IRB deliberations and guide the application of the regulatory criteria to support an informed determination.

[26] 45 CFR 46.107(f) and 21 CFR 56.107(f)

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Section 17. Initial Review of Research

To conduct an initial review, the **Institutional Review Board (IRB)** must have sufficient information to determine that the criteria for approval are met.

At a minimum, **investigators** must submit:

1. A completed IRB application;
2. Informed consent and **assent** documents, when applicable;
3. Recruitment materials, when applicable;
4. **Conflicts of Interest (COI)** statement or outside activity disclosures;
5. Documentation of external site permissions, when applicable;
6. Data collection instruments;
7. A protocol document, when required (e.g., **clinical trials**, biomedical studies, or greater than **minimal risk** research);
8. A copy of the sponsored proposal or grant award, when applicable (excluding the budget details).
9. The IRB may require additional information or modifications as it deems necessary to conduct the risk/benefit analysis or to minimize risk.

17.1 Administrative Pre-Review and Determination of IRB Level of Review

The Office of Research Compliance (ORC) conducts an administrative pre-review of all submissions, including new studies, Continuing Reviews (CR), and modifications submitted through the **Institutional Review Board (IRB)** electronic management system. This review is conducted prior to IRB reviewer assignment and does not constitute IRB approval or regulatory determination.

During administrative pre-review, ORC staff evaluate submissions to ensure that sufficient information is available to support subsequent IRB review under applicable regulatory criteria. When necessary, ORC staff will request clarifications, corrections, or additional documentation from the **Principal Investigator (PI)** to facilitate review.

As part of pre-review, ORC staff are responsible for:

- Verifying completion of required **human subjects** protection training;
- Confirming completion of applicable institutional reporting requirements, including Outside Affiliation Disclosure;
- Assessing the completeness of material and consistency throughout the application; and

- Ensuring that submissions are prepared in accordance with applicable federal, state, and institutional requirements.

This administrative review is intended to ensure that submissions are sufficiently complete to allow the IRB to evaluate the criteria for approval under *Section 15.3, Criteria for IRB Approval of Research*, of this handbook, and UTRGV policies and procedures.

Following completion of administrative pre-review, ORC staff determine the appropriate IRB levels of review based on regulatory definitions and the nature of the proposed **research**: **Exempt**, Exempt with Limited IRB Review, **Expedited**, **Full Board**, or a determination of non-human subjects research.

Administrative pre-review is generally completed within 7–10 business days. The timeline may vary depending on the quality and completeness of the submission and the volume of IRB applications received at a given point.

17.2 Additional Regulatory Requirements

The Office of Research Compliance (ORC), in consultation with the **Institutional Review Board (IRB)** Chair, Human Protections Administrator (HPA), legal counsel, privacy officials, or other institutional subject matter experts as appropriate, will assess whether additional federal, state, local, **sponsor**, or institutional requirements apply to a proposed study.

Investigators are responsible for disclosing sufficient information regarding study design, setting, participant population, data sources, investigational products, and collaborating sites to permit this assessment.

When additional legal or regulatory requirements apply, the ORC and IRB will incorporate those requirements into the review process and, when applicable, into approval conditions, investigator communications, or required **ancillary review**.

17.3 Reviewer Assignment and Distribution of Review Materials

For **human subject research (HSR)** requiring **Full Board review**, the Office of Research Compliance (ORC) assigns a **primary reviewer** based on their role and expertise and, when appropriate, a **secondary reviewer** based on scientific or scholarly expertise, familiarity with the study population, and absence of conflicting interests.

All IRB members scheduled to participate in the convened meeting will receive, at a minimum, the meeting agenda, application documents necessary for review, **informed consent** documents, recruitment materials, and any relevant supporting documents. Primary and secondary reviewers may receive additional materials or instructions to support a more detailed review.

For research reviewed under expedited procedures, the IRB Chair or a designated

experienced IRB member reviewer will be assigned by the IRB Chair or a designee of the ORC on behalf of the IRB Chair. Materials distributed for **Expedited study** review will include the application, protocol or study summary, consent documents when applicable, recruitment materials, and any additional documents necessary to determine whether the criteria for approval are satisfied.

IRB members are responsible for evaluating the research in accordance with applicable regulatory and institutional criteria for approval. Reviewers should complete their assessment before the scheduled review date and identify any concerns regarding risks, informed consent, privacy protections, participant selection, or other approval criteria. The review process and criteria for approval are described in *Section 15.3, Criteria for IRB Approval of Research*, of this handbook.

The ORC is responsible for ensuring timely distribution of review materials and for documenting assigned reviewers in the IRB record.

17.4 Investigator Qualifications and Site Adequacy

As part of initial review, the **Institutional Review Board (IRB)**will consider whether the **Principal Investigator (PI)** and relevant study staff are appropriately qualified by education, training, experience, licensure, or other relevant credentials to conduct the proposed **research** and protect participant rights and welfare.

The IRB will also consider whether the **research site** or sites are adequate for the conduct of the research, including the availability of resources, privacy protections, safety oversight, and support necessary to carry out study procedures. For clinical research, the IRB will collaborate, as appropriate, with the Office of Clinical Research (OCR) to assess site adequacy, operational feasibility, and the resources necessary to conduct the study safely and in compliance with applicable requirements.

When concerns are identified regarding qualifications or site adequacy, the IRB may require additional information, training, monitoring, conditions of approval, or institutional review before approval is granted.

17.5 Investigator Conflict of Interest Review Process

Investigators and study personnel must comply with institutional **Conflicts of Interest (COI)** and outside activity disclosure requirements. When a disclosed interest may affect, or appear to affect, the design, conduct, or reporting of **research** involving **human subjects**, the matter will be reviewed through the applicable institutional COI process.

The **Institutional Review Board (IRB)** will consider the outcome of the institutional COI review and any management plan in determining whether participant protections are adequate. The IRB may require additional protections, including disclosures in the **informed**

consent process, independent monitoring, modification of the investigator's role, or other measures necessary to protect participant rights and welfare.

Final IRB approval may be withheld until require COI review is complete and the IRB has determined that appropriate protections are in place.

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Section 18. Informed Consent Process

Informed consent is an ongoing, interactive process between the participant or **Legally Authorized Representative (LAR)** and the **research** team. Its purpose is to support a voluntary and informed decision about participation. Participants must be provided with understandable information about the purpose of the study, expected duration, procedures, risks, benefits, and alternatives[27].

Researchers are responsible for presenting information in a manner that facilitates comprehension and allows participants adequate opportunity to consider participation. The **informed consent process** must be described in the IRB application, including the setting, timing, and safeguards to minimize **coercion** or undue influence[28].

Informed consent must be obtained prior to initiating any research activities. For research involving **children**, parental permission and, when appropriate, the child's **assent** must be obtained[29].

Consent documents must begin with a concise and focused presentation of key information to assist prospective participants in deciding whether to participate[30]. Consent materials must not include exculpatory language that waives or appears to waive legal rights or releases the **investigator**, **sponsor**, or institution from liability for negligence[31].

Researchers may use IRB-**approved** methods to obtain consent, including written, oral, or electronic formats, provided all regulatory requirements are met[32]. Regardless of the format, the process must support a voluntary and informed decision.

Electronic informed consent (eConsent) is an acceptable method and may include online consent forms, multimedia tools, or remote consent conducted through secure electronic platforms. All electronic methods must comply with applicable regulatory requirements for comprehension, voluntariness, and documentation[33].

The informed consent process must clearly distinguish research from clinical care[34].

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[27] 45 CFR 46.116; 21 CFR 50.25
[28] 45 CFR 46.116; 21 CFR 50.20
[29] 45 CFR 46.408; 21 CFR 50.55
[30] 45 CFR 46.116(a)(5)
[31] 45 CFR 46.116; 21 CFR 50.20
[32] 45 CFR 46.116; 45 CFR 46.117; 21 CFR 50.20; 21 CFR 50.27
[33] 45 CFR 46.116–117; 21 CFR 50.20; 21 CFR 50.25; 21 CFR 50.27; 21 CFR 11
[34] 45 CFR 46.116(a) and 21 CFR 50.20

UTRGV does not issue broad consent.

18.1 Elements of Consent for Exempt Research

For **research** determined to be an **Exempt study**, **informed consent** may be required by institutional policy. **Investigators** must provide prospective participants with sufficient information to support an informed and voluntary decision regarding participation when participant interaction or intervention occurs.

The **informed consent process** for Exempt Studies should be appropriate to the nature of the study and, at a minimum, include:

1. a statement that the activity involves research;
2. the purpose of the research;
3. a description of the procedures or activities in which participants will be asked to take part;
4. the expected duration of participation;
5. any reasonably foreseeable risks or discomforts;
6. any anticipated benefits, if applicable;
7. information regarding the collection, use, storage, and protection of participant information, as applicable;
8. contact information for the investigator or research team;
9. a statement that participation is voluntary and that individuals may decline or discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled; and
10. participants' compensation, if applicable.

The **Institutional Review Board (IRB)** or Office of Research Compliance (ORC) may require additional information when necessary to ensure that prospective participants are provided with adequate information about the research and any associated privacy, **confidentiality**, or informational risks. Investigators are expected to use institutionally **approved** templates for exempt research when available.

18.2 Elements of Informed Consent for Non-Exempt Research

For non-exempt **human subjects research (HSR)**, the **Institutional Review Board (IRB)** must ensure that **informed consent** includes all the elements of consent[35] and, when appropriate, the additional elements of consent.

1. At a minimum, consent must include:
2. a statement that the activity involves **research**;
3. the purpose of the research;
4. the expected duration of participation;
5. a description of study procedures, including identification of any experimental procedures;
6. reasonably foreseeable risks or discomforts;
7. expected benefits, if any;
8. appropriate alternatives to participation, when applicable;
9. information regarding **confidentiality** and privacy protections;
10. information regarding compensation or treatment for research-related injury, when applicable;
11. contact information for questions about the research, participants' rights, and research-related injuries, when applicable; and
12. a statement that participation is voluntary and that participants may refuse or withdraw without penalty or loss of benefits to which they are otherwise entitled.

Additional elements must be included when appropriate:

1. including information regarding unforeseeable risks;
2. circumstances under which participation may be terminated;
3. additional costs;
4. consequences of **withdrawal**;
5. significant new findings;
6. the approximate number of participants;
7. future use of identifiable information or biospecimens;
8. disclosure of research results;
9. commercial profit from biospecimens; and
10. whole genome sequencing, as applicable.

The IRB will determine whether the required elements of informed consent are adequately addressed and whether any additional elements are necessary to ensure that prospective participants are provided with sufficient information to make an informed decision regarding participation.

[35] 45 CFR 46.116(b) and (c); 21 CFR 50.25(a) and (b)

Investigators are expected to use institutionally approved consent templates that incorporate the applicable regulatory requirements. Alternative consent formats may be used provided that all required elements of informed consent are included and presented in language understandable to prospective participants.

Any waiver or alteration of informed consent, or waiver or alteration of one or more consent elements, must be reviewed and approved by the IRB in accordance with applicable regulatory requirements[36].

18.3 Additional Requirements for the Informed Consent Process for Non-Exempt Research

Only Institutional Review Board (IRB) approved and appropriately trained personnel may obtain informed consent. Individuals obtaining consent must be knowledgeable about the study and able to respond to participant questions[37].

When subjects lack decision-making capacity, consent must be obtained from an LAR. The requirement to obtain informed consent is not waived; rather, it must be obtained from the LAR, with additional safeguards as required[38].

The informed consent process must:

- Allow sufficient time for consideration;
- Minimize coercion or undue influence; and
- Promote participant understanding[39].

Failure to ask questions must not be interpreted as evidence of comprehension. Investigators are responsible for assessing understanding.

The IRB may observe, or designate a third party to observe, the informed consent process[40].

Only the most current IRB-approved consent document may be used. Modifications must receive prior IRB approval, and outdated versions must be removed from use.

Investigators must provide participants with new information that may affect their

[36] 45 CFR 46.116(f)
[37] 45 CFR 46.111; 21 CFR 56.111
[38] 45 CFR 46.111(b)
[39] 45 CFR 46.116
[40] 45 CFR 46.109(e)

willingness to continue participation[41].

18.4 Documentation of Informed Consent for Non-Exempt Research

Written documentation of **informed consent** is required unless the **Institutional Review Board (IRB)** approves a waiver in accordance with applicable regulations[42].

Documentation of informed consent must include:

- The signature and date of the subject or the subject's **Legally Authorized Representative (LAR)**;
- The signature of the individual obtaining consent, if a clinical study; and
- Provision of a copy of the signed informed consent document to the subject or LAR[43].

  Signed informed consent documents must be maintained in accordance with federal regulations and institutional record retention requirements[44].

18.5 Documentation of Consent for Exempt Research

For **human subjects research (HSR)** determined to be an **Exempt study**, **investigators** must document consent in accordance with this handbook, unless the **Institutional Review Board (IRB)** approves a waiver or verbal consent.

Documentation of consent may include a signed consent form, electronic consent, or another method approved by the IRB that is appropriate for the study design and level of risk.

18.6 Review of the Informed Consent Process and Documentation

The **Institutional Review Board (IRB)** will review both the content of the **informed consent** document and the process by which consent will be obtained to determine whether the information to be provided to prospective participants or their **Legally Authorized Representatives (LAR)** is adequate, understandable, and consistent with applicable regulatory requirements.

When **enrollment** of individuals who are not proficient in English is anticipated, the **investigator** must provide consent materials in a language understandable to the

[41] 45 CFR 46.116(c)(5)
[42] 45 CFR 46.117; 21 CFR 50.27
[43] 45 CFR 46.117; 21 CFR 50.27
[44] 45 CFR 46.115; 21 CFR 56.115

prospective participant or LAR, using translated documents or a **short form** process, as appropriate under institutional policy and applicable regulations.

When requested by the investigator and permitted under applicable regulations, the IRB may approve a waiver or alteration of informed consent, or a waiver of documentation of consent. The investigator must provide sufficient justification addressing the criteria, and the IRB will document the basis for its determination in the IRB record or meeting **minutes** as applicable.

The IRB will also determine whether additional elements of consent or supplemental participant information are necessary to protect participant rights and welfare.

18.7 Non-English Speaking Subjects

Information provided to prospective subjects or their **Legally Authorized Representatives (LAR)** must be presented in a language understandable to the individual[45].

For subjects who are not proficient in English:

- A translated **informed consent** document must be provided; or
- The IRB-**approved** **short form** **informed consent process** may be used in accordance with regulatory requirements[46].

When necessary, a qualified interpreter must be utilized to facilitate communication and ensure accurate presentation of all required consent elements. The **Institutional Review Board (IRB)** will determine translation requirements based on the study population and level of risk. All translated materials must receive IRB approval prior to use.

18.8 Accessible Consent

a) Braille Consent

For subjects who read Braille, the **Institutional Review Board (IRB)** may approve the use of a Braille consent document. To ensure accuracy, the IRB may require a certified transcription or independent verification of the Braille document.

[45] 45 CFR 46.116; 21 CFR 50.20
[46] 45 CFR 46.117(b)(2); 21 CFR 50.27(b)(2)

When feasible, the subject should sign the Braille consent document. If written documentation is not practicable, consent may be obtained orally, with appropriate witnessing and documentation[47].

b) American Sign Language (ASL) Consent

For subjects who are deaf and communicate primarily using American Sign Language (ASL), the **Institutional Review Board (IRB)** may approve the **informed consent process** conducted in ASL in conjunction with the IRB-**approved** written consent document.

A certified interpreter fluent in ASL must be used to facilitate the informed consent process. All documentation of the informed consent process must comply with applicable regulatory requirements for **informed consent** documentation[48].

18.9 Waiver or Alteration of Informed Consent

The **Institutional Review Board (IRB)** may approve a waiver or alteration of **informed consent** when all applicable regulatory criteria as described below are satisfied[49].

For **research** not subject to **Food and Drug Administration (FDA)** regulations, the IRB must determine and document that:

- The research involves no more than **minimal risk** to subjects;
- The waiver or alteration will not adversely affect the rights and welfare of subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, subjects will be provided with additional pertinent information following participation[50].
- The research must not be subject to the **Protection of Pupil Rights Amendment (PPRA)**, since it must comply with PPRA parental consent requirements, and the IRB may not waive informed consent when such consent is required under PPRA[51].

For research subject to FDA regulations, waivers or alterations of informed consent are limited to:

- certain minimal-risk **clinical investigations**[52];

[47] 45 CFR 46.117
[48] 45 CFR 46.117; 21 CFR 50.27
[49] 45 CFR 46.116(f)
[50] 45 CFR 46.116(f)(3)
[51] 34 CFR 98
[52] 21 CFR 50.22

- emergency use of test articles[53]; and
- emergency research[54].

The IRB must determine and document that all applicable FDA requirements have been met before approving a waiver or alteration of informed consent.

Research involving deception or incomplete disclosure must be submitted to the IRB as a request for alteration or waiver of informed consent, as applicable. The investigator must describe the nature and purpose of the deception, explain why it is necessary to accomplish the research objectives, assess any associated risks, and provide a debriefing plan unless the IRB determines that debriefing is not appropriate or is not necessary to protect participants. When debriefing is required, participants should be informed of the deception as soon as appropriate and given sufficient information to understand the true purpose or procedures of the research.

18.10 Waiver of Documentation of Informed Consent

The Institutional Review Board (IRB) may waive the requirement for written documentation of **informed consent**[55].

Such a waiver may be granted when:

- The only record linking the subject and the **research** would be the **informed consent** document, and the principal risk would be potential harm resulting from a breach of **confidentiality**.
- The research involves no more than **minimal risk** and includes no procedures for which written consent is normally required outside of the research context; or
- The subjects or Legally Authorized Representatives (LAR) are members of a distinct cultural group or community for which signing forms is not customary, and an appropriate alternative mechanism for documenting consent is provided.

When documentation is waived, the IRB may require an alternative method of documenting that informed consent was obtained.

[53] 21 CFR 50.23
[54] 21 CFR 50.24
[55] 45 CFR 46.117(c)

18.11 Short Form Consent

A **short form** consent document is a written statement indicating that the required elements of **informed consent** have been presented orally to the subject or the subject's **Legally Authorized Representatives (LAR)**[56].

When a short form **informed consent process** is utilized, the following requirements must be met:

- A written summary of the information presented orally must be provided.
- A witness must be present during the oral informed consent process.
- The subject or LAR must sign and date the short form document.
- The witness must sign both the short form document and the written summary; and
- The individual obtaining consent must sign the written summary.

A copy of both the signed short form and the written summary must be provided to the subject or LAR.

When consent is presented orally, documentation must comply with short form consent requirements[57].

18.12 Re-Consenting Subjects

Investigators are responsible for informing subjects of any new information that may affect their willingness to continue participation in the **research**[58].

When such information becomes available, an amended **informed consent** document describing the changes to risks, benefits, or study procedures must be submitted for **Institutional Review Board (IRB)** review and approval prior to implementation.

Subjects must be:

- Provided with the updated information;
- Given the opportunity to ask questions; and
- Asked to indicate their willingness to continue participation, typically by signing the revised informed consent document.

Re-consenting is generally required when modifications may reasonably affect a subject's decision to participate. For minor changes that do not alter the risk/benefit profile or affect subject participation, re-consenting may not be required, as determined by the IRB.

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[56] 45 CFR 46.117(b)(2); 21 CFR 50.27(b)(2)
[57] 45 CFR 46.117(b)(2); 21 CFR 50.27(b)(2)
[58] 45 CFR 46.116(c)(5)

18.13 Exception from Informed Consent for Planned Emergency Research

The **Institutional Review Board (IRB)** may approve an exception from prospective **informed consent** for planned emergency **research** involving subjects in life-threatening situations, in accordance with applicable federal regulations, including:

- 21 CFR 50.24 (FDA regulations governing exception from informed consent requirements for emergency research);
- 45 CFR 46.101(i) (DHHS provisions permitting waiver of informed consent in emergency research); and
- 45 CFR 46.116–117 and 21 CFR 50.20, 50.25, and 50.27, which govern informed consent requirements to be applied when consent becomes feasible.

This exception applies only when subjects are unable to provide legally effective informed consent due to their medical condition and obtaining consent from a **Legally Authorized Representatives (LAR)** is not feasible within the therapeutic window.

This exception is not applicable to research involving prisoners[59].

[59] 45 CFR 46.101(i); 45 CFR 46.306(b)

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Section 19. Continuing Review of Research

19.1 Continuing Review (CR) Requirements

Continuing Review (CR) is required for non-exempt **human subjects research (HSR)** unless it meets the regulatory criteria for elimination of CR Under the 2018 Requirements of the **Common Rule** (45 CFR 46.109(f)(1)(i)), CR is not required for most **minimal risk** research eligible for **Expedited study** review, or for research that has progressed to the point that it involves only data analysis and/or access to follow-up clinical data from procedures that participants would undergo as part of clinical care.

CR remains required for research subject to **Food and Drug Administration (FDA)** regulations (21 CFR 56.109(f)) and for research that is conducted or supported by the Department of Justice, which has not adopted the elimination of CR provisions.

The IRB retains the authority to require CR for any research, including research otherwise eligible for elimination of CR, when additional oversight is warranted based on study-specific considerations.

19.2 When Continuing Review (CR) Is Required

The **Institutional Review Board (IRB)** will conduct Continuing Review (CR) at intervals appropriate to the degree of risk, but not less than once per year. CR is required when any of the following apply:

- The **research** was initially reviewed and **approved** by a **Full Board Review** and involves ongoing interventions, interactions, or identifiable private information.
- The research is regulated by the U.S. **Food and Drug Administration (FDA)**[60].
- The research is sponsored or overseen by the Department of Justice[61].
- The research does not meet the criteria for elimination of CR under 45 CFR 46.109(f)(1)(i–iii).
- The IRB determines that CR is necessary to ensure the protection of participants.

CR is not required when all study interventions or interactions are complete, **enrollment** is closed, and remaining activities involve only data analysis or long-term follow-up consistent

[60] 21 CFR 56.109(f)
[61] 28 CFR 46.109(e)

with standard clinical care, unless otherwise required by the IRB, **sponsor**, or applicable regulations.

The IRB may require CR more frequently than annually when additional oversight is warranted to ensure the protection of **human subjects**. Criteria for increased review frequency may include, but are not limited to:

- Research involving greater than **minimal risk**;
- Studies involving vulnerable populations;
- Complex or high-risk interventions;
- Studies with significant safety concerns, **Adverse Events (AE)**, or **Unanticipated Problems (UP)**;
- Prior findings of serious or continuing **non-compliance**;
- **Investigator** inexperience or limited oversight experience;
- **Data and Safety Monitoring Board (DSMB)** recommendations;
- High enrollment volume or rapid **accrual**; and
- Other study-specific factors affecting participant safety or welfare.

In determining the frequency of CR, the IRB will consider the nature of the research, level of risk, uncertainty regarding risks, participant vulnerability, study complexity, safety monitoring mechanisms, investigator and sponsor compliance history, enrollment activity, and any other factors relevant to the protection of participants.

The IRB's determination regarding review frequency will be documented in the IRB record or meeting **minutes** and communicated to the investigator in the approval notice.

a) Annual Status Check-In (Administrative Oversight)

The Annual Status Check-In is an administrative process used by the **Institutional Review Board (IRB)** to maintain accurate records of **research** activity and ensure ongoing oversight for studies that do not require Continuing Review (CR). The Annual Status Check-In applies to **Exempt studies** and **Expedited studies** that are not subject to CR[62].

The Annual Status Check-In is intended to:

- Confirm the current status (e.g., active, inactive, or completed);
- Ensure that studies no longer involving **human subjects** are appropriately closed; and
- Maintain accurate institutional records of all IRB-**approved** research activities.

[62] 45 CFR 46.104 and 45 CFR 46.109(f)

Principal Investigators (PIs) must respond to annual status check-in requests, provide current study information, and ensure that all research personnel are current with the required CITI Training and Outside Activity Disclosure (OAD). The IRB may request additional information, such as the most recent IRB-approved version of the informed consent document and Data and Safety Monitoring Board (DSMB) reports or equivalent monitoring documentation, if applicable.

Submission and approval of an amendment is considered a check-in activity. Upon approval of the amendment, the protocol's next required check-in date will be extended to one year from the amendment approval date.

19.3 IRB Continuing Review (CR) Process

Continuing Review (CR) may be conducted through expedited procedures when the activities involve no more than minimal risk and fall within one or more federally designated Expedited study review categories, or when the submission involves minor changes to previously approved research[63], including studies previously reviewed by a convened Institutional Review Board (IRB) that now qualify for Expedited Category 8 or 9. Otherwise, review must occur at a convened IRB meeting.

During CR, the IRB evaluates:

- Whether the research continues to satisfy the criteria for approval under Section 15.3, *Criteria for IRB Approval of Research*, of this handbook.
- Whether the informed consent process and consent documents remain accurate and complete.
- Whether new information has emerged that may affect participants' willingness to continue.
- Whether verification from sources other than the investigator is necessary to ensure no material changes have occurred.
- Whether additional protections or increased review frequency are warranted.

Possible IRB determinations include approval, approval with required modifications, referral to a convened meeting, or disapproval (disapproval may only occur at a convened meeting).

19.4 Expiration of IRB Approval Prior to Approval of Study Continuation

If the Continuing Review (CR) is not completed before the expiration date, Institutional Review Board (IRB) approval lapses. When approval expires:

[63] 45 CFR 46.110 and 21 CFR 56.110

- All **research** activities must stop, including recruitment, consent, interventions, interactions, and collection or analysis of identifiable private information.
- Study procedures may continue only when discontinuation would place the subjects at increased risk, and only with written justification from the **investigator** and approval from the IRB Chair[64].
- Study procedures may resume only after the IRB approves study continuation.

Timely submission of CR materials is essential to prevent interruption of research activities.

19.5 Investigator Responsibilities for Continuing Review (CR)

When Continuing Review (CR) is required, the **Principal Investigators (PIs)** must submit a complete CR application with sufficient time before the expiration date for the **Institutional Review Board (IRB)** to review and approve continuation of the study. Approval cannot extend beyond one year, and there is no grace period after expiration[65]. A CR should not be submitted 60 days prior to the expiration date.

The CR application must include:

- Total number of participants enrolled.
- Summary of **Adverse Events (AE)**, **Unanticipated Problems (UP)**, and **protocol deviations**.
- Information on participant **withdrawals** and **screen failures** with reasoning.
- Relevant new literature or findings that may affect risk-benefit assessment.
- Updated evaluation of risks and potential benefits.
- **Data and Safety Monitoring Board (DSMB)** or **Data and Safety Monitoring Plan (DSMP)** reports, if applicable.

[64] 45 CFR 46.108(a)(4) and 21 CFR 56.108(b)
[65] 45 CFR 46.109(f); 21 CFR 56.109(f)

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Section 20. Modification (Amendment)

Any change to **Institutional Review Board (IRB)** **approved** research, including modifications to study procedures, recruitment materials, **informed consent processes** or documents, study instruments, personnel, or study sites, must receive IRB review and approval prior to implementation[66].

Changes may be implemented without prior IRB approval only when necessary to eliminate apparent immediate hazards to participants. Such changes must be reported promptly to the IRB[67]. At UTRGV, **investigators** are required to submit this report within 5 business days of implementation.

The IRB will review these changes to determine whether they were justified and to ensure that participant rights, safety, and welfare remain protected. Except as described above, no changes to an approved research study may be implemented without prior IRB review and approval.

20.1 Minor and Major Modifications

A minor modification is a change that does not materially affect the overall risk–benefit profile of the study, the rights, safety, or welfare of participants, the scientific integrity of the study, or the appropriateness of the **approved** level of **Institutional Review Board (IRB)** review. Minor modifications may include administrative updates, non-substantive consent revisions, certain personnel changes, or other changes that do not increase risk or alter key study procedures.

A major modification is a change that may increase risk, affect participant selection, alter study aims or design, change the **informed consent process** in a substantive manner, introduce new procedures or populations, or otherwise require further deliberation by the convened IRB.

The Office of Research Compliance (ORC), in consultation with the IRB Chair or designee, will determine the appropriate level of review for each modification submission.

[66] 45 CFR 46.108(a)(3)(iii) and 21 CFR 56.108(a)(4)
[67] 45 CFR 46.108(a)(3)(iii) and 21 CFR 56.108(b)(2)

20.2 Submission Requirements

The **Principal Investigator (PI)** is responsible for assessing and clearly describing whether the proposed modification affects the study's risk level, participant population, **informed consent process**, study procedures, or data monitoring provisions, to enable the **Institutional Review Board (IRB)** to determine continued compliance with the criteria[68].

All modifications to **human subjects research** must be submitted through the institution's electronic IRB electronic management system. A modification submission must include:

- A completed modification application.
- A summary describing the proposed changes, the rationale for the changes, and an assessment of whether the changes alter the risk–benefit profile.
- Revised study documents, uploaded using version-controlled update procedures.
- Any new study materials requiring review.

Upon IRB approval, all revised documents become the official record of the **approved** study. **Investigators** must ensure that submitted materials are consistent and accurately reflect the current study design.

20.3 Administrative Review of Modifications by ORC Staff (IRB Delegation)

Modifications to **research** previously determined to be an **Exempt study** may be reviewed and **approved** administratively by Office of Research Compliance (ORC) staff when the proposed changes do not alter the original exemption determination or category[69], introduce procedures or activities requiring **Institutional Review Board (IRB)** review under expedited or full board, and do not increase the level of risk beyond that appropriate for the original exemption determination.

If a proposed modification may affect the eligibility for exemption, the study must be referred for re-evaluation of exemption status and reviewed under the appropriate level of IRB oversight.

The IRB delegates authority to qualified ORC staff to conduct administrative review and approval of certain modifications to previously approved research. This delegated review authority is limited to non-substantive changes that do not require review by the convened IRB or by an IRB member under **Expedited study** review procedures.

[68] 45 CFR 46.111 and 21 CFR 56.111
[69] 45 CFR 46.104

20.4 Full Board Review of Modifications

For studies initially **approved** at a **convened IRB meeting**, minor modifications may be reviewed through expedited procedures when they do not increase risk or adversely affect participant rights, safety, or welfare. Modifications that exceed the definition of "minor" (See *Section 20.5, Expedited Review of Modifications*) must be reviewed by **Full Board Review**[70]. An example of minor modifications in Full Board Review is the addition or removal of study personnel, excluding the **Principal Investigator (PI)** and any key personnel whose qualifications, expertise, or role in the **research** were factors in the convened **Institutional Review Board (IRB)**'s approval of the study.

20.5 Expedited Review of Modifications

Upon submission, the Office of Research Compliance (ORC) will conduct an administrative review for completeness and to determine the appropriate level of review. If the modification meets criteria for expedited level of review, the ORC staff will assist the **Institutional Review Board (IRB)**member reviewer to review and approve modifications that involve no more than **minimal risk** and do not adversely affect participant rights, safety, or welfare.

Examples of minor modifications that may be eligible for expedited level of review include, but are not limited to:

- Addition or removal of study personnel, excluding the PI and any key personnel whose expertise was necessary for approval of studies reviewed by the convened IRB.
- Minor adjustments to sample size that do not impact study design or risk
- Addition of non-sensitive survey or interview questions
- Administrative updates to study documents that do not change study intent
- Changes to recruitment methods that do not increase risk
- A designated **Expedited study** reviewer may exercise all authorities of the IRB except disapproval. Disapproval of a modification may only be determined by the IRB at a convened meeting[71].

20.6 Criteria for Approval of Modifications

To approve a modification, the **Institutional Review Board (IRB)** must determine that the **research**, as modified, continues to meet the regulatory criteria for approval for the level of

[70] 45 CFR 46.108(b) and 21 CFR 56.108(c)
[71] 45 CFR 46.110(b) and 21 CFR 56.110(b)

review required. For non-exempt studies, the criteria for approval must match requirements under *Section 15.3, Criteria for IRB Approval of Research* in this handbook.

The IRB must also ensure that any significant new findings that may affect participants' willingness to continue participation are communicated to participants.

20.7 Approval Period for Modifications

Approval of a modification does not change the study's expiration date unless the modification increases the study's level of risk and requires reclassification from **Exempt**, **Expedited**, or **Full Board Review**. The expiration date remains the same as established during the most recent initial or Continuing Review (CR)[72].

20.8 Oversight of Unapproved Changes

The HRPP uses administrative review, **Post Approval Monitoring (PAM)**, compliance review, and other **quality assurance** activities, as applicable, to assess whether **research** is being conducted consistent with **Institutional Review Board (IRB)** **approved** materials. If modifications are identified that were implemented without prior IRB approval and do not qualify for the immediate hazard exception, the matter will be evaluated as potential **non-compliance** and addressed in accordance with institutional procedures.

[72] 45 CFR 46.109(f) and 21 CFR 56.109(f)

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Section 21. IRB Actions and Notifications

21.1 IRB Actions

The **Institutional Review Board (IRB)** may issue one of four actions at the time of review. These determinations ensure that **research** meets the regulatory criteria for approval and that participant rights and welfare remain protected.

- **Approved** - The IRB determines that the research, as submitted, satisfies all regulatory criteria for approval.
- Approved with Contingencies (Modifications Required to Secure Approval) - The IRB requires minor clarifications, revisions, or administrative updates before final approval is granted. Approval is issued once the **investigator** satisfies the required contingencies.
- Tabled/Deferred - The IRB cannot determine whether the regulatory criteria for approval are met due to missing information, unresolved concerns, or required substantive revisions. The investigator must respond to IRB requests for clarification or modification before the IRB can complete its review.
- **Disapproved** - Only a convened IRB may issue a disapproval determination[73]. Disapproval is issued when the IRB determines that the research does not meet the regulatory criteria for approval, presents unacceptable risks, or lacks adequate protections for participants.

Additional actions available to the IRB may include suspension or termination of previously approved research, as described in *Section 39.1 Criteria for Suspension or Termination* of this handbook.

Designated reviewers conducting **Expedited study** review may not disapprove research. Designated reviewers conducting Expedited study review may approve, require modifications to secure approval, refer the research to the convened IRB, or acknowledge administrative matters, but may not disapprove research.

The rationale for any action taken shall be documented in the IRB records.

[73] 45 CFR 46.109 and 21 CFR 56.109

21.2 Notification of IRB Actions

Following completion of a review, the **Institutional Review Board (IRB)** provides written notification to the **Principal Investigator (PI)** of its determination, including the action(s) taken, any request for revision, and, when applicable, the approval period and Continuing Review (CR) requirements.

Investigators receive written notification indicating whether the project has been **approved** as:

- **Exempt Study**,
- Exempt with Limited IRB Review,
- **Expedited Study**, or
- **Full Board Review**

Notifications will identify the applicable IRB action, as described in *Section 21.1, IRB Actions*, and include any required modifications, conditions of approval, deficiencies requiring further review, or administrative determinations, as applicable.

21.3 Investigator Response to Disapproval

When the **Institutional Review Board (IRB)** disapproves a **research** study, modification, Continuing Review (CR) submission, or other research activity, the **investigator** shall be provided with the reasons for the determination in writing.

The investigator may submit a written response addressing the IRB's concerns and may request reconsideration by the convened IRB. Any request for reconsideration shall include sufficient information, revisions, or clarifications to address the reasons for disapproval. Reconsideration shall occur only through review by the convened IRB and shall not be conducted through expedited procedures.

Investigators may also meet with the IRB, IRB Chair, or designated representatives to discuss the basis for the determination and the information necessary for further review. The final authority for approval or disapproval of research rests with the IRB.

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PART VI. ADDITIONAL PROTECTIONS AND REGULATORY OBLIGATIONS

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Section 22. Research Involving Vulnerable Populations

Research involving individuals who may be vulnerable to coercion or undue influence requires the inclusion of additional safeguards to protect their rights and welfare[74]. Vulnerable populations include, but are not limited to, pregnant women, fetuses, neonates, prisoners, children, and individuals with impaired decision-making capacity. In addition to the populations identified under the regulations, the Institutional Review Board (IRB) may identify other vulnerable populations based on local context, including groups that may face economic, linguistic, immigration-related, educational, or power-imbalance vulnerabilities. Investigators must describe the safeguards to be implemented in the IRB application.

The IRB must apply the additional protections set forth in 45 CFR 46 Subparts B, C, and D, and, where applicable, 21 CFR Parts 50 and 56, for federally funded or Food and Drug Administration (FDA) regulated research. For non-federally funded research, the IRB applies these subparts to the greatest extent possible (as applicable).

22.1 Research Involving Pregnant Women, Fetuses, and Neonates

The Institutional Review Board (IRB) must determine and document that all applicable conditions under 45 CFR 46 Subpart B are satisfied prior to approval of research involving pregnant women, fetuses, or neonates.

a) Pregnant Women and Fetuses

The Institutional Review Board (IRB) must determine and document that the following requirements are met[75], including that:

- Where scientifically appropriate, preclinical and clinical studies have been conducted and provide adequate data for assessing potential risks;
- Risks to the fetus are minimized and are caused solely by procedures that hold out the prospect of direct benefit to the pregnant woman or fetus, or, if no such benefit exists, the risk is no greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means;

[74] 45 CFR 46.111(b) and, where applicable, 21 CFR 56.111(b)
[75] 45 CFR 46.204

- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate; and
- Investigators play no role in decisions regarding the timing, method, or procedures used to terminate a pregnancy or determine the viability of a neonate.

The IRB must determine and document that informed consent is obtained in accordance with 45 CFR 46.116 and with 45 CFR 46.204(e), including whether consent is required from the pregnant woman alone or from both the pregnant woman and the prospective father, and applicable exceptions.

b) Neonates

The IRB must determine and document that the following conditions are satisfied[76].

For neonates of uncertain viability, the IRB may approve research only if it determines that:

- The research holds out the prospect of enhancing the probability of survival to viability and any risk is the least possible; or
- The research develops important biomedical knowledge that cannot be obtained by other means and presents no added risk.
- The IRB must determine and document that legally effective informed consent is obtained from one or both parents, as applicable, in accordance with 45 CFR 46.205(c).

For nonviable neonates, the IRB must determine and document that:

- Vital functions will not be artificially maintained;
- The research will not terminate the neonate's heartbeat or respiration;
- The research presents no added risk; and
- The purpose is the development of important biomedical knowledge that cannot be obtained by other means.

The IRB must determine, and document that informed consent is obtained from both parents, except as permitted under 45 CFR 46.205(c)(5).

22.2 Research Involving Prisoners

Research involving prisoners requires additional safeguards due to the potential for coercion. For federally funded research, the Institutional Review Board (IRB) must comply with 45 CFR 46 Subpart C.

[76] 45 CFR 46.205

The IRB must review such research at a convened meeting and must include a prisoner representative with appropriate background and experience. The IRB must determine and document that:

- The research falls within one of the permissible categories under 45 CFR 46.306(a)(2);
- The criteria for approval under 45 CFR 46.305(a) are satisfied, including that participation is voluntary and free from coercion;
- Risks are commensurate with risks accepted by nonprisoner volunteers;
- The selection of subjects is equitable within the prison population;
- Information is presented in language understandable to the subjects[77].

For federally funded research, the IRB must ensure certification to OHRP prior to initiation.

If a subject becomes incarcerated during participation, the IRB must reassess the research under Subpart C and determine whether continued participation is permissible.

22.3 Research Involving Children

Research involving **children** must comply with 45 CFR 46 Subpart D and, where applicable, 21 CFR Part 50 Subpart D.

The **Institutional Review Board (IRB)** must determine and document that the research meets the criteria of one of the permissible categories under 45 CFR 46.404 – 407, including the level of risk, the prospect of direct benefit, and the justification for approval.

The IRB must determine and document that adequate provisions are made for obtaining **assent** of the child and permission of the parent(s) or guardian(s) in accordance with 45 CFR 46.408, including:

- Whether assent is required and how it will be documented;
- Whether the permission of one or both parents is required, based on the applicable category;
- Whether assent may be waived in accordance with regulatory criteria.

The IRB must ensure that safeguards are in place to minimize undue influence and that compensation is not coercive. When a child enrolled in research reaches the age of majority, the **investigator** must obtain the subject's legally effective **informed consent**, unless waived.

[77] 45 CFR 46.116

For children who are wards of the state or another entity, the IRB must determine and document that the research meets the conditions under 45 CFR 46.409 and must require the appointment of an independent advocate for each child who is a ward to represent the child's best interests throughout participation.

a) School-Based Research Considerations

In addition to the requirements of 45 CFR Part 46, Subpart D (Additional Protections for Children Involved as Subjects in Research), research conducted in school settings must comply with applicable federal laws, including the **Family Educational Rights and Privacy Act (FERPA)**[78] and the **Protection of Pupil Rights Amendment (PPRA)**[79] as well as applicable institutional and school district policies. The IRB must ensure that parental permission and consent requirements are consistent with applicable federal and state law, and that additional protections are implemented when required to safeguard the rights and welfare of student subjects. Waivers of parental permission or documentation may be restricted for research under the PPRA and must be evaluated accordingly.

FERPA protects the privacy of student education records and restricts the disclosure of **Personally Identifiable Information (PII)**. Written authorization from the parent or eligible student is required prior to disclosure, unless an exception applies under 34 CFR 99.31. In the context of **human subjects research (HSR)**, investigators must obtain FERPA-compliant authorization or use data that are **de-identified** such that the identity of the student cannot reasonably be determined. Investigators must not use education records obtained for educational or administrative purposes for research activities without prior IRB review and FERPA compliance.

The PPRA establishes additional safeguards for minor students involved in research conducted or funded by the U.S. Department of Education. It applies to surveys, evaluations, or data collection involving protected categories of information, including political beliefs, mental or psychological conditions, sexual behavior, illegal or self-incriminating conduct, religious beliefs, and income. When research involves these categories, parents must be provided the opportunity to review study materials and provide permission prior to student participation. Parental permission is required and may not be waived by the IRB for research involving protected information under PPRA. Investigators are responsible for complying with PPRA requirements and applicable local educational agency (e.g., school district) policies prior to initiating research activities.

Before submitting an IRB application, investigators must communicate with the educational institution to confirm the study's feasibility. Investigators are also responsible for obtaining

[78] 20 U.S.C. §1232g; 34 CFR Part 99
[79] 20 U.S.C. §1232h; 34 CFR Part 98

written approval from the school district and complying with FERPA, PPRA, and any other applicable school district policies.

22.4 FDA-Regulated Research Involving Vulnerable Populations

For **research** subject to **Food and Drug Administration (FDA)** regulations, the **Institutional Review Board (IRB)** shall be particularly cognizant of the special problems of research involving vulnerable populations and shall ensure that additional safeguards are included when participants may be vulnerable to **coercion** or undue influence[80]. Under FDA regulations, vulnerable populations may include **children**, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

22.5 UTRGV-Affiliated and Other Context-Specific Vulnerable Populations

In addition to the populations described above, the **Institutional Review Board (IRB)** recognizes that individuals within the UTRGV environment or **research** context may be vulnerable to **coercion** or undue influence due to institutional relationships, access to identifiable data, language barriers, or personal circumstances.

The IRB must determine and document that research involving these populations includes appropriate safeguards to protect their rights and welfare[81].

a) Research Involving Decisionally Impaired Adults

The IRB must determine and document that research involving individuals with impaired or diminished decision-making capacity includes appropriate safeguards to ensure legally effective consent and protection of autonomy[82].

The IRB must determine and document that:

- Inclusion of such individuals is scientifically justified and necessary, and that the research cannot practicably be conducted with individuals capable of providing consent[83];
- Risks are reasonable in relation to anticipated benefits and the importance of the knowledge expected[84].

[80] 21 CFR 56.111(a)(3) and (b)
[81] 45 CFR 46.111(b)
[82] 45 CFR 46.111(b), 46.116, and 46.117, and, where applicable, 21 CFR Part 50
[83] 45 CFR 46.111(a)(3), (b)
[84] 45 CFR 46.111(a)(1)–(2)

When subjects lack decision-making capacity, the IRB must ensure that consent is obtained from a **Legally Authorized Representatives (LAR)**[85] and applicable law, and that decisions reflect the subject's preferences or best interests.

The IRB must require **assent** when individuals retain some capacity and must respect any dissent or **withdrawal**. The IRB may require procedures to assess and document decision-making capacity and may require additional safeguards, such as independent monitoring of the **informed consent process**.

If a subject regains decision-making capacity, the **investigator** must obtain the subject's **informed consent** to continue participation.

b) Educationally and Economically Disadvantaged Populations

The IRB must determine and document that appropriate safeguards are in place to protect individuals who are educationally or economically disadvantaged and may be vulnerable to coercion or undue influence[86].

The IRB must ensure that:

- Selection of subjects is equitable and justified[87];
- Recruitment practices minimize the potential for undue influence;
- Compensation is not excessive or coercive;
- The informed consent process is understandable and appropriate to the subject population[88].

The IRB may require additional protections, such as enhanced oversight of the informed consent process or additional measures to ensure voluntary participation and equitable subject selection.

c) UTRGV Students as Participants

At UTRGV, the use of student education records in **human subjects research (HSR)** must comply with the **Family Educational Rights and Privacy Act (FERPA)** as well as institutional policies and procedures governing access to student information. In general, UTRGV requires written authorization from the student or parent prior to the use or disclosure of **Personally Identifiable Information (PII)** from education records for research purposes, unless a regulatory exception applies[89]. Investigators may not use education records obtained through their institutional roles (e.g., instructor access to class records) for

[85] with 45 CFR 46.102(c)
[86] 45 CFR 46.111(b) and 21 CFR 56.111(b)
[87] 45 CFR 46.111(a)(3))
[88] 45 CFR 46.116(a)(3)
[89] 34 CFR 99.30; 34 CFR 99.31

research without prior IRB review and FERPA-compliant authorization or documentation that the data are appropriately **de-identified**. UTRGV permits the use of de-identified education records for research when all direct and indirect identifiers are removed and the student cannot reasonably be identified. Investigators seeking access to institutional data must follow UTRGV data request procedures and obtain necessary approvals, including coordination with the Office of Strategic Analysis and Institutional Reporting (SAIR) and, when applicable, authorization from external educational institutions.

The IRB must ensure that:

- Participation or non-participation will not affect academic standing, grades, or access to services;
- Recruitment avoids undue influence, including when investigators have instructional or evaluative roles;
- Alternative activities are provided when participation is associated with course credit;
- Use or disclosure of education records complies with FERPA, including written authorization where required or appropriate de-identification;
- Investigators do not use education records obtained through institutional roles for research without prior IRB approval and FERPA-compliant authorization or de-identification;
- Access to institutional data follows UTRGV data governance procedures and required approvals.

d) Position of Power and Influence

Individuals who have dependent, subordinate (e.g., supervisors with employees) or unequal relationships with the investigator or research team (e.g., patients of medical doctors, mentees of a mentor), as well as individuals with limited English proficiency, may be vulnerable to coercion, undue influence, or reduced ability to provide fully informed consent due to power differentials, dependency relationships, or communication barriers.

The IRB must determine and document, when applicable, that:

- Recruitment processes are designed to minimize undue influence, including avoiding recruitment by individuals in positions of authority or direct supervisory, instructional, clinical, or evaluative roles;
- Participation or non-participation will not affect employment status, academic standing, access to services, or professional relationships;
- The distinction between research and employment, clinical care, or educational activities is clearly communicated;
- **Confidentiality** of participation and responses is maintained;

- The **informed consent process** is conducted in a language understandable to the subject;
- IRB-**approved** translated consent materials and a qualified interpreter or translation services are used when appropriate;
- Reasonable measures are implemented to confirm subject comprehension prior to **enrollment**.

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Section 23. Recruitment and Compensation

23.1 Recruitment and Advertising Review

All recruitment methods, materials, and advertisements intended to solicit participation in **human subjects research (HSR)** must receive prior review and approval by the **Institutional Review Board (IRB)** before implementation.

Recruitment strategies must be equitable, non-coercive, and consistent with the ethical principles of respect for persons and justice, as articulated in the Belmont Report, as well as the regulatory requirement for equitable subject selection[90].

The IRB evaluates recruitment methods and materials to ensure that the information provided is accurate, not misleading, and does not overstate potential benefits or minimize risks. Recruitment content must not exert undue influence or **coercion** on prospective subjects and must support informed and voluntary participation.

23.2 Compensation and Reimbursement of Subjects

All proposed compensation and reimbursement for **research** participants must be reviewed and **approved** by the **Institutional Review Board (IRB)** to ensure that such payments are reasonable and do not constitute undue influence. Compensation must not be presented in a manner that compromises a subject's ability to make a voluntary and informed decision regarding participation in research[91].

The amount, timing, and method of compensation and reimbursement must be appropriate to the nature of the study and proportional to the time, effort, inconvenience, and burden required of participants. These details must be clearly described during the **informed consent process** and implemented in accordance with the IRB-approved study and consent documents.

At The University of Texas Rio Grande Valley (UTRGV), all compensation practices must comply with institutional policies and procedures governing the administration, documentation, and reporting of payments to research participants. **Investigators** are responsible for ensuring that:

- Compensation is provided only as described in the IRB-approved study and **informed consent** materials; and

[90] 45 CFR 46.111(a)(3)
[91] 45 CFR 46.116 and 21 CFR 50.20

- Payment processes are conducted in accordance with institutional procedures to ensure appropriate fiscal accountability and reporting.

UTRGV requires that compensation provided to research participants be properly documented, limited to what is necessary, and, when applicable, tracked through approved institutional mechanisms to ensure privacy, **confidentiality**, and compliance with institutional data security requirements. Investigators must maintain adequate records of compensation, including payment logs or supporting documentation, as part of the study record and ensure that these records are available for audit or review.

Additional requirements regarding participant compensation, reimbursement, payment methods, documentation, record retention, and fiscal accountability are described in UTRGV Standard Operating Procedures, Compensation for Research Participants.

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Section 24. FDA-Regulated Research

Research involving products regulated by the U.S. Food and Drug Administration (FDA), including drugs, biologics, medical devices, and other FDA-regulated test articles, must comply with applicable FDA regulations and institutional requirements. These requirements apply to investigational products and, in certain circumstances, approved products used in a manner that constitutes a clinical investigation.[92]

The Institutional Review Board (IRB) will determine whether a proposed activity is subject to FDA regulations and will apply FDA definitions of clinical investigation and human subject when making that determination. Investigators are responsible for providing sufficient information and documentation to support FDA-related determinations, including any applicable Investigational New Drug (IND), Investigational Device Exemption (IDE), FDA authorization, or exemption.[93]

Investigators serving as sponsor-investigators assume the responsibilities of both the sponsor and the investigator and must comply with all applicable FDA requirements.[94]

24.1 Determination of FDA Applicability

The Institutional Review Board (IRB) will evaluate whether a proposed activity constitutes an Food and Drug Administration (FDA) regulated clinical investigation and whether FDA authorization or an exemption is required.[95]

When research involves a test article, the Institutional Review Board (IRB) will evaluate:

- Whether the activity meets the definition of a clinical investigation
- Whether the use of the test article requires submission to the FDA (e.g., Investigational New Drug (IND) or Investigational Device Exemption (IDE))
- Whether documentation of FDA authorization or exemption has been provided

Investigators are responsible for determining whether FDA requirements apply and for providing documentation to support IND or IDE status, or an applicable exemption.

24.2 Investigational New Drug (IND) Requirements

Clinical investigations involving drugs or biologics must comply with 21 CFR Part 312.

[92] 21 CFR 56.102(c)
[93] 21 CFR 56.102(c); 21 CFR 56
[94] 21 CFR 312.3(b); 21 CFR 812.3(o)
[95] 21 CFR 56

An Investigational New Drug (IND) application is required unless the investigation meets criteria for exemption[96].

The Institutional Review Board (IRB) will verify:

- Documentation of an IND number provided by the sponsor or Food and Drug Administration (FDA), or
- Justification that the investigation qualifies for an IND exemption

IRB approval may be contingent upon receipt of documentation confirming IND authorization or exemption, as applicable.

24.3 Investigational New Drug (IND) Exemptions

Clinical investigations of drugs may be exempt from Investigational New Drug (IND) requirements[97] when specific regulatory criteria are satisfied, including, but not limited to:

- Investigations of a drug lawfully marketed in the United States when all criteria for exemption are satisfied[98], including the criteria relating to the study's purpose, labeling and advertising, risk, Institutional Review Board (IRB) review, and informed consent[99].
- Investigations involving in vitro diagnostic biological products that meet the applicable exemption criteria
- Investigations involving a drug intended solely for tests in vitro or in laboratory research animals[100], including applicable shipping requirements, are satisfied.
- Investigations involving the use of a placebo when an IND would not otherwise be required.

Investigators must provide sufficient documentation to support an IND exemption determination. The IRB will document its determination in the study record.

24.4 Investigational Device Exemptions (IDE) and Risk Determination

Clinical investigations involving medical devices must comply with 21 CFR Part 812.

The Institutional Review Board (IRB) is responsible for determining whether a device study is:

- Significant Risk (SR), requiring an approved Investigational Device Exemption (IDE), or
- Non-Significant Risk (NSR), for which abbreviated IDE requirements apply[101].

[96] 21 CFR 312.2(b)-(c); 21 CFR 812.66
[97] 21 CFR 312.2(b)
[98] 21 CFR 312.2(b)(1)
[99] 21 CFR 312.7
[100] 21 CFR 312.2(b)(3)
[101] 21 CFR 812.2(b)

- Exempt from IDE requirements because the study satisfies the applicable Food and Drug Administration (FDA) exemption criteria and does not require an IDE[102].

The IRB's risk determination is based on the proposed use of the device in the study and must be documented.

Investigators must provide sufficient information to support this determination, including:

- Device description and prior use data
- Sponsor and/or FDA determinations, if available
- Study protocol and monitoring plan

24.5 Expanded Access (Treatment Use)

Expanded access to investigational drugs or devices for treatment purposes must comply with 21 CFR 312.305–312.320 (drugs/biologics) or applicable Food and Drug Administration (FDA) guidance for devices.

Categories of expanded access include:

- Individual patient access, including emergency use[103]
- Intermediate-size population access[104]
- Treatment IND or treatment protocols for widespread use[105]

Expanded access requires prospective Institutional Review Board (IRB) review and approval, except in emergency situations as permitted under FDA regulations.

Investigators serving as sponsor-investigators in expanded access contexts assume all applicable regulatory responsibilities[106].

24.6 Emergency Use of FDA-Regulated Test Articles

Emergency use of an investigational drug or device without prior Institutional Review Board (IRB) approval may occur only when the conditions permitted by Food and Drug Administration (FDA) regulations[107] are satisfied, including situations in which a patient has a life-threatening or severely debilitating condition, no acceptable alternative treatment is available, and there is insufficient time to obtain prospective IRB approval.[108]

[102] 21 CFR 812.2(c)
[103] 21 CFR 312.310
[104] 21 CFR 312.315
[105] 21 CFR 312.320
[106] 21 CFR 312
[107] 21 CFR 50 and 21 CFR 56
[108] 21 CFR 56.104(c)

The investigator must notify the IRB and Office of Research Compliance (ORC) and submit the required report within five working days.[109] Informed consent must be obtained unless the criteria for an exception are met and appropriately documented.[110]

Any subsequent use of the investigational product requires prospective IRB review and approval unless another emergency circumstance exists.

24.7 Reporting Emergency Use of an FDA-Regulated Test Article

An investigator who conducts or intends to conduct an emergency use of an Food and Drug Administration (FDA) regulated test article must notify the Office of Research Compliance and Institutional Review Board (IRB) in accordance with institutional policy. The report must include the clinical circumstances, justification for emergency use, participant protections implemented, informed consent process or exception applied, and outcome of the use.

The IRB will review the report, document receipt and any required follow-up, and determine whether additional oversight, reporting, or prospective review is required before future use.

24.8 Informed Consent Requirements (FDA-Regulated Research)

For Food and Drug Administration (FDA) regulated clinical investigations, investigators must obtain legally effective informed consent and document consent[111], unless an exception, waiver, or alteration permitted by FDA regulations applies. An IRB may waive or alter informed consent for certain minimal-risk clinical investigations when the criteria are satisfied and documented[112]. Other exceptions to the informed consent requirements may apply as permitted[113], including certain emergency situations in which obtaining informed consent is not feasible before the use of a test article, and specific emergency research conducted under FDA regulations that permit an exception from informed consent when stringent regulatory and Institutional Review Board (IRB) requirements are satisfied.

Research proposing an exception from informed consent in emergency settings may be approved only when all applicable FDA requirements have been satisfied and the IRB documents its findings accordingly.

24.9 Emergency Research Exception from Informed Consent

For research proposing an emergency research exception from informed consent, the Institutional Review Board (IRB) will review the submission in accordance with applicable federal requirements and institutional policy. The investigator must provide sufficient

[109] 21 CFR 56.104(c)
[110] 21 CFR 50
[111] 21 CFR Part 50
[112] 21 CFR 50.22
[113] 21 CFR 50.23 and 21 CFR 50.24

documentation addressing the regulatory criteria, including the justification for the exception, the circumstances under which prospective participants will be enrolled, plans for community consultation and public disclosure when applicable, and procedures for informing participants or Legally Authorized Representatives (LAR) as required after enrollment.

Research involving an exception from informed consent for emergency research may be approved only when all applicable regulatory criteria are met, and the IRB documents its findings in the meeting minutes and IRB record.

24.10 Documentation and Recordkeeping

The Institutional Review Board (IRB) will maintain documentation of determinations and actions related to Food and Drug Administration (FDA) regulated research[114], including:

- Investigational New Drug (IND) or Investigational Device Exemption (IDE) status
- Risk determinations for device studies
- IRB review and approval actions
- Reports related to emergency use or expanded access

Additional procedures and requirements for FDA-regulated research are described in the applicable FDA-related UTRGV Clinical Research SOPs.

24.11 FDA-Regulated Expanded Access / Treatment Use

For Food and Drug Administration (FDA) regulated research involving individual patient expanded access, intermediate-size patient populations, or treatment protocols, the Institutional Review Board (IRB) will review requests in accordance with applicable FDA regulations[115] and institutional policy. The submission must include sufficient information regarding the clinical circumstances, the investigational product, the treatment plan, participant protections, and informed consent, when applicable.

24.12 Humanitarian Use Device (HUD)

Requests for use of a Humanitarian Use Device will be reviewed by the Institutional Review Board (IRB) in accordance with applicable Food and Drug Administration (FDA) requirements[116]. The submission must include sufficient information regarding the device, intended use, participant protections, informed consent process when applicable, and any institutional requirements governing clinical use and oversight.

[114] 21 CFR 56.115
[115] 21 CFR Part 312 Subpart I
[116] 21 CFR 814 Subpart H

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Section 25. Health Insurance Portability and Accountability Act (HIPAA) Regulations

The **Health Insurance Portability and Accountability Act of 1996 (HIPAA),** including the Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) and the Security Rule (45 CFR Part 160 and Subparts A and C of Part 164), establishes federal standards governing the use, disclosure, and protection of **Protected Health Information (PHI)**.

Under HIPAA, covered entities, including health care providers, health plans, and health care clearinghouses, are generally prohibited from using or disclosing PHI for **research** purposes without a valid written Authorization from the individual, unless an exception or waiver applies.[117]

At The University of Texas Rio Grande Valley (UTRGV), the **Institutional Review Board (IRB)** serves as the Privacy Board[118] and is responsible for reviewing research involving PHI. In this capacity, the IRB evaluates and approves requests for Authorization, Waiver, or Alteration of Authorization in accordance with applicable regulatory criteria.

Consistent with its responsibilities under the **Common Rule (45 CFR 46)** and, where applicable, **Food and Drug Administration (FDA)** regulations (21 CFR 50 and 21 CFR 56), the IRB ensures that:

- The use or disclosure of PHI is justified, limited, and consistent with the minimum necessary standard[119];
- Adequate provisions are in place to protect the privacy of research participants and maintain the **confidentiality** of data[120]; and
- Appropriate authorization or IRB-**approved** waiver/alteration has been obtained and documented.

The IRB determines whether:

1. A HIPAA Authorization must be obtained from each subject in addition to **informed consent**; or
2. A Waiver or Alteration of Authorization is appropriate, including for screening, recruitment, or other research activities involving PHI.

Research activities that qualify as an **Exempt Study** as outlined in *Section 16.1, Exempt*

[117] 45 CFR 164.508; 164.512
[118] 45 CFR 164.512(i)
[119] 45 CFR 164.502(b)
[120] 45 CFR 46.111(a)(7)

Study Level of Review, may still require HIPAA Authorization or an IRB-approved waiver if PHI is accessed, created, used, or disclosed.

All **investigators** must obtain either:

- A valid HIPAA Authorization from the subject; or
- An IRB-approved Waiver or Alteration of Authorization prior to use or disclosure of PHI for research purposes.

25.1 Protected Health Information (PHI)

Any identifiable health information relating to the subject's past, present, or future physical or mental health condition or payment for health care is considered **Protected Health Information (PHI)**. When health information is individually identifiable and is held by a "covered entity" (health plan, healthcare clearinghouses, and healthcare providers who electronically transmit any health information in connection with transactions for which DHHS has adopted standards), it is likely to be PHI. Under the **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** Privacy Rule, 18 identifiers are considered direct identifiers (45 CFR 164.514(b)(2)), including:

1. Patient names;
2. Dates (except Dates and ages over 89 must be handled in accordance with 45 CFR 164.514(b)(2)(i)(C).) directly related to an individual (e.g., date of birth, death, hospital admission, and discharge) ;
3. Patient postal addresses including city, state, & zip code;
4. Patient telephone;
5. Patient fax numbers;
6. Patient e-mail addresses;
7. Patient social security numbers;
8. Patient medical records;
9. Patient health plan ID numbers;
10. Account numbers;
11. Certificate/license numbers belonging to a patient;
12. Patient vehicle identifiers;
13. Device identifiers and/or device serial numbers specific to a particular patient;
14. URLs;
15. IP address numbers;
16. Biometric identifiers, including finger and voice prints, belonging to a patient;

17. Full face photos and other comparable images of a patient;

18. Any other unique patient-identifying characteristic or code.

All **investigators** must obtain written permission (authorization) from subjects for the use of their PHI or obtain a waiver or alteration of authorization from the **Institutional Review Board (IRB)**. This includes:

- UTRGV investigators and **research** team conducting research;
- Personnel within Affiliated Covered Entities (ACE); and
- External collaborators accessing PHI for research through UTRGV covered entities.

25.2 Required Elements of a HIPAA Authorization

A **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** Authorization for the use or disclosure of **Protected Health Information (PHI)** for research purposes must include the following information:

- A description of the information to be used or disclosed presented in a specific and meaningful fashion;
- The name or other specific identification of the person(s), or class of persons, to whom the use or disclosure will be made;
- A description of each purpose of the requested use or disclosure;
- An expiration date or event that relates to the individual or the purpose of the use or disclosure;
- A statement of the subject's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the subject may revoke the authorization;
- A statement indicating when the authorization for use and disclosure occurs; e.g., at the end of the **research**;
- Signature of the subject and date. If the authorization is signed by a personal representative of the subject, a description of such representative's authority to act for the subject must also be provided.

In addition to the core elements, the authorization is required to contain statements adequate to place the subject on notice of all the following:

1. The subject's right to revoke the authorization in writing and either:
   a. The exceptions to the right to revoke and a description of how the subject may revoke the authorization; or
   b. To the extent that the information in the Waiver of **informed consent** is included in the notice required by 45 CFR 164.520, a reference to the covered entity's notice.
2. The ability or inability to condition treatment, payment, **enrollment**, or eligibility for

benefits on the authorization, by stating either:

a. The covered entity may not condition treatment, payment, enrollment, or eligibility for benefits on whether the subject signs the authorization when the prohibition on conditioning of the authorization applies; or
b. The consequences to the subject of a refusal to sign the authorization, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

3. The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer protected.
4. The authorization must be written in plain language.
5. The subject must be provided with a copy of the signed authorization.

25.3 Waiver or Alteration of Authorization

The **Institutional Review Board (IRB)**, in its role of Privacy Board for **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** purposes, may approve a waiver or alteration of HIPAA Authorization[121]. In order to use or disclose **Protected Health Information (PHI)** without an authorization signed by the subject, the **Investigator** must obtain one of the following:

1. Documentation that an amendment or waiver of the subjects' authorizations, for use/disclosure of PHI, has been **approved** by the IRB. The determination is made by the IRB; however, the review may be assigned to the Privacy Officer. This provision of the rule might be used, for example, to conduct records **research** when Investigators are unable to use **de-identified** information. The IRB may waive the requirement (45 CFR 164.512) for the investigator to obtain a signed HIPAA consent form for some or all subjects if it finds any of the following:
   a. The use or disclosure of PHI involves no more than a **minimal risk** to the privacy of individuals, based on, at least, the presence of the following elements:
      i. An adequate plan to protect the identifiers from improper use and disclosure;
      ii. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
      iii. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this subpart;
   b. The research could not practicably be conducted without the waiver or alteration; and
   c. The research could not practicably be conducted without access to and use of the PHI.

[121] 45 CFR 164.512(i)

2. Documentation where Investigators represent:
   a. That the research is only for purposes of preparing a study or similar uses preparatory to research,
   b. That the Investigator will not remove any PHI from a covered entity, and
   c. That PHI is necessary for the research purpose;

3. Documentation to disclose PHI of descendants where the Investigator represents that the use or disclosure of PHI is:
   a. Solely for research on the PHI of descendants,
   b. Necessary for research, and
   c. Documentation of the death of the individuals about whom PHI is sought and provided.

25.4 Limited Data Sets (LDS) and Data Transfer and Use Agreements (DTUA)

A **Limited Data Set (LDS)** is information from which certain direct identifiers have been removed in accordance with **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** requirements. An LDS may not include direct identifiers, such as an individual's name, Social Security number, medical record number, or full-face photographic images (45 CFR 164.514(e)). Additionally, the data must not contain information that would directly identify an individual or otherwise constitute **Protected Health Information (PHI)** under applicable laws, regulations, or institutional policies.

LDS may include, however, zip codes, dates of service, dates of birth and death, and geographic information (not street address). A covered entity may use and disclose a LDS for **research** activities conducted by itself, another covered entity, or an **Investigator** who is not a covered entity, if the disclosing covered entity and the LDS recipient enter into a Data Transfer and Use Agreement (DTUA).

This DUA provides covered entities with satisfactory assurances that the recipient of the LDS will use or disclose the PHI in the data set only for specified purposes.

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Section 26. Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) protects the privacy of **research** participants by limiting the disclosure of identifiable, sensitive research information. CoCs are authorized under Section 301(d) of the Public Health Service Act (42 U.S.C. §241(d)) and prohibit the disclosure of identifiable, sensitive research information in federal, state, local, civil, criminal, administrative, legislative, or other proceedings, except as permitted by law. CoC protections supplement, but do not replace, the privacy and **confidentiality** safeguards required[122].

For purposes of CoC protections, identifiable, sensitive information includes information collected or used during research through which an individual may be identified directly or for which there is at least a very small risk that the individual's identity could be deduced through a combination of available information.

Research funded wholly or in part by the National Institutes of Health (NIH) that collects or uses identifiable, sensitive information is automatically deemed to have a CoC. NIH guidance emphasizes that CoC applicability is based on the identifiability of the information rather than the sensitivity of the research topic. Other federal agencies within the U.S. Department of Health and Human Services (DHHS), including Centers for Disease Control and Prevention (CDC), **Food and Drug Administration (FDA)**, Health Resources and Services Administration (HRSA), Indian Health Service (IHS), and Substance Abuse and Mental Health Services Administration (SAMHSA), may issue CoCs or provide comparable protections for research conducted under their authority. Eligibility and application requirements vary by funding agency and research activity.

A CoC provides strong protection against compelled disclosure; however, identifiable, sensitive information protected by a CoC may be disclosed when:

- Required by federal, state, or local law;
- Authorized by the participant;
- Necessary for the medical treatment of the participant and made with the participant's consent; or
- Used for other scientific research conducted in accordance with applicable **human subjects** protection requirements.

[122] 45 CFR 46.111(a)(7), and when applicable, 21 CFR 56.111(a)(7)

The **Institutional Review Board (IRB)** evaluates the adequacy of privacy and confidentiality protections, including the applicability of a CoC, as part of its review of:

- Risk minimization requirements[123];
- Privacy and confidentiality protections under[124]; and
- **Informed consent** disclosures[125].

Investigators are responsible for:

- Determining whether their study is subject to CoC requirements;
- Obtaining a CoC when required or appropriate;
- Describing CoC protections, limitations, and exceptions in the **informed consent process**, when applicable;
- Maintaining appropriate privacy, confidentiality, and data security protections;
- Limiting disclosures of identifiable, sensitive information to circumstances permitted by law or policy; and
- Ensuring that collaborators, **sponsors**, contractors, or other recipients of CoC-protected information understand and comply with applicable CoC requirements.

The Office of Research Compliance and the IRB may provide guidance regarding the applicability of CoCs and investigator responsibilities; however, investigators remain responsible for complying with all applicable federal, state, sponsor, and institutional requirements governing the protection of identifiable, sensitive research information.

[123] 45 CFR 46.111(a)(1)
[124] 45 CFR 46.111(a)(7)
[125] 45 CFR 46.116 and, when applicable, 21 CFR 50.25

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PART VII. COLLABORATIVE , MULTI-SITE, & INTERNATIONAL RESEARCH

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Section 27. External Sites and Site Authorization (UTRGV-Initiated Studies)

UTRGV **investigators** (including faculty, staff, students, and residents) conducting **human subjects research (HSR)** at external or off-campus sites must submit an application to the UTRGV IRB in accordance with UTRGV *HOP ADM 07-104, Human Subjects Research*. These requirements apply to all UTRGV-affiliated investigators conducting **research** at external sites, regardless of funding source or location of research activities.

The **Institutional Review Board (IRB)** application must include documentation of site authorization, such as a signed letter of support or permission from an individual with appropriate authority at the external site. This documentation must confirm that the site is aware of the proposed research and grants permission for the research to be conducted at its facility.

IRB approval by UTRGV signifies that the study meets regulatory requirements for the protection of **human subjects**. However, such approval does not constitute authorization to access external facilities. Investigators remain responsible for obtaining all necessary institutional, operational, and administrative approvals required by the external site to conduct the research at this facility.

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Section 28. Multi-Site Research and Collaborative Research

When non-exempt **human subjects research (HSR)** involves more than one institution engaged in cooperative **research**, federal regulations generally require the use of a single Institutional Review Board (sIRB) to review and oversee the **research** activities conducted in the United States[126]. The sIRB, also known as the reviewing **Institutional Review Board (IRB)** or IRB of record, performs IRB review on behalf of participating institutions to streamline IRB oversight, reduce duplicative review, and promote consistent protection of **human subjects** across study sites. Institutions engaged in cooperative research must rely on a single IRB unless an exception is permitted by law or determined by the supporting federal agency.

UTRGV may serve as the IRB of record or rely on an external IRB through formal reliance agreements, and, if applicable, in accordance with **Food and Drug Administration (FDA)** requirements for multi-site studies. **Investigators** must consult the Office of Research Compliance (ORC) to determine whether a reliance agreement is required and which institution will act as the IRB of record.

The Office of Research Compliance (ORC), in consultation with the IRB Chair, Human Protections Administrator (HPA), and other appropriate institutional officials, will determine whether a reliance arrangement is appropriate and whether the institution will serve as the reviewing IRB or rely on an external IRB.

The reliance file must include the applicable agreement or authorization, delineation of responsibilities, communication plan, reporting expectations, and documentation of local context considerations, as applicable.

Documentation of IRB approval from external institutions must be reviewed and accepted by UTRGV prior to initiating research activities.

Investigators may not initiate research under a reliance arrangement until the institution confirms the applicable IRB review pathway and all required institutional approvals are complete.

When UTRGV serves as the lead or coordinating site for a multi-site study, the **Principal Investigator (PI)** must identify this role in the IRB application and provide the following:

1. A list of all participating institutions **engaged in human subjects research**;

[126] 45 CFR 46.114

2. Confirmation that each engaged institution holds a valid **Federalwide Assurance (FWA)**, when required;
3. Contact information for the PI at each participating site; and
4. A description of the communication plan among sites and IRBs.

The communication plan must address the management and timely exchange of **Unanticipated Problems (UP)** involving risks to subjects or others; research modifications; and relevant interim findings or safety information.

The IRB will evaluate whether the proposed coordination and communication processes are adequate to ensure the protection of human subjects across all sites.

For all collaborative or multi-site studies, the PI is responsible for:

- Ensuring compliance with UTRGV policies, federal regulations, and any terms of reliance agreements;
- Maintaining effective communication with external collaborators; and
- Reporting required information to the IRB in accordance with institutional and regulatory requirements.

Investigators must coordinate with the following offices, as applicable:

- Office of Research Compliance (ORC) for IRB review and reliance agreements;
- Office of Research Contracts and Industry Agreements (RCIA) for MTAs, DUAs, and other contractual arrangements; and
- Other institutional units as required for access, feasibility, and operational approvals.

28.1 Material Transfer Agreements (MTA) and Data Transfer and Use Agreements (DTUA)

When **research** involves the transfer, use, or sharing of materials or data with external entities, **investigators** must coordinate with the Office of Research Contracts and Industry Agreements (RCIA) to determine whether a Material Transfer Agreement (MTA) or Data Transfer and Use Agreement (DTUA) is required.

In accordance with institutional policy and 2 CFR Part 200 (Uniform Administrative Requirements for Federal Awards), research activities involving external materials or data must not begin until all required agreements are fully executed and **approved** by the appropriate institutional officials.

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Section 29. International Research

Human Subjects' Research conducted outside the United States presents additional ethical, legal, cultural, and operational considerations that may affect the protection of human subjects. The University of Texas Rio Grande Valley (UTRGV) Institutional Review Board (IRB) applies the same ethical principles and regulatory standards required for domestic research while recognizing that local laws, customs, cultural practices, community expectations, and oversight requirements may differ between jurisdictions. Consistent with applicable regulations, the IRB will consider local context when evaluating research conducted internationally.

29.1 International Research Requirements

Investigators conducting human subjects' research outside the United States are responsible for identifying and complying with applicable local laws, regulations, institutional requirements, and ethical standards governing the conduct of human subjects research (HSR) in the foreign country where the study is taking place.

As part of the Institutional Review Board (IRB) submission, investigators must provide sufficient information regarding:

- The country or countries where research activities will occur;
- Local approvals, permissions, or ethics reviews required by the host country or institution;
- Cultural, social, or legal considerations that may affect participant protections;
- Translation needs and language considerations; and
- Any local requirements that differ from U.S. regulatory requirements.
- Investigator's qualifications to conduct research in the specified country.

Investigators remain responsible for obtaining all required local authorizations before initiating research activities.

29.2 Local Context Considerations

When reviewing international research, the Institutional Review Board (IRB) will consider information regarding local customs, community standards, literacy levels, participant vulnerabilities, standards of care, economic conditions, cultural expectations, and local legal requirements that may influence the conduct of the research or the protection of participants.

The Institutional Review Board (IRB) may require investigators to provide supporting documentation or may seek consultation from individuals knowledgeable about the local research context when additional expertise is necessary to adequately evaluate the research and participant protections.

29.3 Local Ethics Review

When the foreign country has a human subjects research (HSR) review board, research ethics board, or equivalent oversight body, the principal investigator must obtain documentation of foreign country local ethics review or authorization before UTRGV Institutional Review Board (IRB) approval becomes effective.

29.4 Conflicts Between Regulatory Requirements

If foreign laws, regulations, or ethical requirements differ from U.S. regulatory requirements, investigators must indicate so in the Institutional Review Board (IRB) application and provide sufficient information for evaluation.

The IRB will assess whether the proposed human subjects' research provides protections for participants that are equivalent to, or greater than, those required by UTRGV policies and applicable federal regulations. When necessary, the IRB may require additional safeguards to ensure adequate protection of participants.

29.5 Additional Participant Protections

The Institutional Review Board (IRB) may require additional protections for international human subjects' research when warranted by local conditions at the foreign country, participant vulnerability, language barriers, limited access to healthcare, economic disparities, political instability, or other factors that may affect the rights and welfare of participants.

Additional protections may include, but are not limited to:

- Community engagement or consultation;
- Additional oversight or monitoring;
- Independent verification of study activities;
- Enhanced recruitment safeguards; or
- Additional consent procedures.

29.6 International Travel and Institutional

Requirements Investigators conducting international research are responsible for ensuring that all required UTRGV international travel registrations, approvals, and risk management

requirements are completed prior to engaging in research activities outside the United States.

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Section 30. Reliance Agreements and Single IRB Review

30.1 Reliance Agreements

The University of Texas Rio Grande Valley (UTRGV) may rely on an external **Institutional Review Board (IRB)**, or serve as the reviewing IRB for other institutions in Cooperative Research) and, where applicable, 21 CFR 50 and 56. All reliance arrangements for non-exempt **human subjects research (HSR)** must be formalized through a written reliance agreement executed by the **Institutional Official (IO)** or designee.

A reliance agreement establishes the respective roles and responsibilities of the reviewing IRB and the relying institution, including provisions for regulatory compliance, communication, and reporting obligations. The reliance agreement file will include the fully executed agreement and any amendments.

A reliance agreement is required when UTRGV **investigators** are **engaged in human subjects research** for which another IRB will serve as the reviewing IRB. The agreement must be fully executed prior to the initiation of any **research** activities involving UTRGV personnel.

Reliance arrangements are generally appropriate in the following circumstances:

- Cooperative or multi-site research subject to the single IRB requirement[127]
- Research involving federally designated or sponsor-required central IRBs
- Circumstances in which a specific IRB is required by applicable law, regulation, or **sponsor** policy

A reliance agreement is not required when UTRGV investigators are not engaged in human subjects research (e.g., involvement limited to analysis of **de-identified** data).

At a minimum, reliance agreements must address:

- Allocation of IRB review responsibilities, including initial review, Continuing Review (CR) when applicable, and review of modifications
- Reporting and review of **Unanticipated Problems (UP)** involving risks to subjects or others, and serious or continuing **non-compliance**
- Institutional responsibilities, including **Conflicts of Interest (COI)** review, investigator qualifications, and ancillary approvals
- Communication pathways among the reviewing IRB, relying institution, and investigators

[127] 45 CFR 46.114

- Access to research records and oversight activities, as applicable
- Provisions for termination of reliance and transfer of oversight, if necessary

30.2 Reliance on an External IRB

All **human subjects research (HSR)** in which UTRGV **investigators** are engaged must be submitted to the Office of Research Compliance (ORC), regardless of whether UTRGV serves as the reviewing **Institutional Review Board (IRB)**. When requesting that UTRGV rely on an external IRB, the **Principal Investigator (PI)** must submit the following to the Office of Research Compliance (ORC), as applicable:

- Documentation of the external IRB approval, including the approval letter and approval period.
- The **approved** IRB application, **research** protocol, **informed consent** documents, recruitment materials, and other study documents approved by the reviewing IRB.
- Information sufficient to assess UTRGV local context considerations, including any site-specific requirements or investigator qualifications.
- Documentation of all required institutional reviews and ancillary approvals, as applicable.
- Identification of the reviewing IRB, the reviewing IRB contact person, the reviewing IRB PI, the UTRGV PI, and other UTRGV key study personnel.
- A communication and reporting plan describing how **reportable events**, protocol modifications, **non-compliance**, study closure, and other required information will be communicated between the reviewing IRB, the UTRGV study team, and institutional officials.

The ORC will conduct an institutional review to ensure compliance with UTRGV policies and applicable regulatory requirements. This review includes:

- Verification of investigator qualifications and required training
- Completion of **Conflicts of Interest (COI)** review
- Confirmation of required ancillary approvals
- Assessment of local context considerations, as applicable

The ORC will evaluate whether the external IRB is appropriate to serve as the reviewing IRB, including consideration of regulatory compliance, **Federalwide Assurance (FWA)** status (if applicable), and capacity to provide adequate oversight.

Reliance agreements will be executed only after institutional review is complete and all conditions for reliance have been satisfied. Investigators are responsible for complying with both UTRGV institutional requirements and the policies and determinations of the reviewing IRB.

30.3 UTRGV as the Reviewing IRB

When UTRGV serves as the reviewing **Institutional Review Board (IRB)**, the IRB will conduct review and oversight in accordance with UTRGV *HOP ADM 07-104, Human Subjects Research,* and this handbook, as well as institutional policies and procedures.

The UTRGV IRB is responsible for:

- Initial review and approval of **research**
- Review of modifications to previously **approved** research
- Continuing Review (CR), when required
- Review of **reportable events**, including **Unanticipated Problems (UP)**, **non-compliance**, and suspensions or terminations

The IRB will communicate its determinations to **investigators** and relying institutions and will make relevant IRB policies and records available, as appropriate.

Relying institutions are responsible for providing sufficient local context information to enable the IRB to determine that the research complies with applicable local requirements. Requests to add participating sites must be submitted for UTRGV IRB review and approval in accordance with established procedures.

30.4 Contingency Planning for Transfer of IRB Oversight

If the **Institutional Review Board (IRB)** is unable to continue oversight of one or more studies due to institutional disruption, loss of infrastructure, emergency conditions, or cessation of IRB operations, the institution may implement a contingency plan to transfer oversight to another qualified IRB.

The contingency plan will be coordinated by the Human Protections Administrator (HPA), Office of Research Compliance (ORC), and IRB leadership, and will include identification of affected studies, prioritization based on participant risk, communication with **investigators** and relying institutions as applicable, secure transfer of records, and documentation of the transition of oversight responsibilities.

The institution will take reasonable steps to ensure continuity of participant protections during any transfer of oversight.

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Section 31. Transfer of IRB Oversight

Transfer of **Institutional Review Board (IRB)** oversight occurs when responsibility for an active study is transferred from one IRB to another. Such transfers must ensure continuous IRB oversight and uninterrupted protection of **human subjects**, consistent with federal regulatory expectations.

To initiate a transfer of oversight to UTRGV, the **Principal Investigator (PI)** must submit a new application identifying the request for transfer. The UTRGV IRB will review the study and, if **approved**, will assume oversight as of the effective date specified in the approval documentation.

When applicable, transfers must be documented through a written agreement between the relinquishing and receiving IRBs. The agreement should address:

- Identification of studies subject to transfer
- Transfer and retention of regulatory records
- Effective date of the transfer of oversight
- Review and acceptance of the study by the receiving IRB
- Determination of the next review date, as applicable
- Required updates to study documents, including **informed consent**
- Notification of **investigators**, **sponsors**, and other relevant parties

At no time may there be a lapse in IRB approval or oversight during the transfer process.

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PART VIII. POST-REVIEW AND COMPLIANCE OVERSIGHT

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Section 32. Verification from Sources Other Than Investigator

The **Institutional Review Board (IRB)** has established procedures for determining when verification from sources other than the **investigator** is warranted to ensure that no material changes have occurred since previous IRB review[128]. Such verification is most commonly used for non-exempt **research** studies, studies undergoing Continuing Review (CR), studies with identified compliance concerns, or studies for which the IRB determines that independent confirmation is necessary. **Exempt studies** may be subject to institutional monitoring or compliance reviews; however, the verification procedures described in this section generally apply to non-exempt research.

Verification may be required when:

- The research involves more than **minimal risk**;
- There are concerns regarding investigator compliance or prior **non-compliance**;
- **Post Approval Monitoring (PAM)** identifies discrepancies or areas requiring further review;
- The study involves vulnerable populations or complex interventions;
- There is conflicting or incomplete information in investigator reports;
- The IRB determines that additional oversight is necessary to protect participants.

Verification activities may include:

- Review of source documents, reports, or study records;
- Confirmation from **sponsors** or study monitors;
- PAM visits or audits;
- Review of **Data and Safety Monitoring Board (DSMB)** reports;
- Independent observation of the **informed consent process** or study conduct.

All verification activities and findings will be documented in the IRB record.

[128] 45 CFR 46.108(a)

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Section 33. Data and Safety Monitoring

As part of the **Institutional Review Board (IRB)** review process, **research** protocols must include an appropriate plan for monitoring data and subject safety commensurate with the level of risk. The IRB shall determine when appropriate that adequate provisions are in place to monitor data collected to ensure the safety of subjects[129].

For studies involving greater than **minimal risk**, the IRB may require a formal **Data and Safety Monitoring Plan (DSMP)** or the establishment of a **Data and Safety Monitoring Board (DSMB)**. Monitoring activities must include clear procedures for the review of **Adverse Events (AE)**, **protocol deviations**, **Unanticipated Problems (UP)** involving risks to participants or others, and any protocol-defined stopping rules.

The **Principal Investigator (PI)** is responsible for developing and implementing a DSMP appropriate to the nature, complexity, and risk level of the research. The IRB will evaluate the adequacy of the proposed monitoring plan as part of its review and may require modifications to ensure participant safety.

A DSMB may be required for higher-risk studies, multicenter **clinical trials**, studies involving vulnerable populations, or when otherwise required by a **sponsor**, funding agency, federal regulation, or the IRB. The sponsor, funding agency, coordinating center, or lead institution is generally responsible for establishing and appointing DSMB members. For investigator-initiated studies without an external sponsor, the PI is responsible for proposing an appropriately qualified and independent DSMB, subject to IRB review and acceptance.

A DSMB is an independent group of individuals with relevant scientific, clinical, statistical, and ethical expertise who are responsible for periodically reviewing accumulated study data to protect participant safety and evaluate the ongoing risk-benefit profile of the research. DSMB responsibilities may include:

- Reviewing study progress, participant **enrollment**, retention, and protocol adherence;
- Reviewing AE, **Serious Adverse Events (SAE)**, UP, and other safety information;
- Evaluating data quality, study conduct, and protocol compliance;
- Reviewing interim analyses and accumulating outcome data, when applicable;
- Assessing whether risks to participants remain reasonable in relation to anticipated benefits;

[129] 45 CFR 46.111(a)(6) and 21 CFR 56.111(a)(6)

- Recommending continuation, modification, suspension, or termination of the study based on safety, efficacy, futility, or other predefined stopping criteria; and
- Communicating recommendations to the sponsor, lead **investigator**, and other responsible oversight bodies, as applicable.

When a DSMB is utilized, the PI must submit documentation describing the DSMB's membership, independence, responsibilities, meeting frequency, reporting procedures, and any recommendations that may affect the conduct of the study. The IRB may request DSMB reports or summaries as part of its continuing oversight responsibilities.

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Section 34. Post-Approval Monitoring of IRB Approved Research

The purpose of the University of Texas Rio Grande Valley (UTRGV) **Post Approval Monitoring (PAM)** Program is to promote adherence to regulatory requirements and **research** best practices for studies **approved** by the **Institutional Review Board (IRB)**. The PAM Program functions as an internal **quality assurance** and compliance mechanism that supports the proactive identification, assessment, and resolution of potential regulatory or ethical concerns. The program also provides targeted education, guidance, and training to **investigators** and research personnel to support ongoing compliance and the protection of **human subjects**.

The PAM Program is informed by and operates in alignment with applicable federal regulations, including, but not limited to:

- The authority of the IRB to observe, or have a third party observe, the **informed consent process** and the conduct of the research[130].
- The research plan, when applicable, must include adequate provisions for monitoring data collected to ensure the safety of subjects[131].
- The ongoing oversight and monitoring requirement of studies conducted under a reliance arrangement and conditions.

The PAM Program applies to all active **human subjects research (HSR)** studies approved by or conducted under reliance agreements with the UTRGV IRB. The PAM Program does not address concerns or allegations of research misconduct, which are managed under separate institutional policies and procedures. However, should a concern of research misconduct arise as a result of PAM, the monitor will bring such allegations to the attention of the Research Integrity Officer consistent with *HOP ADM 07-102 – Misconduct in Research*.

PAM study reviews may be conducted through routine, direct, or **Principal Investigator (PI)**-requested selection. PI and study personnel are expected to cooperate with PAM activities and provide access to records, documentation, and study-related materials as requested. The PAM program will notify a PI (up to three times) of an upcoming review. Failure to respond to a third PAM notification will result in escalation to the IRB Chair, who may provide formal notice to the PI and relevant institutional officials. Continued nonresponse or lack of cooperation may result in an administrative pause of research activities and referral for review as potential **non-compliance**. Such matters will be addressed in accordance with

[130] *45 CFR 46.109(g) and 21 CFR 56.109(f)*
[131] *45 CFR 46.111(a)(6) and 21 CFR 56.111(a)(6)*

applicable UTRGV IRB policies and procedures governing non-compliance and corrective actions.

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Section 35. Reportable Events and Reporting Requirements

Federal regulations require the **prompt reporting** of certain events related to the conduct of **human subjects research (HSR)**. The **Institutional Review Board (IRB)** and the institution must ensure that **Unanticipated Problems (UP)** involving risks to participants or others, and serious or continuing **non-compliance**, are promptly reported to appropriate institutional officials, federal agencies, and **sponsors**, as applicable[132].

For purposes of this handbook, prompt reporting is defined as reporting as soon as sufficient information is available to determine reportability and without undue delay unless another regulatory timeframe applies.

Principal Investigators (PIs) are responsible for ensuring that **reportable events** are submitted to the IRB promptly and are also reported to any required monitoring entities (e.g., **sponsor**, data coordinating center, independent medical monitor, or **Data and Safety Monitoring Board (DSMB)**) in accordance with the IRB-**approved** study and sponsor requirements.

35.1 Reporting of Reportable Events to Institutional Officials and Regulatory Authorities

The **Institutional Review Board (IRB)**, in coordination with the Office of Research Compliance (ORC) and the **Institutional Official (IO)**, maintains procedures to ensure **prompt reporting** of events requiring institutional or external notification[133].

The following events must be reported:

- **Unanticipated Problems (UP)** involving risks to participants or others
- Serious **non-compliance** with federal regulations, institutional policies, or IRB determinations
- Continuing non-compliance
- Suspension or termination of IRB approval

When required, reports will be submitted to the Office of Human Research Protection (OHRP), **Food and Drug Administration (FDA)**, **sponsors**, and other oversight entities in accordance with applicable regulations and institutional procedures.

[132] 45 CFR 46.108(a)(4) and 21 CFR 56.108(b)
[133] 45 CFR 46.108(a)(4) and 21 CFR 56.108(b)

35.2 Unanticipated Problems Involving Risks to Subjects or Others

Investigators must promptly report Unanticipated Problems (UP) involving risks to subjects or others to the Institutional Review Board (IRB), in accordance with institutional requirements (within 5 business days), using the designated electronic reporting system.

An UP involving risks to subjects or others is defined as any incident, experience, or outcome that meets all of the following criteria:

1. Unexpected in nature, severity, or frequency given the IRB-approved study, informed consent document, and characteristics of the study population
2. Related or possibly related to participation in the research
3. Suggests that the research places subjects or others at greater risk of harm than was previously known or recognized

This definition is consistent with federal guidance[134].

Events requiring reporting include, but are not limited to:

- Adverse Events (AE) that meet the criteria above
- External safety reports determined to be UP
- New risk information (e.g., interim findings, sponsor safety communications, Data and Safety Monitoring Board (DSMB) reports)
- Changes implemented without prior IRB approval to eliminate immediate hazards[135]
- Protocol deviations that increase risk or have recurrence potential
- Subject complaints indicating increased risk or unresolved concerns
- Incarceration of a participant in research not previously approved under special requirement for prisoners.

35.3 IRB Review of Reportable Events

Upon receipt of a report, the Office of Research Compliance (ORC) will conduct an initial assessment to determine whether the report appears to meet the criteria for an Unanticipated Problem (UP) and whether additional review is required.

Reports that potentially meet the criteria for an UP, or that suggest serious or continuing non-compliance, will be referred to the Institutional Review Board (IRB) Chair or a designated reviewer and, when appropriate, to the convened IRB for final determination.

[134] 45 CFR 46.108(a)(4) and 21 CFR 56.108(b)
[135] 45 CFR 46.108(a)(3)(iii); 21 CFR 56.108(a)(4)

All reportable events will also be evaluated to determine whether non-compliance has occurred.

For research conducted under reliance agreements, communication will occur in accordance with the reliance agreement terms.

35.4 Reporting Workflow and Process

To ensure timely and consistent handling of reportable events, the Institutional Review Board (IRB) follows an operational reporting workflow:

1. The investigator identifies a reportable event (e.g., Unanticipated Problems (UP), Adverse Event (AE), or non-compliance).
2. The event is submitted to the IRB through the designated electronic system within the required timelines.
3. The Office of Research Compliance (ORC) conducts an initial review to determine the completeness of the report and assess whether the event meets reporting criteria.
4. If applicable, the event is escalated to IRB Chair or designee for preliminary assessment, or referred to the convened IRB for review.
5. The IRB determines whether the event meets criteria for an UP or non-compliance and requires corrective actions or modifications.
6. The Institutional Official (IO) or designee ensures reporting to OHRP, Food and Drug Administration (FDA), sponsors, and other entities as required.
7. All actions, determinations, and communications are documented, and any required follow-up actions are tracked to completion.

This workflow supports timely response, regulatory compliance, and protection of research participants.

35.5 IRB Determinations and Required Actions

When an event is determined to be an Unanticipated Problem (UP) involving risks to subjects or others, the Institutional Review Board (IRB) will take actions necessary to protect the rights, safety, and welfare of participants[136].

Following review of an UP, noncompliance allegation, or compliance investigation, the IRB may take one or more of the following actions, as appropriate:

- Require additional information from the investigator;

[136] 45 CFR 46.111, 45 CFR 46.113 and 21 CFR 56.111, 56.113

- Require modifications to the protocol, **informed consent** documents, recruitment materials, or study procedures;
- Require additional participant protections or monitoring activities;
- Require retraining of investigators or **research** staff;
- Require corrective and preventive action plans;
- Increase the frequency of Continuing Review (CR);
- Require independent verification from sources other than the investigator;
- Refer concerns to institutional officials or other oversight entities;
- Suspend study activities in whole or in part;
- Terminate IRB approval of the research;
- Make any other determination necessary to protect the rights, welfare, or safety of research participants; or
- Determine that no further action is required.

The rationale for all IRB determinations and actions shall be documented in the IRB records and, when reviewed by the convened IRB, reflected in the meeting **minutes**.

35.6 Reporting to Institutional Officials and Regulatory Agencies

For funded **research**, the **Institutional Official (IO)**, or designee, will report the following[137], as applicable:

- **Unanticipated Problems (UP)** involving risks to subjects or others
- Serious or continuing **non-compliance**
- Suspension or termination of IRB approval

Reports will be submitted to other institutional officials (as appropriate), and coordination will be done for proper reporting to federal agencies (e.g., Office of Human Research Protection (OHRP), **Food and Drug Administration (FDA)**), and **sponsors** within required timeframes, without undue delay.

35.7 Notification to Investigators

Investigators will be notified in writing of the **Institutional Review Board (IRB)**'s determinations regarding **reportable events**. Notifications will include:

[137] 45 CFR 46.108(a)(4) and 21 CFR 56.108(b)

- Whether the event meets the criteria for an **Unanticipated Problem (UP)**
- Required corrective actions or modifications, if applicable
- Reporting obligations to external entities, if required

35.8 Adverse Events

An **Adverse Event (AE)** is any untoward or unfavorable medical occurrence associated with participation in **research**, including abnormal signs, symptoms, or diseases.

Under federal regulations, not all AE are reportable to the IRB. Only AE that meet the definition of an **Unanticipated Problem (UP)** require **prompt reporting**[138].

A **Serious Adverse Event (SAE)** includes events that result in:

- Death
- Life-threatening condition
- Inpatient hospitalization or prolongation of hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly or birth defect
- Other important medical events that may require intervention

SAEs that meet the criteria for an UP must be reported to the **Institutional Review Board (IRB)**. **Investigators** conducting **Food and Drug Administration (FDA)** regulated research must also comply with all applicable **sponsor** and **Food and Drug Administration (FDA)** reporting requirements[139]. Depending on the nature of the FDA-regulated research, these requirements may include reporting:

- Unanticipated adverse device effects (UADEs);
- Serious and unexpected suspected adverse reactions or other significant safety findings;
- Sponsor safety reports that may affect participant safety or the risk-benefit assessment of the research;
- Changes or deviations implemented without prior approval to eliminate immediate hazards to subjects;
- **Emergency use** of a test article without prospective **informed consent**, when permitted by FDA regulations;
- **Withdrawal** of IRB approval;

[138] 45 CFR 46.108(a)(4) and 21 CFR 56.108(b)
[139] 21 CFR 312.32 and 21 CFR 812.150

- Data and Safety Monitoring Board (DSMB) findings, interim analyses, or other new information that may affect the risk-benefit assessment of the research;
- Other safety reports or notifications required by the sponsor, investigation plan, or applicable FDA regulations.

Table 51. Summary of Reportable Events, Responsible Parties, and Reporting Timelines

Event	Reporter → Recipient	Timeline
Unanticipated problems; serious or continuing noncompliance; suspension or termination of IRB approval	Institution/IRB → OHRP, FDA, appropriate institutional officials, sponsors, and other oversight entities, as applicable	Promptly, without undue delay, in accordance with applicable requirements
Unanticipated problem	Investigator → IRB	Within 5 business days, consistent with institutional requirements
IND safety report: fatal or life-threatening suspected adverse reaction	Sponsor → FDA and participating investigators	Within 7 calendar days (21 CFR 312.32(c)(2))
IND safety report: other serious and unexpected suspected adverse reaction	Sponsor → FDA and participating investigators	Within 15 calendar days (21 CFR 312.32(c)(1))
Serious adverse event in an IND study	Investigator → Sponsor	Immediately (21 CFR 312.64(b))
Unanticipated adverse device effect (UADE)	Investigator → Sponsor and reviewing IRB	As soon as possible, but no later than 10 working days after the investigator first learns of the effect (21 CFR 812.150(a)(1))
Emergency use of an investigational device without informed consent	Investigator → Sponsor and reviewing IRB	Within 5 working days after the use of the device (21 CFR 812.150(a)(4))
IRB withdrawal of approval of an IDE investigation	Investigator → Sponsor	Within 5 working days after the investigator is notified (21 CFR 812.150(a)(5))

35.9 Documentation and Recordkeeping

The Institutional Review Board (IRB) will maintain documentation of all reportable events, determinations, and actions[140] as described in *Section 40.2, Research Record Retention*, of this handbook.

[140] 45 CFR 46.115 and 21 CFR 56.115

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Section 36. Non-Compliance, Investigation, and Reporting

36.1 Noncompliance

Non-compliance is defined as failure to adhere to applicable federal regulations, institutional policies, or **Institutional Review Board (IRB)** determinations governing the conduct of **human subjects research (HSR)**. Non-compliance may involve **investigators**, **research** staff, the institution, or the IRB.

Non-compliance is categorized as:

- Serious non-compliance: Noncompliance that adversely affects the rights, safety, or welfare of participants, or compromises the integrity of the research or the Human Research Protection Program
- Continuing non-compliance: A pattern of repeated non-compliance or failure to correct previously identified deficiencies

Examples of non-compliance include, but are not limited to:

- Conducting research without IRB approval
- Implementing changes to **approved** research without prior IRB approval, except when necessary to eliminate immediate hazards
- Failure to obtain or document **informed consent** in accordance with regulatory requirements
- Failure to comply with IRB determinations including the approved application or conditions of approval

Investigators are responsible for promptly reporting instances of non-compliance in accordance with institutional requirements.

36.2 Responsibilities for Reporting

The **Principal Investigator (PI)** is responsible for promptly reporting **reportable events**, including **Unanticipated Problems (UP)**, potential **non-compliance**, **protocol deviations** requiring review, and changes implemented to eliminate immediate hazards, to the **Institutional Review Board (IRB)** through the designated reporting system.

The Office of Research Compliance (ORC) is responsible for conducting initial administrative assessments, coordinating IRB review as applicable, preparing institutional reporting materials, maintaining documentation, and facilitating communication with the **investigator** and institutional officials.

The **Institutional Official (IO)**, or designee authorized under institutional policy, is responsible for final institutional reporting to the Office of Human Research Protection, **Food and Drug Administration (FDA)**, **sponsors**, and other oversight entities, when required.

36.3 Initial Assessment

Upon receipt of a complaint, allegation, or report of **non-compliance**, the Office of Research Compliance (ORC) will conduct an initial assessment to determine whether the matter involves non-compliance and whether it may meet the criteria for serious or continuing non-compliance.

The Human Protections Administrator (HPA) or designee, in consultation with the **Institutional Review Board (IRB)** Chair as appropriate, will:

- Evaluate the available information
- Request additional information as necessary
- Determine whether further investigation is warranted
- Identify whether immediate actions are necessary to protect **research** participants

When necessary to protect the rights, safety, or welfare of participants, the IRB Chair or designee may implement interim measures, including suspension of research activities[141].

36.4 Investigation and IRB Review

Allegations that may involve serious or continuing **non-compliance** will be led by the Human Protections Administrator (HPA), and the involvement of the **Institutional Review Board (IRB)** Chair, or designee, as necessary. An ad hoc review group may be convened as needed. Individuals with **Conflicts of Interest (COI)** will not participate in the review.

If the investigation indicates that serious or continuing non-compliance may have occurred, the matter will be referred to the convened IRB for review.

The IRB will determine:

- Whether non-compliance occurred
- Whether the non-compliance constitutes serious or continuing non-compliance
- Appropriate corrective actions or sanctions

[141] 45 CFR 46.113 and 21 CFR 56.113

The **investigator** will be notified in writing of the IRB's determination and any required actions.

The HPA will be responsible for documenting the investigation and preparing a complete investigation report with supporting documentation. If the HPA is conflicted, the matter will be delegated to another qualified employee within the Office of Research Compliance.

36.5 Assessment of Serious or Continuing Noncompliance

In determining whether **non-compliance** is serious, the **Institutional Review Board (IRB)** will consider factors such as the actual or potential effect on participant rights, safety, welfare, or privacy; the impact on the integrity or validity of the **research**; whether the event involved failure to obtain required IRB approval or **informed consent**; and whether the non-compliance reflects disregard of regulatory or institutional requirements.

In determining whether non-compliance is continuing, the IRB will consider whether the matter reflects a pattern of repeated non-compliance, repeated failure to correct previously identified deficiencies, or recurrence of similar events despite prior notice, education, or corrective actions.

The basis for the IRB's categorization of non-compliance will be documented in the IRB record and the minutes when reviewed in a **convened IRB meeting**.

36.6 Corrective Actions and IRB Determinations

In fulfilling its responsibility to protect the rights and welfare of **research** participants, the **Institutional Review Board (IRB)** may require corrective actions as appropriate, including:

- Modifications to the **approved** research or **informed consent process**
- Additional training or oversight of research personnel
- Enhanced monitoring of the research
- Suspension or termination of IRB approval[142]
- Notification of participants when the information may affect their willingness to continue participation

When IRB approval is suspended or terminated, the IRB will consider the rights and welfare of enrolled participants and determine whether additional protections or notifications are necessary.

[142] 45 CFR 46.113 and 21 CFR 56.113

36.7 Reporting Requirements

The **Institutional Official (IO)**, or designee, will report the following, as applicable, to appropriate institutional officials, federal agencies, and **sponsors**[143] as described in Section 34. *Reportable Events and Reporting Requirements* in this handbook.

36.8 Documentation and Record Retention

The Office of Research Compliance (ORC) will maintain records of complaints, allegations, investigations, **Institutional Review Board (IRB)** determinations, and corrective actions[144] as described in Section 40.2, *Research Record Retention*, of this handbook.

[143] 45 CFR 46.108(a)(4) and 21 CFR 56.108(b)
[144] 45 CFR 46.115 and 21 CFR 56.115

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Section 37. Research Misconduct Involving Human Subjects Research

Allegations of research misconduct involving **human subjects research (HSR)** conducted under an **Institutional Review Board (IRB) approved research** study are managed in accordance with UTRGV *HOP ADM 07-102, Misconduct in Research*.

When an allegation is received, the allegation should be promptly referred to the UTRGV Research Integrity Officer (RIO). The RIO will conduct the appropriate assessment and, if warranted, inquire into and investigate in accordance with institutional policy to determine whether there is a finding of research misconduct.

The IRB, through the Human Protections Administrator (HPA) and the IRB Chair (or designee), will collaborate with the RIO, as appropriate, to provide subject-matter expertise related to **human subjects** protections, preserve relevant research records, and support the development and implementation of any required corrective actions involving approved research.

Any subsequent inquiry, investigation, institutional action, and required reporting shall be conducted in accordance with *HOP ADM 07-102, Misconduct in Research,* and applicable federal, state, and institutional requirements.

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Section 38. Mandatory Reporting and Researcher Legal Obligations

38.1 Reporting of Abuse and Neglect (Texas Law)

In accordance with Texas Family Code § 261.101, any individual who has reasonable cause to believe that a **child**, elderly individual, or person with a disability has been subjected to abuse or neglect is required to report such concerns to the Texas Department of Family and Protective Services (DFPS). Certain individuals, including UTRGV employees, are designated as mandatory reporters under Texas law.

Consistent with institutional policy and ethical requirements under 45 CFR 46 (Protection of Human Subjects) and the **Food and Drug Administration (FDA)**, researchers must obtain **informed consent** from adult participants and parental permission and child **assent**, as applicable. When **research** activities may reasonably elicit disclosure of abuse or neglect, **investigators** must clearly disclose their mandatory reporting obligations during the consent and assent process.

38.2 Title IX Reporting Obligations in Research Contexts

Pursuant to Texas law and UTRGV policy (ADM 03-300), all UTRGV employees are required to report known incidents of sexual assault, sexual harassment, dating violence, or stalking involving individuals who were UTRGV students or employees at the time of the incident.

These reporting requirements apply when **research** participants are affiliated with UTRGV as students or employees. In general, they do not apply to participants without such affiliation, unless otherwise required by law or institutional policy.

38.3 Research Involving UTRGV Students

Researchers conducting **Institutional Review Board (IRB) approved** studies involving UTRGV student participants are designated as Confidential Employees. In this role, researchers must:

- Report only the type of incident (e.g., sexual assault, stalking, sexual harassment, or dating violence);
- Submit reports using **de-identified**, statistical information only; and
- Ensure that no **Personally Identifiable Information (PII)** is disclosed.

Reports must be submitted as soon as practicable to the Title IX Coordinator using the reporting tool specified on the website.

38.4 Research Involving UTRGV Employees

When **research** involves UTRGV employees, **investigators** are required to report all known information regarding incidents of sexual misconduct to the Title IX Coordinator using the reporting tool specified on the website.

Questions regarding sexual misconduct reporting obligations should be directed to the Office of Institutional Equity at: otixeo@utrgv.edu.

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Section 39. Complaints

39.1 Complaints and Concerns, and Inquiries

The University of Texas Rio Grande Valley (UTRGV) provides mechanisms for faculty, staff, students, **research** participants, and the public to report concerns, complaints, or questions related to **human subjects research (HSR)**, including concerns regarding **coercion**, undue influence, or potential **non-compliance**.

This mechanism is separate from the research team and is intended to ensure that participants have access to an impartial institutional resource to address concerns related to their rights, safety, and welfare. **Informed consent** documents must include contact information for a representative of the research team to allow participants to ask questions or report concerns about their rights as research subjects.

For questions regarding the research study or research participant's rights, please contact:

- Office of Research Compliance (ORC) and **Institutional Review Board (IRB)**
  - Phone: (956) 665-3364
  - Email: IRB@utrgv.edu

For complaints or concerns about the IRB, ORC, or HRPP, please contact:

- UTRGV Office of Institutional Compliance Hotline
  - Phone: (877) 882-3999
  - Online Reporting: utrgv.ethicspoint.com

Anonymous reports may also be submitted through the UTRGV Office of Institutional Compliance hotline.

All concerns will be handled confidentially to the extent permitted by law, reviewed and addressed in accordance with the institutional processes described above and applicable regulatory requirements. The ORC is responsible for ensuring that all complaints and allegations are assessed and addressed in accordance with applicable federal regulations and institutional policies[145].

These reporting mechanisms are designed to ensure **confidentiality**, impartial review, and protection from retaliation to the extent permitted by law.

[145] 45 CFR 46.108(a)(4) and 21 CFR 56.108(b)

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Section 40. Suspension, Termination, Temporary Pause, and Reinstatement of Research

The Institutional Review Board (IRB) may suspend or terminate approval of research that is not conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects[146].

To support preliminary assessment of potential non-compliance or risk, the IRB, Institutional Official (IO), IRB Chair, or designee may require a temporary pause of research activities. A pause is an administrative action intended to protect participants while additional information is gathered and does not constitute a final determination.

All suspensions or terminations of IRB approval must include a written statement of the reasons for the action and be promptly reported to the Principal Investigator (PI), appropriate institutional officials, and applicable federal agencies, as required by regulation.

40.1 Criteria for Suspension or Termination

The Institutional Official (IO) and other authorized institutional officials may suspend or terminate research that has received Institutional Review Board (IRB) approval when warranted by justifiable circumstances. Before terminating a study, the institution will coordinate with the IRB, as appropriate, to ensure that adequate provisions are in place to protect the rights, safety, and welfare of participants and to ensure an orderly closure of research activities.

The IRB may suspend or terminate a study based on, but not limited to, the following findings:

1. Inappropriate involvement of human subjects in research;
2. Violation of the rights or welfare of participants or others;
3. Serious or continuing non-compliance with federal regulations, IRB requirements, or institutional policies;
4. New information indicating an increase in risk to participants or others; or
5. Unanticipated Problems (UP) involving risks to participants or others, including Serious Adverse Events (SAE).

Determination may be based on information obtained through Continuing Review (CR), Post

[146] 45 CFR 46.113 and 21 CFR 56.113

Approval Monitoring (PAM), audits, or reported concerns/complaints.

When implementing a suspension or termination, the IRB (or designee) must ensure adequate protection for participants, including:

- Immediate actions necessary to protect participant rights and welfare;
- Safe and appropriate withdrawal, transfer, or continued monitoring of enrolled participants, when applicable;
- Determination of whether participants should be informed of the action; and
- Reporting and management of Adverse Events (AE) or outcomes, as applicable.

The Principal Investigator (PI) will be notified promptly in writing of any suspension or termination. In urgent situations, verbal notification may precede written confirmation. The notification will include effective date of the action; description of the research activities affected; reason(s) for the action; required corrective actions, if applicable; instructions regarding participant notification and management, as applicable; and submission requirements for PI response.

40.2 Authority for Suspension or Termination of IRB Approved Study

The Principal Investigator (PI) is responsible for immediately implementing the suspension or termination; notifying the Institutional Review Board (IRB) in writing of the circumstances leading to the suspension or termination of the study; submitting a plan, if applicable, for participant notification and safe withdrawal or follow-up care; and providing any additional information requested by the IRB.

The IRB will review the PI's response at a convened meeting (or by expedited procedures, as appropriate) and determine whether additional actions or modifications are required.

Authority to suspend or terminate research is as follows:

- IRB (convened board) holds primary authority to suspend or terminate IRB approval.
- IRB Chair (or designee) may temporarily pause approval to eliminate immediate hazards to participants or when there is sufficient evidence of non-compliance affecting participant safety. Actions are reported to the convened IRB for review.
- An Institutional Official (IO) or other authorized institutional official may suspend or terminate a research study for justifiable reasons beyond the scope of the IRB.

40.3 IRB Review and Reporting

All suspensions and terminations must be reviewed by the convened Institutional Review Board (IRB), which will evaluate the basis for the action; review the Principal Investigator (PI)'s response and corrective action plan; and determine whether the suspension should

be lifted or the termination upheld.

Consistent with federal requirements[147], the IRB will report suspensions or terminations, including the reasons for the action, to institutional officials; the Office for Human Research Protections (OHRP), when applicable; the **Food and Drug Administration (FDA)**, where applicable; and other oversight entities, as required.

40.4 Reinstatement of Research

Only the **Institutional Review Board (IRB)** may lift a suspension. Reinstatement may occur through **Expedited study** review when criteria are met and authority has been delegated, or through convened IRB review when required.

The IRB Chair may lift a temporary pause if the pause was imposed by the Chair; the IRB or **Institutional Official (IO)** explicitly delegated such authority; or the IRB determines that Expedited study review is appropriate.

A suspension may be lifted only after the IRB determines that all concerns have been adequately addressed and participant protections have been sufficiently restored. Written notification of reinstatement will be provided to the PI and all previously notified parties.

[147] 45 CFR 46.113; 21 CFR 56.113

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Section 41. Study Completion, Closure, and Record Retention

41.1 Study Completion and Closure

The **Principal Investigator (PI)** is responsible for notifying the **Institutional Review Board (IRB)** when a **research** study is completed and should be closed. Study completion occurs when all research activities involving **human subjects** and identifiable human subject data are finished, including data collection and any interventions or interactions with subjects.

To formally close a study, the PI must submit a study closure request (referred to as project closure in the IRB electronic management system) to the IRB.

The Office of Research Compliance (ORC) will review all study closure submissions to verify that:

- All **human subjects research (HSR)** activities have been completed;
- No further interaction or intervention with subjects is occurring; and
- The use of identifiable private information or biospecimens, if applicable, has concluded or is being maintained in accordance with IRB approval and applicable regulations.

The ORC will review closure submissions for completeness and update institutional records to reflect study closure. The ORC may request additional information or clarification from the PI to ensure that the study has been appropriately conducted.

In limited circumstances, the ORC, on behalf of the IRB, may administratively close a study without a PI-submitted closure when necessary to maintain compliance and accurate institutional records. These circumstances include, but are not limited to:

- The PI is no longer affiliated with UTRGV, and no qualified, IRB-**approved investigator** is available to assume responsibility for the study.
- IRB approval has been terminated by the IRB review[148] (*See section 39.1 Criteria for Suspension or Termination*).

Once IRB approval lapses or expires, it is not required for the PI to submit a report to the IRB. However, **Food and Drug Administration (FDA)** regulated studies may require submission of a final report or other end-of-study report under the applicable **Investigational New Drug**

[148] 45 CFR 46.113; 21 CFR 56.113

(IND) or Investigational Device Exemption (IDE) regulations, even if IRB approval has expired[149].

41.2 Research Record Retention

Record retention requirements continue to apply after closure in accordance with applicable regulations and institutional policy. Investigators are responsible for maintaining complete and accurate research records and ensuring that all study-related documents are stored securely following study closure. The required retention period varies depending on the nature of the research, applicable regulations, sponsor requirements, funding source, and the types of data collected. UTRGV requires that all human subjects research (HSR) records be retained for at least three (3) years after completion of the research. Additional retention periods may apply under other agency, sponsor, or regulatory requirements, as outlined below:

- HSR including Health Insurance Portability and Accountability Act (HIPAA) subject research records must be retained for at least six (6) years.
- Food and Drug Administration (FDA) regulated research records must be at least two (2) years following the applicable FDA regulatory event, which may include FDA approval of a marketing application, study termination or completion, or the date records are no longer needed to support a regulatory submission.
- Grant-funded or sponsor-funded research records must be generally retained for seven (7) years after submission of the final financial report. Some funded research records must be retained for a longer period of time as specified in the agreement, contract, or award terms.

When multiple retention requirements apply, records must be retained for the longest applicable period. The Principal Investigator (PI) is responsible for ensuring compliance with all applicable record retention requirements.

[149] 21 CFR 312.33 or 21 CFR 812.150(a)(6)

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PART IX. Additional Requirements for Federal Agency-Funded Research

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Section 42. Department of War (DOW)–Supported Research

Human subjects research (HSR) that is conducted, supported, or otherwise involves the Department of War (DOW), must comply with DOW Directive 3216.02, applicable DOW Component policies, and, where applicable, 32 CFR 219 (DOW adoption of the Common Rule), in addition to 45 CFR 46 and 21 CFR 50 and 56.

DOW requirements apply to research that involves:

- Funding from a DOW component, including subawards
- Collaboration, cooperation, or agreements with a DOW component
- Use of DOW property, facilities, or assets
- DOW-affiliated personnel as the intended subject population

These requirements do not apply when DOW personnel participate incidentally, and the research is not otherwise DOW-supported.

The Office of Research Compliance (ORC) will notify investigators when DOW requirements are applicable.

42.1 DOW-Specific Requirements

In accordance with DOW Directive 3216.02, the definition of minimal risk may not be interpreted relative to risks ordinarily encountered in participants' occupational or environmental settings. Risk determinations must be based on the general population and not on the inherent risks of a subject's profession or condition.

DOW-supported research requires scientific review prior to Institutional Review Board (IRB) review for all new non-Exempt studies and for substantive study modifications, consistent with DOW Directive 3216.02.

All individuals involved in the design, conduct, or review of DOW-supported human subjects research (HSR) must complete human subjects protection training, as required under DOW Directive 3216.02. Additional training requirements may be imposed by the supporting DOW Component. The Principal Investigator (PI) is responsible for ensuring compliance.

For research involving greater than minimal risk, an independent research monitor must be appointed in accordance with DOW Directive 3216.02. The IRB must review and approve the monitor's qualifications, independence, and scope of responsibilities.

The research monitor is authorized to:

- Oversee study conduct and participant protections
- Review safety information and **approved** study compliance
- Report observations and findings to the IRB or designated official
- Take actions necessary to protect participant safety, including suspension of research activities, when warranted

Consent Limitations for Experimental Subjects:

Pursuant to 10 U.S.C. §980 and DOW Directive 3216.02, research involving "experimental subjects" may not include a waiver or alteration of **informed consent** unless specifically approved by the DOW Human Research Protection Official (DOHRP) or designee. Such waivers are permitted only under limited DOW-defined conditions.

42.2 Additional DOW Administrative Review

Final IRB approval does not authorize initiation of DOW-supported **research**. **Investigators** must obtain DOW Component-level administrative approval prior to initiating research activities, as required by DOW Directive 3216.02.

Additional DOW review may be required for:

- Research conducted outside the United States
- Research involving waiver of consent
- Research involving fetal subjects
- Collection of Large-Scale Genomic Data (LSGD)
- Other categories as determined by the supporting DOW Component

When DOW-affiliated personnel are recruited:

- Participation must be voluntary and free from undue influence
- Command or supervisory personnel must not be present during subject recruitment or the **informed consent process**
- Additional consent disclosures must be included, such as DOW involvement and potential impacts on duty status
- An independent ombudsperson may be required for certain research settings, particularly for greater than **minimal risk** research

DOW policy prohibits:

- Research involving detainees or individuals under the control of DOW personnel
- Research involving prisoners of war

Research involving vulnerable populations (e.g., pregnant women, prisoners, **children**) is subject to additional DOW-specific restrictions and IRB review requirements beyond those described in Subparts B, C, and D of 45 CFR 46. Investigators must consult ORC prior to submission.

For research conducted outside the United States:

- Investigators must obtain applicable local approvals or ethical review
- Local laws, regulations, and cultural standards must be followed
- Additional DOW approvals may be required prior to study initiation

Research involving LSGD from DOW-affiliated personnel must include:

- Enhanced administrative, technical, and physical safeguards
- Application for a Certificate of **Confidentiality**
- DOW Component security review and DOHRP approval, as applicable

Reporting Requirements

Investigators and the institution must comply with DOW reporting requirements, including **prompt reporting** to the appropriate DOW Human Research Protection Office of:

- Significant study modifications
- Changes in IRB oversight
- Study closure
- **Unanticipated Problems (UP)** involving risks to subjects or others
- Serious or continuing **non-compliance**
- Suspension or termination of research

Reporting timelines are governed by DOW Component requirements, generally within 30 days unless otherwise specified.

In accordance with DOW Directive 3216.02, study records related to DOW-supported research must be made available for inspection and copying by authorized DOW representatives at reasonable times and in a reasonable manner.

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Section 43. Department of Education (ED) Requirements

43.1 Family Educational Rights and Privacy Act (FERPA) – 34 CFR Part 99

a) Use of Student Education Records in Research

The Family Educational Rights and Privacy Act (FERPA)[150] is a federal law that protects the privacy of student education records and establishes conditions for their disclosure.

Under 34 CFR § 99.30, educational institutions must obtain signed and dated written authorization from the parent or eligible student prior to disclosing Personally Identifiable Information (PII) from education records, unless an exception under 34 CFR § 99.31 applies.

In the context of human subjects research (HSR) (45 CFR 46):

- Access to education records for institutional or employment purposes does not authorize their use for research.
- When identifiable student information is used, FERPA authorization and IRB approval are generally required.
- Investigators must submit studies to the UTRGV Institutional Review Board (IRB) for review and approval prior to accessing or using educational records, including those to which they may have routine access.

b) Directory Information

FERPA permits disclosure of directory information without written authorization, unless the student has opted out in accordance with institutional procedures (34 CFR § 99.37).

At UTRGV, directory information may include:

- Name, address, and telephone number
- UTRGV-issued email address
- Date and place of birth
- Major field of study
- Participation in officially recognized activities and athletics
- Dates of attendance
- Most recent previous institution attended
- Classification

[150] 20 U.S.C. § 1232g; 34 CFR Part 99

- Degrees, awards, and honors (including selection criteria)
- Date of graduation
- Height and weight of athletes
- Photographs

c) Important Limitation

Use of directory information for **research** recruitment must still align with IRB requirements and FERPA principles. For example, accessing a class roster from another instructor to recruit students constitutes use of education records and requires FERPA authorization. To minimize FERPA implications, **investigators** should consider recruitment via the course instructor, who has a legitimate educational interest.

d) FERPA-Protected Information (Education Records)

Education records under FERPA include any records that are directly related to a student and maintained by an educational agency or institution (34 CFR § 99.3).

Examples include:

- Student ID numbers and Social Security numbers
- Grades and GPA
- Academic standing and transcripts
- Class rosters and schedules
- Emails or notes containing student information
- Learning management system data (e.g., Canvas discussions)
- Graded assignments, exams, and papers
- Audio/video recordings of class participation

e) Disclosure Requirements (34 CFR § 99.30):

FERPA authorization for the release of the educational record in the **informed consent** and **assent** must contain:

1. The records to be disclosed
2. The purpose of disclosure
3. The recipient(s) of the information

f) Use of De-identified Data

FERPA permits disclosure of education records for research without authorization if all Personally Identifiable Information (PII) has been removed such that a student's identity is not reasonably identifiable[151].

De-identification must remove:

- Direct identifiers (e.g., name, student ID)
- Indirect identifiers (e.g., date of birth, demographic combinations)
- Biometric identifiers (e.g., images, voice, handwriting)
- Any data combinations that could reasonably re-identify an individual

Investigators must ensure that data are **de-identified** consistent with both FERPA requirements and **human subjects** protections under 45 CFR 46.102(e) (identifiability standard).

g) Institutional Data Requests (UTRGV)

After obtaining IRB approval, investigators seeking institutional data must submit a request through the UTRGV Office of Strategic Analysis and Institutional Reporting (SAIR) using the official request system. Approval from SAIR is required prior to data release.

h) Research Involving Records from Other Institutions

Investigators must:

- Comply with the FERPA policies of each institution
- Obtain required authorizations or confirm applicable exceptions
- Provide documentation in the IRB application, such as a letter of support or Data Transfer and Use Agreement (DTUA). When the external educational institution requires an IRB approval letter before releasing records or permitting research activities, investigators should confirm that the institution is aware of the proposed research and that the study is feasible before proceeding.

i) Research Conducted by Instructors Using Their Own Students

Faculty conducting research using data from their own courses must:

- Obtain IRB approval before accessing, using, or analyzing student data for research.
- Confirm whether FERPA authorization is required or whether an applicable FERPA exception permits the use of course records for research.
- Ensure that student participation is voluntary and free from **coercion** or undue influence, consistent with 45 CFR 46.116.

[151] 34 CFR § 99.31(b)(1)

- Use a co-investigator or other research personnel, rather than the course instructor, to conduct the **informed consent process** when informed consent is required.
- De-identify student data before analysis whenever possible.
- Maintain a clear separation between academic records and **research** data.

43.2 Protection of Pupil Rights Amendment (PPRA) – 34 CFR Part 98

The **Protection of Pupil Rights Amendment (PPRA)** (20 U.S.C. § 1232h; 34 CFR Part 98) applies to:

- Elementary and secondary schools receiving U.S. Department of Education funding
- **Research** funded by the U.S. Department of Education

While PPRA generally does not apply to postsecondary institutions, it does apply when UTRGV research involves minors, including:

- Dual **enrollment** students
- Early college/high school programs
- Participants under 18 years of age

a) Protected Information Categories (PPRA)

PPRA requires parental notification and consent before students are invited to participate in surveys addressing the following categories:

1. Political affiliations or beliefs
2. Mental or psychological problems
3. Sex behavior or attitudes
4. Illegal, antisocial, self-incriminating, or demeaning behavior
5. Critical appraisals of close family members
6. Legally recognized privileged relationships
7. Religious practices or beliefs
8. Income (except as required for eligibility determinations)

b) IRB Considerations under PPRA

The IRB cannot waive parental permission when PPRA applies. Parents must be provided an opportunity to review all study materials prior to participation. **Investigators** must comply with local educational agency policies, which may include additional requirements.

c) Investigator Responsibilities

Researchers must:

- Incorporate PPRA requirements during study design and recruitment planning

- Coordinate with school districts or educational agencies early
- Ensure transparent communication with parents/guardians
- Align consent/permission processes with both PPRA and 45 CFR 46 Subpart D (Additional Protections for **Children**)

Section 44. State of Texas

44.1 Genomic Research and Security of Genetic Information

Research involving genome sequencing, analysis of the human genome, or the collection, storage, transfer, or use of genomic information must comply with all applicable federal, state, and institutional requirements, including Texas Health and Safety Code Chapter 174 (Texas Genomic Act of 2025). This law applies to medical facilities, research facilities, companies, and nonprofit organizations conducting research on or testing involving genome sequencing or the human genome in the State of Texas.

a) Restrictions on Genome Sequencing Technologies

Texas law prohibits the use of genome sequencers and related software that are produced by, on behalf of, or controlled by certain foreign entities. Investigators conducting genomic research must ensure that any genome sequencing technologies used in research activities comply with applicable state requirements.
Prohibited technologies include genome sequencers or software produced by or on behalf of:

- A foreign adversary;
- A state-owned enterprise of a foreign adversary;
- A company or nonprofit organization domiciled within a foreign adversary country; or
- An owned or controlled subsidiary or affiliate of a company or nonprofit organization domiciled within a foreign adversary country.

b) Storage and Security of Genomic Information

Investigators are responsible for ensuring that genome sequencing data generated from Texas residents is stored and protected in accordance with applicable legal, institutional, and information security requirements.

To comply with Texas law:

- Genome sequencing data of Texas residents may not be stored within the borders of a foreign adversary.
- Genome sequencing data stored by a third-party vendor or cloud-storage provider must be protected through reasonable encryption safeguards, access restrictions, and other applicable cybersecurity practices.
- Genome sequencing data of Texas residents, except for legally authorized open data, must be protected against unauthorized access, intrusion, or compromise by persons located within a foreign adversary.

c) Investigator Responsibilities

Investigators proposing genomic research must:

1. Describe the genomic information that will be collected or generated.
2. Identify any genome sequencing technologies, software platforms, or third-party vendors that will be used in the research.
3. Describe procedures for data collection, transmission, storage, sharing, retention, and destruction.
4. Implement appropriate safeguards to protect the privacy and confidentiality of genomic information.
5. Obtain any required institutional approvals related to information security, data storage, data-sharing agreements, or third-party service providers.
6. Ensure continued compliance with applicable federal, state, sponsor, and institutional requirements throughout the conduct of the study.

d) IRB Review Considerations

For research involving genomic information, investigators should provide sufficient information for the IRB to evaluate:

- The nature and scope of the genomic information being collected or generated;
- Privacy and confidentiality protections;
- Data storage and security safeguards;
- Data-sharing plans and external collaborations;
- Use of third-party sequencing technologies or software platforms; and
- Compliance with applicable legal and institutional requirements governing genomic information.

The IRB may request additional information or require modifications when necessary to ensure adequate protections for research participants and compliance with applicable regulatory, state, and institutional requirements.

e) Institutional Compliance

IRB approval does not relieve investigators of responsibilities imposed by Texas law, sponsor requirements, contractual obligations, or institutional policies governing genomic information. Investigators remain responsible for ensuring that all genomic research activities comply with Texas Health and Safety Code Chapter 174 and any related institutional requirements.

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PART X. APPENDICES

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Appendix 1. Federalwide Assurance (FWA)

FWA #: **FWA00000805** OMB No. 0990-0278
Institution: **The University of Texas Rio Grande Valley**
Expires: **11/05/2029**

Federalwide Assurance (FWA)
for the Protection of Human Subjects

1. Institution Filing Assurance

Legal Name: **The University of Texas Rio Grande Valley**

City: **Edinburg** State/Province: **TX** Country: **USA**

2. Institutional Components

List below component organizations over which the institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the institution operates.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the institution providing this Assurance and all component organizations listed below.

Name of Component Organization or Alternate Names Used	City	State (or Country if Outside U.S.)

3. Applicability

This Assurance applies whenever this institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

4. Assurance of Compliance with the Terms of the Federalwide Assurance

This institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance, which are contained in a separate document on the Office for Human Research Protections (OHRP) website here: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html.

5. Institutional Review Boards (IRBs)

This institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies.

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: **Eric** Middle Initial: Last Name: **Allen**

Degrees or Suffix: **MA, CIP. CPIA** Institutional (i.e., Job) Title: **Director: Office of Research Compliance**

Institution: **The University of Texas Rio Grande Valley**

Telephone: **956 665-3249** E-Mail: **eric.allen@utrgv.edu**

Address: **1201 W University Drive, MRIOB**

City: **Edinburg** State/Province: **TX** Country: **USA**

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of the Federalwide Assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human research protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature: **Glorimar Colon JD, MHEA, ECoP**

Date: **11/05/2024**

First Name: **Glorimar** Middle Initial: Last Name: **Colon**

Degrees or Suffix: **JD, MHEA, ECoP** Institutional (i.e., Job) Title: **Assistant Vice President: Research Integrity**

Institution: **The University of Texas Rio Grande Valley**

Telephone: **956 665-3008** E-Mail: **glorimar.colon@utrgv.edu**

Address: **1201 West University Drive, MRIOB 4.341**

City: **Edinburg** State/Province: **TX** Country: **USA**

8. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects submitted to HHS by the above Institution is hereby approved.

Assurance Number: **FWA00000805** Expiration Date: **11/05/2029**

Signature of HHS Approving Official: **Michael Stidham** Approval Date: **11/05/2024**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0278 . The time required to complete this information collection is estimated to average 20 minutes per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer.

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Appendix 2. IRB Meeting Minutes Templates

INSTITUTIONAL REVIEW BOARD
Meeting Minutes
[Meeting Date]

ATTENDANCE

Voting Members Present:

	IRB Position	*Area of Expertise or Department*
[Name]	*[Chair, Vice-Chair, Scientist, Non-Scientist, Non-Affiliated Community Member, Ex-Officio]*	*[Academic/administrative department or Community Member]*

Voting Members Absent:
(Without Representation)

	IRB Position	*Area of Expertise or Department*
[Name]	*[Chair, Vice-Chair, Scientist, Non-Scientist, Non-Affiliated Community Member]*	*[Academic/administrative department or Community Member]*

Ex-Officio Non-Voting Members Present:

	IRB Position	*Area of Expertise or Department*
[Name]	Ex-Officio, [Scientist or Non-Scientist]	*[Academic/administrative department or Community Member]*

Ex-Officio Non-Voting Members Absent:

	IRB Position	*Area of Expertise or Department*
[Name]	Ex-Officio, [Scientist or Non-Scientist]	*[Academic/administrative department or Community Member]*

Total Voting Members Present: [#]

Guests:

	Capacity
[Name]	[Describe the capacity in which guest(s) is/are serving.]

Consultants:

	Expertise
[Name]	Provide a brief description of the consultant expertise here along with the name of the project consultants are serving for.

[NOTE: Due to public health emergency related to COVID-19, this meeting was conducted virtually (voice and video) through Zoom. Each member was provided access to all pertinent materials previously to the meeting.]

QUORUM

The quorum requirement for this meeting was [#] voting members (more than 50% of the [#] total voting members) with at least one non-scientist member being present. Upon quorum being assembled, the meeting was called to order by the Chair at [00:00 _m]. There were [#] voting members including the Chair and Vice Chair] present at the beginning of the meeting. Quorum was maintained throughout the entire meeting, for every vote.

A. WELCOME

The [Chair/Vice Chair] welcomed the Board Members. [Optional: The group then introduced themselves to the new members and Research Compliance staff in attendance.]

B. STATEMENT OF CONFIDENTIALITY

The [Chair Chair reminded Board Members to hold in confidence information related to studies that might contain intellectual property now or in the future. The Chair also reminded Board Members not to disclose information to any third parties, including investigators and research personnel, that would attribute comments or concerns to a particular person on the IRB. Further clarification was provided to remind Board Members that they are allowed to contact investigators to ask questions that will help Members understand projects under review. Finally, the Chair instructed the Board Members to refrain from disclosing or discussing any unnecessary commentary made during deliberations.

C. REVIEW AND APPROVAL OF PREVIOUS IRB MEETING MINUTES

1. Review of meeting minutes dated **[MONTH, DAY YEAR].**

    a. A motion was made and seconded to approve the minutes.
    b. All were in favor of approval.
    c. [Name of voting member that is not present at current meeting] was not present, and therefore did not vote. [Name of person that is not present at the meeting which minutes are voted on] was not present during the [date of the meeting] meeting and abstained from voting.
    d. Total Voting = [#] Vote: For = [#], Against = [#], Abstained = [#]

D. REPORTS TO THE IRB:

1. Approvals Report for the month of [MONTH]

    The Office of Research Compliance provided a list of approvals for the month of [Name of the month]. A summary (appended to this minutes) was provided to the Board detailing the number of approved modifications, continuations, new projects (exempt, expedited and full). The [Chair/Vice Chair] asked if there were any questions, concerns, or if the Members wanted to review any of the applications approved through the expedited review process. No Board Members raised questions, voiced concerns, or requested further review. [Or, In the alternative, describe the concerns or request of further review.]

E. UPDATES AND ANNOUNCEMENTS:

1. [Describe any updates and announcements made].

F. CONFLICTS OF INTEREST:

The Chair reminded Board Members of their responsibility to declare any conflicts of interest prior to the discussion of any study included as an agenda item. Members were reminded that conflicts of interest include financial (e.g., Member or Member's family hold a financial interest in the research sponsor) and non-financial (e.g. Member is part of a study research team). Board Members were polled for any conflicts of interest with the projects being reviewed. None were noted/disclosed. [Or note here which Members declared any conflicts and add the following: This/these Member(s) remained in the meeting room to provide information requested by the IRB but was/were asked to leave the meeting room during the deliberations and voting on the study protocol where he/she/they had a conflicting interest.]

G. OLD BUSINESS

None. [Or in the alternative, list the studies using the format under New Business]

H. NEW BUSINESS

1. **IRB# IRB-[##]-[####]**
   Project Title: [Insert Title]
   Sponsor: [Insert Sponsor Name]

Principal Investigator:	[Insert Name]
Type of Submission:	[New Project; Modification/Amendment; Continuing Review; Adverse Event]
Primary Reviewer:	[Name of Primary Reviewer]
Level of Risk:	[Minimal Risk; Greater than Minimal Risk]
FDA Regulated:	[Yes; No]
Board Action:	[Approved; Disapproved; Deferred; Approved upon Meeting Stipulations]
Continuing Review Period:	No later than a year from date of initial approval. [Or earlier, if the Board decides otherwise and such basis is provided as part of the discussion.]
Total Voting = [#]	Vote: For = [#], Against = [#], Abstained = [#]; The following [#] members had a conflicting interest and recused themselves, therefore did not vote: (name the members).

Purpose of the Study:
[Add a sentence describing in lay terms the purpose of the study].

Summary:
The primary reviewer provided a synopsis of the proposed study.
For new studies, include relevant summary information that contributes to the understanding of IRB findings and determinations under the *Discussion* section, including how the research will be conducted and a description of the subjects to be recruited (and whether these are vulnerable populations).

For new studies including drugs and/or devices include statements that reflect:

- Name of the drug or device
- Whether the drug/device is FDA approved
- Any investigational new drug (IND) subject to the requirements of 21 CFR 312.20 and whether the sponsor has requested and received an approved application for IND from FDA or if the IND qualifies for an exemption under 21 CFR 312.2
- For devices, an indication on whether (1) FDA has already made a risk determination for a device study (e.g., significant risk (SR) or non-significant risk (NSR)), or (2) the study is exempt in accordance with 21CFR 812.(c), of (3) the sponsor made the initial risk determination and has presented it to the IRB for consideration. In case of #3, the IRB must make its own SR/NSR determination, document the reason in the minutes, and

indicate whether the IRB agrees/disagrees with the sponsor's risk determination as per 21 CFR 56.108 and 21 CFR 812.66.

For Continuing Review projects include statements that reflect whether:

- the study is open to enrollment and research procedures continue
- how many participants have been authorized to be enrolled, how many have enrolled and how many completed the study
- there have been any withdrawals, adverse events and/or anticipated problems reported
- personnel are up to date in their training
- there is new information that will alter the IRB's previous conclusion that the research satisfies all criteria for approval under 45 CFR 46.116 (Subparts B, C, and D, if applicable and 21 CFR 50 and 56.111, if applicable).

For Modifications/Amendments include statements that summarizes the change, such as:

- The submission provides additional questions on the questionnaire.
- The submission provides for a change of principal investigator
- The submission provides additional responses in regard to the consent and the protocol
- The submission provides for a new Informed Consent Form or updates to the Informed Consent Form (as appropriate)
- The submission provides for changes in the recruitment or study procedures (as appropriate).

Discussion:
[Include a summary of the discussion of controverted issues and their resolutions AND select one of the OPTIONS from below depending on the action the Board takes]. No controverted issues were identified. – OR-- The following controverted issues were identified: (describe them).

[OPTION #1 APPROVALS:

-----For New Projects-----
The Board determined that the study meets the regulatory criteria for approval under 45 CFR 46.111 (and Subpart(s) ____, if applicable). NOTE: For FDA regulated projects add the proper FDA citations as well: 21 CFR 50 and 56.111.

Add the following for **Consents, Waivers and Alterations**, as applicable, and include the basis for approval:

- The Board determined that the **Informed Consent** is appropriately documented as per 45 CFR 46.111 (and/or 21 CFR 56.111) and that the **Form** meets the regulatory criteria for approval.

- The Board determined that the **Waiver of Consent** is appropriate under 45 CFR 46.116 due to (describe the finding). NOTE the correct citation for waiver of consent is 45 CFR 46.116 (e) for *research involving public benefit and service programs conducted by or subject to the approval of state or local officials*, OR 45 CFR 46.116 (f) for *a general waiver of consent*.
- The Board determined that the **Alteration of Consent** is appropriate under 45 CFR 46.116 due to (describe the finding). NOTE the correct citation for alteration of consent is 45 CFR 46.116 (e) for *research involving public benefit and service programs conducted by or subject to the approval of state or local officials*, OR 45 CFR 46.116 (f) for *a general alteration of consent*.
- The Board determined that the **Waiver of Documentation of Consent** is appropriate under 45 CFR 46.117 due to (describe the finding). NOTE the correct citation for waiver of documentation of consent is 45 CFR 46.117 (c)(1).
- The Board found that the **HIPAA Waiver of Authorization** meets the regulatory criteria of 45 CFR 164.512(i) due to (describe the finding). (Elaborate as necessary, for example: *"The study recruitment procedures have been determined to involve no more than minimal risk to the privacy of the subjects as evidenced by the fact that the Board found the following to be acceptable: (1) the plan to protect identifiers from improper disclosure; (2) the plan to destroy identifiers is at the earliest opportunity; (3) written assurance that the Protected Health Information (PHI) will not be reused or disclosed to any other person or entity, except as required by law; (4) the statement from the Principal Investigator on that the study cannot be practicably carried out without a HIPAA Waiver of Authorization and the research could not practicably be conducted without the access to and use of PHI."*) The Board approved the HIPAA Waiver of Authorization.
- The **Alteration of HIPAA Authorization** for the (describe the alteration) meets the regulatory criteria of 45 CFR 164.512(i) due to _____. The Board approved the Alteration of HIPAA Authorization.
- **For Emergency Research involving an exception from Informed Consent:** the IRB found that the proposed research satisfies the criteria found in OHRP Secretarial Waiver and/or FDA's regulations at 21 CFR 50.2. NOTE: look for guidance on Emergency Research!

Add the following, as applicable, **if the study involves Children**:

- The Board determined that the study satisfy the conditions of all applicable sections under 45 CFR 46, Subpart D (and 21 CFR 50, Subpart D, if subject to FDA)
- In addition, the Board determined the research/clinical investigations do not present greater than minimal risk to the subjects, meeting the conditions of 45 CFR 46.404 (and 21 CFR 50.51, if subject to FDA) due to [add the rationale for the pediatric risk determination].

  –or—

  In addition, the Board determined the research/clinical investigations presents greater than minimal risk to the subjects, holding the prospect of direct benefit to individual subjects. Therefore, the Board found the study meets the conditions of 45 CFR 46.405

(and 21 CFR 50.52, if subject to FDA) due to [add the rationale for the pediatric risk determination].

--or—

In addition, the Board determined the research/clinical investigations presents greater than minimal risk to the subjects with no prospect of direct benefit. [Add here the rationale for pediatric risk determination]. However, it is likely that the study yields to generalizable knowledge about the subjects' disorder or condition. Therefore, the Board found the study meets the conditions of 45 CFR 46.406 (and 21 CFR 50.53, if subject to FDA).

--or—

In addition, the Board determined that the proposed research/clinical investigations is not approvable under 45 CFR Part 46, Sections 404-406 (and 21 CFR Part 50, Sections 51-53, if subject to FDA). However, it presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, meeting the regulatory requirements of 45 CFR 46.407 (and 21 CFR 50.54, if subject to FDA). NOTE: Look for OHRP additional guidance!

- The Board determined that the requirements for permission by parents or guardians and for assent of children are met under 45 CFR 46.408 (and 21 CFR 50.55, if subject to FDA). NOTE: if a waiver or alteration is requested, it must also be documented…refer to the above section on Waivers and Alterations.

Add the following, as applicable, **if the study involves Pregnant Women, Human Fetuses, and Neonates:**

- The proposed study meets the requirements of 45 CFR 46, Subpart B.
- **For pregnant women and fetuses:**
  - The Board reviewed the application and (found/did not find) an indication that there are previous studies that have been conducted and provide data for assessing potential risk to pregnant women and fetuses (45 CFR 46.204).
  - The Board determined that the risk to the fetus is solely caused by interventions or procedures that hold the prospect of direct benefit for the woman or the fetus. **–or—**The Board determined that the study does not hold a prospect benefit to the subjects, however the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.
  - The risks listed are the least possible for achieving the objectives of the research.
  - The Board verified that no inducements are offered to terminate pregnancy and that individuals engaged in the research will have no part in any decisions as tot the timing, method or procedures used to terminate pregnancy
- **For neonates of uncertain viability:**
  - The Board reviewed the application and (found/did not find) an indication that there are previous studies that have been conducted and provide data for assessing potential risk to neonates (45 CFR 46.205).

- All the individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- The Board verified that individuals engaged in the research will not take part in determining the viability of the neonate

- **For neonates of certain viability:**
  - NOTE: add all the previous 3 statements and the following:
    - The Board determines that the research hold out the prospect of enhancing the probability of survival of the neonate to the point of viability and any risk is the least possible and the purpose of the research is the development of important biomedical knowledge that cannot be otherwise obtained.
- **For non-viable neonates:**
  - The Board verified that the vital functions of the neonate will not be artificially maintained; the research will not terminate the heartbeat or respiration of the neonate; there will be no added risk to the neonate resulting from the research; and, the purpose of the research is the development of important biomedical knowledge that cannot be otherwise obtained.

Add the following, as applicable, **if the study involves Prisoners:**

- The Board determined that the research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2) (indicate the specific category).
- In addition, the Board found that: (1) advantages provided to the prisoners as a result of the proposed research does not impair the ability of the prisoner to weigh the risk of participating in the research against the value of the advantages; (2) the risks of the proposed research are commensurate with risks that would be accepted by a non-prisoner; (3) procedures for the selection of prisoners are fair and free from arbitrary intervention from prison authorities; and (4) the information is presented to the prisoners in a language that is understandable.
- The Board also verified that adequate assurances exist to make sure parole boards will not take into account a prisoners participation in their decisions regarding parole and that each prisoner will be clearly informed in advance that their participation in the research will not will have no effect on their parole.
- (Where applicable) The Board found there may be a need for follow-up examination or care of participants after the end of participation and had verified that adequate provisions have been made for such examination or care by (describe the additional provisions). Prisoners have also been informed of such follow up examinations or additional care.
- The Board had certified to the Secretary of DHHS that the Board has complied with all the duties imposed by 45 CFR 46, Subpart C.

The Board determined the project was greater than minimal risk and granted approval for one year. A continuing review will be required before the end of the year from the date of initial approval (or earlier if the Board so decides, explaining the basis for it). **---or---** The Board

determined the project was (less than minimal risk or minimal risk) and that the study meets the criteria for an Expedited review under Category ____ with (no continued review or a continuing review of one year from the date of approval).

A motion was entered and seconded to approve the study. All voted in favor (or explain the vote here).

-----For Continuing Reviews-----
The Board determined that the study continues to meet the regulatory criteria for approval under the regulations at 45 CFR 46.111 (and Subpart(s) ____, if applicable). NOTE: For FDA regulated projects add the proper FDA citations as well: 21 CFR 50 and 56.111.
A motion was entered and seconded to approve the continuation of the study. All voted in favor (or explain the vote here).

-----For Reportable Events-----
The Board determined that the event meet the criteria that was neither serious or non-continuing (modify as necessary). The Board determined that the research continues to satisfy the requirements for IRB approval under 45 CFR 46.111 (and Subparts ____ (if applicable). NOTE: For FDA regulated projects add the proper FDA citations as well: 21 CFR 50 and 56.111.
The Board also determined that the corrective action plan is appropriate, and no additional actions were necessary. The Principal Investigator will continue to monitor the study and report to the IRB according to applicable policies and procedures.

A motion was entered and seconded to accept the issue as a noncompliance that is not serious or continuing. No change to the current approval period is made. All voted in favor (or explain the vote here).

-----For Modifications/ Amendments-----
The Board determined that the study continues to meet the regulatory criteria for approval under the regulations at 45 CFR 46.111 (and Subpart(s) ____, if applicable). NOTE: For FDA regulated projects add the proper FDA citations as well: 21 CFR 50 and 56.111. NOTE: If the Board indicates that as a result of the modification, subjects needs to be reconsented, include a statement to address it v.

A motion was entered and seconded to approve the continuation of the study. All voted in favor (or explain the vote here).

<u>OPTION #2 DISAPPROVALS</u>:

The Board found the proposed study does not meet the criteria for approval under 45 CFR 46.111 (and Subpart(s)____, if applicable). (Elaborate to include the reasons why the project does not meet the criteria for approval.) NOTE: For FDA regulated projects add the proper FDA citations as well: 21 CFR 50 and 56.111.

A motion was entered and seconded to disapprove the study based on (describe the basis for disapproving). All voted in favor (or explain the vote here). The decision of the Board will be notified in writing and the Principal Investigator will be provided with an opportunity to respond to the Board within 15 calendar from the date of the notification.

OPTION #3 DEFERRALS:

The Board found that the information provided in the application is not sufficient in detail to make a determination on whether the proposed study meets the criteria for approval (and/or whether the risks to the subjects have been minimized). (Elaborate as necessary).

Stipulations:
Based on (describe the basis for requiring changes; basis for requesting changes must be documented in the minutes) the Board has directed the Principal Investigator to address the following substantive (S) and non-substantive (NS) issues:

1. (List all the stipulations and indicate which ones are S and NS…consider dividing them by the document where the changes need to be reflected, e.g., Application, Protocol, Informed Consent, etc.)

Because (some or all) the above of the listed changes are substantive in nature, consideration of the items for approval was deferred to a later IRB convened meeting.

A motion was entered and seconded to defer the study until the requested changes have been addressed. All voted in favor (or explain the vote here).

OPTION #4 APPROVED UPON MEETING STIPULATIONS:

Stipulations:
The Board directed the Principal Investigator to address the following changes:

1. (List all the stipulations…consider dividing them by the document where the changes need to be reflected, e.g., Application, Protocol, Informed Consent, etc. The basis for requesting the change must be included in the minutes!)

The Board determined that with the above stipulations the study meets the regulatory criteria for approval under 45 CFR 46.111. NOTE: For FDA regulated projects add the proper FDA citations as well: 21 CFR 50 and 56.111.

(Add as appropriate: Language about waivers, the basis for using it and whether they meet the regulatory criteria for approval. Refer to OPTION 1 for details).

Because the above listed changes are non-substantive, the review of the responses by the IRB Chair and/or her designee is appropriate. The IRB Chair designated the Primary Reviewer to review the responses to the requested changes.

The Board determined the project was greater than minimal risk and granted approval contingent meeting stipulations for one year. A continuing review will be required before the end of the year from the date of initial approval (or earlier and explain the basis why). ---OR--- The Board determined the project was (less than minimal risk or minimal risk) and that the study meets the criteria for an Expedited review under Category ____ with (no continued review or a continuing review of one year from the date of approval).

A motion was entered and seconded to approve upon meeting stipulations. All were in favor (or explain the vote here).

---END OF OPTIONS]

I. ADJOURNMENT
The meeting was adjourned at ____.

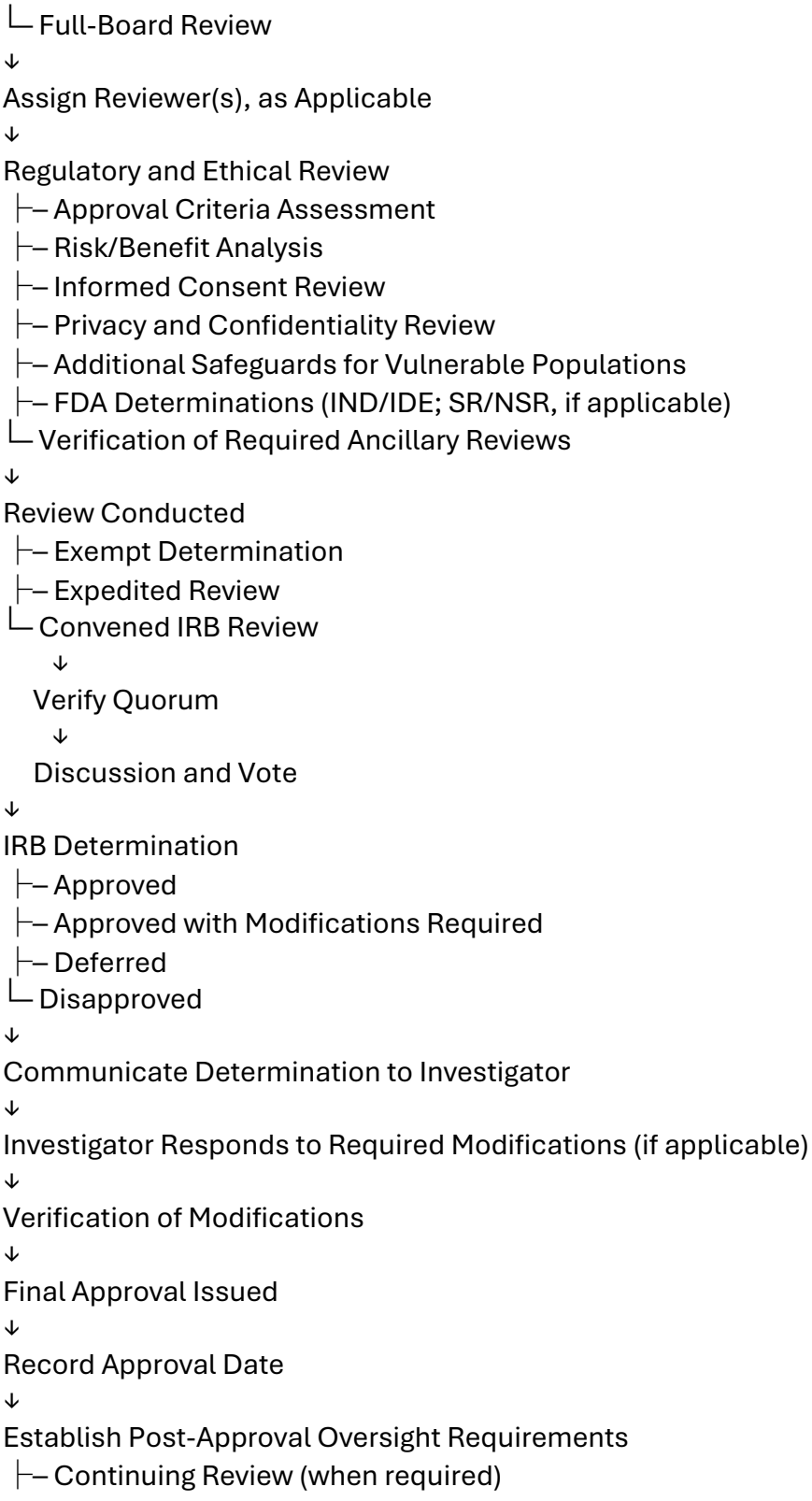
----APPROVAL OF MINUTES ----
These minutes were approved by the IRB on **1/14/26.**

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Appendix 3. Initial Review Procedure Flowchart

The Initial Review Procedure Flowchart provides a visual summary of the IRB review process from study submission through IRB determination. The flowchart outlines key review activities, including administrative screening, review pathway determinations, regulatory and ethical review, IRB determinations, and initiation of post-approval oversight. The process may vary depending on the nature of the research and applicable requirements. This flowchart is intended as a reference tool and should be used in conjunction with the procedures described in Sections 17 to 21 of this handbook. In the event of a discrepancy, the written procedures govern.

START
↓
Investigator Submits Study Application
↓
Administrative Pre-Review by ORC
↓
Submission Complete?
├– NO → Return to Investigator for Revisions
└– YES
↓
Administrative Screening
├– Human Subjects Research Determination
├– FDA-Regulated Research?
├– Reliance Request?
├– Ancillary Reviews Required?
└– Conflict of Interest Disclosure Review
↓
Conflict of Interest Review (if applicable)
↓
Ancillary Reviews Completed (if applicable)
↓
Determine Review Category
├– Not Human Subjects Research
├– Exempt Review
├– Expedited Review


└ Full-Board Review
↓
Assign Reviewer(s), as Applicable
↓
Regulatory and Ethical Review
├ Approval Criteria Assessment
├ Risk/Benefit Analysis
├ Informed Consent Review
├ Privacy and Confidentiality Review
├ Additional Safeguards for Vulnerable Populations
├ FDA Determinations (IND/IDE; SR/NSR, if applicable)
└ Verification of Required Ancillary Reviews
↓
Review Conducted
├ Exempt Determination
├ Expedited Review
└ Convened IRB Review
↓
Verify Quorum
↓
Discussion and Vote
↓
IRB Determination
├ Approved
├ Approved with Modifications Required
├ Deferred
└ Disapproved
↓
Communicate Determination to Investigator
↓
Investigator Responds to Required Modifications (if applicable)
↓
Verification of Modifications
↓
Final Approval Issued
↓
Record Approval Date
↓
Establish Post-Approval Oversight Requirements
├ Continuing Review (when required)

├─ Reportable Event Reporting
├─ Protocol Modification Review
├─ Study Closure Requirements
└─ Post-Approval Monitoring (PAM), as applicable
↓
END

Note: This flowchart is provided as a summary tool and does not replace the written procedures in this handbook. In the event of a discrepancy, the written procedures govern.

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Appendix 4. Continuing Review Procedure Flowchart

The Continuing Review Procedure Flowchart provides a visual overview of the continuing review process for research that requires ongoing IRB oversight. The flowchart summarizes key review activities, including submission and review of continuing review materials, assessment of study progress and safety information, IRB determinations, and post-approval oversight requirements. It should be used in conjunction with the continuing review procedures described in this handbook.

START
↓
Continuing Review Reminder Sent to Investigator
↓
Investigator Submits Continuing Review Materials
├– Progress Report
├– Enrollment Status
├– Adverse Events/UPIRTSOs
├– Protocol Deviations
├– Current Consent Documents
└– New Risk Information
↓
Administrative Pre-Review by ORC/IRB Staff
├– Incomplete Submission?
│ ├– YES → Return to Investigator
│ └– NO
↓
Determine Review Pathway
├– Expedited Continuing Review
└– Convened IRB Review
↓
Assign Reviewer(s)
↓
Evaluate:
├– Risk/Benefit Changes
├– Subject Complaints

├─ Enrollment Progress
├─ New Safety Information
├─ Compliance Issues
├─ DSMB Reports (if applicable)
├─ Monitoring Findings
└─ Need for Additional Safeguards
↓
Determine Whether:
├─ Research Continues to Meet Approval Criteria
├─ More Frequent Review Needed
├─ Verification from Other Sources Needed
└─ Corrective Actions Required
↓
IRB Review Conducted
├─ Expedited Reviewer Action
└─ Convened IRB Discussion/Vote
↓
IRB Determination
├─ Continued Approval
├─ Approval with Conditions
├─ Deferred
├─ Suspended
└─ Terminated
↓
Communicate Determination to Investigator
↓
If Approval Granted:
├─ Record New Approval Period
├─ Update Tracking System
└─ Schedule Next Continuing Review
↓
If Approval Lapses:
├─ Stop New Enrollment
├─ Stop Research Interventions
├─ Evaluate Subject Safety Needs
└─ Determine Whether Activities May Continue for Safety
↓
Post-Approval Monitoring/Oversight
↓
END

Note: This flowchart is intended as a reference tool and does not replace the written procedures. In the event of a discrepancy, the written procedures govern.

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Appendix 5. OHRP/FDA Written Procedures Checklist Crosswalk

Item	OHRP/FDA Checklist Requirement	Handbook Section(s)
1	Convened IRB review procedures, including quorum, conflicts of interest, reviewer assignments, meeting format, and loss of quorum procedures	10, 16- 21
2	Expedited review procedures and method for informing all IRB members of expedited approvals	16.3, 18, & 21
3	Determining that criteria for IRB approval are met	15.3
4	Review of informed consent process and documentation, including waivers and non-English consent	18
5	Additional safeguards for vulnerable populations	22
6	Exception from informed consent requirements for emergency research	18.11, 24.9
7	FDA investigational new drug (IND) determinations	24
8	FDA investigational device exemption (IDE) and SR/NSR determinations	24
9	Additional protections for pregnant women, fetuses, neonates, and prisoners	22
10	Research involving children	22.3
11	Investigator qualifications and adequacy of research site	17.4
12	Determining effective approval dates and subsequent continuing review dates	19
13	Communication of IRB findings and actions to investigators and institution	21.1-21.2
14	Expanded access/treatment use reviews	24.5 & 24.11
15	Emergency use of FDA-regulated test article	24.6 & 24.12
16	Humanitarian Use Device (HUD) review	24.13
17	Determination of approval period and continuing review interval	19
18	Verification from sources other than the investigator	31
19	Reporting proposed changes in research to the IRB	20
20	Review of changes in research	20
21	Communication of actions on modifications and investigator responses to disapproval	21.1 & 21.2
22	Responsibility for reporting unanticipated problems, noncompliance, suspensions, and terminations	35, 36, & 40
23	Review of unanticipated problems involving risks to subjects or others	35

Item	OHRP/FDA Checklist Requirement	Handbook Section(s)
24	Review of serious or continuing noncompliance	36
25	Suspension or termination of IRB approval	40
26	Development, scope, maintenance, revision, and review of written procedures	4.5
27	Institutional authority and IRB independence	5.5, & 9.2
28	Ethical principles governing human subjects protection	4.1
29	Regulatory definitions	3
30	Other applicable federal regulations	4.2
31	Administrative review and approval processes following IRB approval	5.4, 5.5 & 6
32	Relationship of IRB to institutional officials, investigators, and regulatory agencies	5 & 6
33	Number of IRB members	9.1
34	Diversity of IRB membership	9.1
35	Appointment, qualifications, categorization, and terms of members and alternates	9.3–9.10
36	Management of IRB member conflicts of interest	10.5
37	Education and training of IRB members, staff, and investigators	7
38	Determination of whether a study is subject to IRB review	15.1, 17.1, & 17.2
39	Determination of exemption status	16.1 & 16.2
40	Cooperative research arrangements and reliance agreements	27 - 30
41	Reporting emergency use of FDA-regulated test articles	24.7
42	Use of consultants by the IRB	10.4
43	Identification and management of investigator conflicts of interest	10.5 & 17.5
44	Applicability of federal, state, and local laws	4.2 & 17.2
45	Tracking approvals and preventing lapses in IRB approval	10.8 & 19.5
46	Handling participant complaints, concerns, and questions	39
47	Administrative support staff duties	5.4
48	Study completion and closeout procedures	40
49	IRB registration and maintenance of registration	9.12
50	Providing access to IRB requirements and written procedures	6.5
51	Contingency planning and transfer of oversight	30.4 & 31
52	Maintaining required IRB records	10.7 & 40.2
53	Record storage locations and formats	10.7
54	Preparation and maintenance of IRB meeting minutes	10.6
55	Record retention and accessibility	10.7 & 40.2