HUMAN SUBJECTS RESEARCH PROTECTION PROGRAM AND INSTITUTIONAL REVIEW BOARD INTERNAL POLICIES & PROCEDURES

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Section 1: Overview

Human subjects are often used in medical and clinical research as well as social, behavioral and educational research. The University of Texas Rio Grande Valley (UTRGV) is committed to the protection and the welfare of human subjects involved in university research-related activities. To assure compliance with federal regulations that protect the rights of subjects used in research, UTRGV has established and maintains an Institutional Review Board (IRB) for the Protection of Human Subjects in Research.

The MISSION of the IRB at UTRGV is to ensure that all research participants are treated fairly and ethically and to assist researchers at UTRGV in designing and implementing studies that comply with federal regulations and institutional policies to protect human research participants. The IRB is composed of UTRGV staff, faculty, and members of the community. Students may be also considered for membership.

This handbook includes the internal policies and procedures governing the Institutional Review Board and Human Subjects Protection Program at UTRGV.

Section 2: Definitions

Adverse Events – a subset of unanticipated problems involving risks to the subject or others and are related to untoward or unfavorable study related events, including but not limited to, any abnormal sign, symptom or disease temporarily associated with the subject's participation in the research or clinical trial.

Anonymity – refers to when the identity of a research subject cannot be readily ascertained by anyone, including the Principal Investigator, either directly or using coded data.

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 IRB as written with no explicit conditions.

Assent – an affirmative agreement to participate in research or clinical investigation. Mere failure to object an absence of affirmation agreement may not be construed as assent. This most often is applicable to children or individuals with decisional impairment.

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, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues.

Code of Federal Regulations (CFR) – is used as an acronym for Code of Federal Regulations. The Code of Federal Regulations is a document that delineates general rules and regulations that is used in order to protect human research subjects.

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. Some funding agencies may define children differently.

Clinical Investigation – is a systematic research study that is conducted in order to gather information about a product such as a drug, device, or biological substance used on human subjects.

Clinical Trials – any research study that prospectively assigns human participants o groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc.

Coded Information/Data – is identifying information that would enable the Investigator to ascertain the identity of the individual to whom the private information or specimens pertain by replacing it with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Coercion – an overt or implicit threat of harm that is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that his or her grades might suffer if they do not participate in the research.

Collaborator – anyone who plays a part in the research study and has access to study records.

Common Rule – refers to the general rule from the Department of Health & Human Services, on the protection of human subjects in research (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 study research purposes.

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. Members of an Institutional Review Board (IRB) may not review, deliberate on, or approve research if they have a conflict of interest related to the research.

Data and Safety Monitoring Plan (DSMP) – The document that sets forth mechanisms for reviewing and evaluating unanticipated problems and other study-relevant data. The rationale for requiring a DSMP is the need to enhance research subject safety by clearly defining safety related issues prior to subjects being enrolled in a study. These issues include:

1. Monitoring the safety of the environment including the safe handling of drugs, solutions, specimens, physical space, and equipment;
2. Monitoring and protecting the validity and integrity of the data collected for the study; and
3. Documenting, grading, attributing, and reporting unanticipated problems involving risks to subjects or others.

De-Identified – information or data where direct identifiers such as name and address have been removed. In common use, the term refers to data where it may still be possible to identify individuals by interference 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 research, means intentionally giving research subjects false information in order to establish false beliefs during a research study.

Designated Reviewer – experienced IRB Member, defined in this handbook as being an IRB member who has been trained on the expedited process and has been assigned with the review of a particular study.

Disapproved – means the research study does not comply with the criteria for approval as per federal regulations and this handbook. The research study and/or other documents need to be completely re-written and re-submitted as a new submission. Principal Investigators may request reconsideration of a determination for disapproval in writing and possibly be invited to attend an Institutional Review Board (IRB) meeting and presenting reasons for consideration.

Engaged in human subjects research – Refers to when individuals, for the purposes of the research study, obtain:

1. Data about the subjects of the research through intervention or interaction with them.
2. Identifiable private information about the subjects of the research.
3. Informed consent of human subjects for the research.

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

Exempt Study – 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. Exempt studies are exempt from some parts of the federal regulations but still subject to institutional policies and compliance with this handbook.

Expedited - research study includes minimal risk to participants but does not fulfill the criteria for Exemption.

Food and Drug Administration (FDA) - The Food and Drug Administration 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 of Privacy Act (FERPA) - FERPA is a Federal law that ensures the privacy of student academic records.

Federal Wide Assurance (FWA) – the documentation of an institution's commitment to comply with Federal regulations and maintain policies and procedures for the protection of human subjects participating in research.

Full Review Studies– Research studies that place human subjects at more than minimal risk or include certain vulnerable populations.

Health Insurance Portability and Accountability Act (HIPAA) - HIPPA is a Federal law that controls the access to individual's private information.

U.S. Department of Health and Human Services (HHS) - The mission of the HHS is to enhance and protect the well-being of all Americans by providing effective health and human services and fostering advances in medicine, public health, and social services.

Human Subject (also known as research study participants) - HHS defines a human subject as a living individual about whom a research investigator obtains data through identifiable private information or through an intervention, or interaction with the individual (45 CFR 46.102(e)(1)).

Informed Consent – the knowing agreement of an individual or his/her legally authorized representative, situated as to be able to exercise free power of choice without undue inducement or any element of force, deceit, duress, or other form of constraint or coercion.

Investigational Device Exemption (IDE) – allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data.

Institutional Official (IO) – The individual who is legally authorized to act for UTRGV, and on behalf of UTRGV, binds the institution to the terms of the Federal Wide Assurance. The Executive Vice President for Research, Graduate Studies and New Program Development serves as the IO.

Investigator - This includes any individual who is part of carrying out or preparing the research project. Investigator encompasses individuals who are part of the research team.

Institutional Review Board (IRB) - is used as an acronym for Institutional Review Board. The Institutional Review Board protects the rights of human subjects who participate in research studies by reviewing all research studies to ensure they fall within ethical guidelines, federal regulation requirements, and this handbook

IRB Administrator The individual who has direct administrative oversight and coordination of biomedical and clinical research, as well as social and behavioral research involving human subjects.

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

Minutes - is a written record of the events, responses, and decisions that occurred during a convened meeting.

Investigational New Drug Application (IND) – is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved drug application.

Non-Compliance – non-adherence to Federal Regulations and/or The University of Texas Rio Grande Valley policies, procedures, requirements, or IRB determinations for conducting research involving human subjects.

Office for Human Research Protections (OHRP) – the office that provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

Personal Health Information (PHI)–personal health information, which is protected under the HIPAA regulations.

Principal Investigator - The individual who oversees carrying out and preparing a research project.

Protocol Deviation – means a deviation from IRB-approved activities related to a research study.

Quorum - A minimum number of attendees that must be present during a meeting for the meeting to be held or considered valid.

Research - a systematic investigation that includes research development, testing, and evaluation in order to develop or contribute to generalizable knowledge.

Research Site – a site where research is being conducted.

Sponsor – person or entity that takes responsibility for funding a study.

Unaffiliated Member – an IRB member who has no affiliation with UTRGV, and no affiliated immediate family members. Immediate family includes a spouse or dependent children. Retirees may return as unaffiliated members after 1 year.

Unanticipated problem– any problem, event, occurrence, or new information related to the research study that is reasonably unanticipated and indicates that subjects or others are at increased risk of harm.

Section 3. Administrative Structure of the Human Subjects Research Protection Program, Guiding Principles, and Laws

3.1 Organizational Structure and Overview

3.1.1 The Institutional Official

The Institutional Official (IO) is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents UTRGV in the Federal Wide Assurance (FWA).

The Executive Vice President for Research, Graduate Studies and New Program Development serves as UTRGV's IO.

Although the IO has authority to disapprove human subjects research studies that have been approved by the IRB, no one, including the IO, may approve research studies involving human subjects that have not been approved by the IRB.

Administrative Obligations of the IO:

1. Designating one or more IRB Panels that will review research covered by the University's FWA; providing enough resources, space, and staff to support the IRB's review and record keeping duties;
2. Providing training and educational opportunities for the IRB, staff supporting the IRB and Investigators;
3. "Setting the tone" by promoting an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is supported at the highest levels of the organization;
4. Ensuring effective institution-wide communication and guidance on human subjects research;
5. Ensuring that Investigators fulfill their responsibilities;
6. Designating one or more IRB Panels that will review research covered by the University's FWA; providing enough resources, space, and staff to support the IRB's review and record keeping duties;
7. Providing training and educational opportunities for the IRB, staff supporting the IRB and Investigators;
8. Ensuring effective institution-wide communication and guidance on human subjects research;
9. Ensuring that Investigators fulfill their responsibilities;
10. Ensuring that no one at the institution interferes with the IRB's ability to fulfill its obligations to protect human subjects;
11. Serving as a knowledgeable point of contact for OHRP and other federal agencies or delegating this responsibility to another appropriate individual;
12. Signatory authority for the FWA;

13. Suspending or terminating the IRB membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and obligations;
14. Appointing the IRB Chairs or Vice-Chairs. Suspending or termination the appointment of any Chair or Vice-Chair who is not fulfilling his/her responsibilities and obligations;
15. Completing recommended Assurance training for the IO;
16. Ensuring that the IRB functions independently and that its Chair or Vice-Chairs and Members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB;
17. Ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of the HRPP.

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3.1.2 IRB Administrative Director

The Executive Director of Research Compliance and Export Controls oversees the offices of Research Compliance, the Animal Care Program, and serves as the IRB Administrative Director.

Administrative Obligations of the IRB Administrative Director:

1. Performing periodic evaluation of the performance of the IRB chairs and co-chairs and administrative staff;
2. Being the point of contact for correspondence addressing human subjects research with the OHRP, FDA and other agencies.

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3.1.3 The Office of Research Compliance

The Office of Research Compliance (ORC) staff is responsible for providing administrative and professional support to the IRB under the supervision of the Executive Director for Research Compliance and Export Controls. Administrative procedures are created to be efficient and effective to ensure that the IRB Members have adequate time to thoroughly assess proposed studies for study design, procedures, and conditions.

The ORC staff conducts initial reviews for all research studies submitted involving human subjects, making a determination for non-human subjects research studies, and/or Exempt studies, and refers their findings and recommendations to the UTRGV IRB. The ORC staff also provides assistance to Investigators who are preparing IRB applications and maintains records of IRB reviews and approvals for Investigators.

Administrative Obligations of the Office of Research Compliance:

1. Ensuring that IRB Members and Investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
2. Developing and implementing an educational plan for IRB Members, staff and Investigators;

3. Ensuring that IRB Members and Investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
4. Recruiting qualified Members to include expert, non-scientific and unaffiliated representation on the IRB;
5. Reviewing and approving Standard Operating Procedures (SOPs) for the IRB and HRPP; Overseeing daily operations of the IRB and HRPP in accordance with the SOPs.

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3.1.4 The IRB as an Administrative Body

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of UTRGV.

At UTRGV, the IRB also serves as the Privacy Board and acts upon requests for a waiver or alteration of Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a research study. As the Privacy Board, the IRB may waive or alter all or part of the Authorization requirements for a specified research project or study

The IRB operates under the auspices of the Institutional Official (IO) who is ultimately responsible for binding UTRGV under its FWA.

The IRB is charged with the responsibility of reviewing, prior to its initiation, all research studies (whether funded or not) involving human participants. The IRB is concerned with protecting the welfare, rights, and privacy of human subjects. The IRB has the authority to approve, disapprove, monitor, and require modifications in all research activities that fall within its jurisdiction as specified by the federal regulations, and institutional policy, including the terms contained in this handbook.

The IRB has authority to determine whether:

1. The rights and welfare of the research subjects are protected adequately;
2. The risks to subjects are outweighed by the potential benefits of the research;
3. The selection of subjects is equitable;
4. Informed consent will be obtained and, when appropriate, documented.

The IRB also has authority over conducting continuing reviews at intervals determined by the IRB, reviewing adverse events and protocol deviations, evaluating waivers of consent and documentation of consent, and the authority to suspend or terminate approval of research associated with unexpected serious harm to participants or not conducted in compliance with the IRB's conditions of approval, the federal regulations, or institutional policies regarding the protection of human subjects.

Research projects approved by the IRB may be subject to further review by other administrative institutional officials. Administrative institutional officials may decide that an IRB approved study may not be conducted (e.g., because of budgetary limitations); however, administrative officials (including the IO), may not approve research that has been disapproved or not yet acted upon by the IRB.

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3.2 Ethical Principles, Regulatory Requirements, and Laws that Govern the IRB

The UTRGV IRB is guided by the ethical principles regarding research studies involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the "Belmont Report"]), by regulations of the U.S. Department of Health and Human Services and others as described below.

The Belmont Report

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published the Belmont Report that identified three basic ethical principles as related to human subjects research. The principles are; respect for persons, beneficence, and justice. These principles are now accepted as the three quintessential requirements for the ethical conduct of research involving human subjects.

1. Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. Respect for persons underlies the need to obtain informed consent.
2. Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. Beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks.
3. Justice requires that the benefits and burdens of research be distributed fairly. Justice requires that subjects be fairly selected.

The Nuremburg Code

The Nuremburg Code was created as a result of the atrocities committed in the name of scientific research against humans during World War II. It addressed the significance of obtaining informed consent, of ensuring that this consent was voluntary and of ensuring that any individual "who initiates, directs, or engages in the experiment" bears responsibility for the quality of consent.

The Declaration of Helsinki

The significances of the Nuremberg Code were further articulated and expanded in the Declaration of Helsinki, which was originally set forth in 1964. The Declaration's significance was that it called for prior approval and ongoing monitoring of research by independent ethical review committees.

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3.2.1 Federal-Wide Assurance (FWA)

A Federal-Wide Assurance (FWA) is a binding agreement between UTRGV and OHRP. The FWA states that UTRGV is guided by the ethical principles of the Belmont Report and will comply with 45 CFR 46 for

all human subjects research. It also describes the responsibilities of the Institution, the Institutional Official (IO), and the Investigators. All Investigators at UTRGV are expected to conduct research in accordance with the provisions of the Federal-Wide Assurance and ensure that the rights and welfare of human subjects are protected. The UTRGV FWA document can be found in **APPENDIX A**.

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3.2.2 Federal, State, and Local Laws

UTRGV abides by all federal, state, and local laws regarding research practices including, but not limited to:

1. Code of Federal Regulations (CFR) Title 45 Department of Health and Human Services (HHS) Part 46
2. Food and Drug Administration (FDA) CFR Title 21
3. Health Insurance Probability Accountability Act (HIPAA)
4. Family Educational Rights and Privacy Acts Regulations (FERPA)
5. Texas law and all other pertinent regulations and guidelines.

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Section 4. General Rules Pertaining to the IRB

4.1 Number of IRBs

UTRGV may have as many IRBs as the Institutional Official deems necessary to adequately protect the rights of human subjects. UTRGV currently has two IRB panels registered under its Federal-Wide Assurance (FWA00000805). The requirements of this policy apply to all IRB panels.

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4.2 Composition of Each IRB, Members Selection, Chair Selection, IRB Duties, and Related IRB Procedures

4.2.1 Composition of the IRB

The composition of the Institutional Review Board (IRB) for the Protection of Human Subjects in Research at UTRGV conforms to the requirements described in the applicable federal regulations (45 CFR 46.107 and 21 CFR 56.107).

In agreement with federal regulations, each IRB shall be composed of at least five (5) voting Members who possess varying professional and educational backgrounds, including at least one scientist, one non-scientist, and one non-affiliated member. Special considerations are made to have representatives from each of the university's colleges.

When selecting Members, UTRGV considers the following:

1. The IRB is sufficiently qualified through the experience and expertise of its Members, and the diversity of its Members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
2. Every non-discriminatory effort is made to ensure that no IRB consists entirely of men or entirely of women.
3. No IRB consists of entirely Members of one profession.
4. Unaffiliated Members and non-scientist Members are essential to the composition of the IRB, as they represent the perspective of research participants.
5. For each IRB that reviews research involving vulnerable subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration must be given to the inclusion of one or more voting Members who are knowledgeable and experienced in working with those human subjects.
6. For all research projects that involve prisoners as a vulnerable category, at least one individual who is a prisoner representative is required to participate in the review of any research involving prisoners as a subject.
7. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to all available on the IRB. These individuals do not vote with the IRB.
8. Alternate members may serve in substitution for voting Members at a convened meeting. The list of IRB Members must identify the Member(s) for whom each alternate member is authorized to substitute. Alternates must have equivalent expertise as a Member within the same field.

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4.2.2 IRB Duties

1. Reviewing, approving, requiring modifications to secure approval, or disapproving all research activities covered by these policies prior to commencement of the research;
2. Requiring that information given to participants as part of informed consent is in accordance with appropriate laws, regulations, and international standards. The IRB may require that additional information be given to the participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants;
3. Requiring documentation of informed consent or waive documentation in accordance with applicable laws and regulations;
4. Conducting continuing review of research covered by these policies at intervals appropriate to the degree of risk, but not less than once per year, (unless the research qualifies for an Exemption or has been classified as Expedited, after January 20, 2019). The IRB has the authority to observe or have a third party observe the consent process and the research;
5. Acting upon requests for waiver or alterations of the HIPAA Authorization requirement under the HIPAA Privacy Rule for uses and disclosures of protected health information (PHI) for research studies;

6. 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. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the Investigator, Institutional Official, and the department or agency head.

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4.2.3 IRB Members Selection

The Office of Research Compliance identifies potential board members through consultation with the IRB Chairs, and Vice-Chairs, current IRB members, Deans, and Department Chairs. After evaluating their CVs and ascertaining their willingness to serve, the Office of Research Compliance submits the names of potential new members along with their curriculum vitae to the Institutional Official for review and approval.

Upon approval, an appointment letter is issued indicating the specific role of the member (scientist, non-scientist, unaffiliated member), voting rights, and term of service. For purposes of quorum, an appointment is considered effective as of the date written on the appointment letter.

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4.2.4 IRB Member Duties

1. Serving as Primary Reviewer for research studies within their area of expertise;
2. Attending and participating in Board meetings;
3. Voting on proposed research activity at the Board meetings;
4. Maintaining a working knowledge of regulations and relevant University policies;
5. Attending trainings and conferences related to IRB activities;
6. Reviewing and approving proposed research activities falling under an expedited category of review;
7. Requesting consultants when needed;
8. Attending full Board meetings and relevant trainings.

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4.2.5 IRB Chairs and Vice Chairs Selection

The Office of Research Compliance requests input from the academic colleges and current IRB members to identify potential candidates to serve as the IRB chairperson based on expertise and experience. Candidates submit their curriculum vitae to the Office of Research Compliance and the Institutional Official for review and approval.

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4.2.6 IRB Chairs and Vice Chairs Duties

1. Supervising Board meetings to ensure approved research is consistent with all applicable regulatory requirements under ethical and federal policies
2. Approving and signing documents relevant to the review and approval of human subject research activities;
3. Ensuring that Members who have conflict of interests are not present during deliberation and voting;
4. Managing time during meetings to guarantee enough discussion time for each topic on the agenda;
5. Ensuring a decision is made for each action item on the agenda;
6. Engaging in IRB policy development and discussions;
7. Reviewing and acting upon reports of adverse event and protocol deviations;
8. Assisting in the planning and implementation of continuing education for the Board;
9. Providing feedback to the IRB Administrative Director and the Institutional Official regarding the quality and adequacy of staff support;
10. Providing input for allocating training funds provided to the Board;
11. Representing the Board to outside agencies and organizations.

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4.2.7 IRB Roster

The Office of Research Compliance is responsible for maintaining a current roster of all Members serving on the 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
2. Name of Member
3. Gender
4. Earned degree(s)
5. Scientific or nonscientific status
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

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4.2.8 Related Procedures

4.2.8.1 Determining Whether Prospective Members are "Unaffiliated"

1. Unaffiliated Members of the IRB may not be current University employees, students or vendors.

2. An individual with no affiliation to the University other than as a Member of the IRB or whose only association with UTRGV is that of healthcare patient or research participant, may be considered *unaffiliated*.
3. Paying an unaffiliated 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.
4. A former University employee or student who has not been employed by or enrolled as a student at the University for at least two years may be considered unaffiliated. Retirees may return as unaffiliated members after 1 year.
5. Family members that are not immediate. Immediate family includes a spouse or dependent children.

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4.2.8.2 Determining Whether a Member is considered a Scientist vs. Non-Scientist (based upon general guidance from the Office of Human Research Protections, OHRP)

1. Scientist/Non-scientist: Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline are considered a scientist. Members, whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline are considered a non-scientist.
2. For the purposes of determining IRB member status, a scientist is a person who routinely utilizes the scientific method in the conduct of his or her discipline related scholarship fields in which persons designated as scientists commonly practice may include, but are not limited to: medicine, dentistry, nursing, pharmacy, physical therapy, nutrition, anthropology, economics, political science, psychology, sociology, physics, biology, chemistry, math, statistics, and earth sciences.
3. For the purposes of determining IRB member status, a non-scientist is a person who does not routinely utilize the scientific method in the conduct of his or her discipline related scholarship. Fields in which persons designated as non-scientists commonly practice may include, but are not limited to art, classics, drama, English, music, philosophy, and religion.
4. Not everyone from a scientific field is automatically considered to be a scientist, nor is everyone from a typically non-scientific field automatically considered to be a non- scientist. Classification for purposes of appointment to the IRB depends primarily on the degree to which the individual has familiarity with and experience utilizing the scientific method. The final determination shall be made by the EVP for Research, Graduate Studies & New Program Development in consultation with the IRB Chair(s) and the Office of Research Compliance.

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4.2.8.3 Length of Term

IRB Members, Chairs, and Vice-Chairs are appointed to 1 to 3-year term that can be renewed at the discretion of the Institutional Official for additional terms.

For new and renewing members, the appointment is 2 years. For Chair and Vice-Chair appointments, the term is 3 years and can be renewed for terms of equal duration. There is no limit on the amount of terms.

The Institutional Official will consider the following when deciding on renewal terms:

1. Attendance
2. Timeliness
3. Overall Review Quality
4. Performance
5. Participation in the review of IRB policies and procedures

The Institutional Official and the IRB Administrative Director, or designee, with input from ex-officio Members, evaluates the IRB Chair and Vice-Chair performance and provides feedback on an annual basis. The Institutional Official is responsible for addressing issues with the Chair/Vice-Chair and for selecting new appointees when necessary.

IRB Members are evaluated on an annual basis by the IRB Administrative Director in consultation with the Chair and Vice-Chair of the respective board. IRB Chairs and Vice-Chairs are evaluated on an annual basis by the IRB Administrative Director in consultation with the IRB Members. Written copies of evaluations are provided and may be included in the members' tenure, promotion, or annual evaluation dossier at their discretion.

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4.2.8.4 Registering and Maintaining IRB Registration

The U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46, subpart E, require all IRBs to register with HHS assurance of compliance approved for federal-wide use (i.e., an FWA) by OHRP.

The UTRGV IRB is registered electronically by the Office of Research Compliance through http://ohrp.cit.nih.gov/efile. Registration becomes effective for 3 years after it is reviewed and accepted by OHRP. Registration is updated within 90 days after changes occur regarding the Institutional Official or the IRB Administrative Director. The updated information must be submitted in accordance to §46.504.

Renewals or updates that are submitted to, and accepted by, OHRP begin a new 3-year effective period.

UTRGV's decision to inactivate a registered IRB which it is operating must also be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or supported research.

ORC must maintain official updated records of IRB rosters for all panels and corresponding Members.

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4.2.8.5 Access to Information and IRB Policies and Procedures

The IRB and the Office of Research Compliance (ORC) records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

The IRB maintains written procedures in this handbook as required by 46 CFR 46.103 and 21 CFR 56.108(a). These documents are developed and maintained by the ORC in consultation with the IRB.

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4.2.8.6 Creation and Implementation of IRB Policies and Procedures

The authority to create, change, and implement institutional human subjects protections policies is shared between the IRB and the Office of Research Compliance (ORC). New policies or modifications may be presented to the IRB for input. The Institutional Official (IO) and the IRB Subcommittee may also be asked to review and comment on new or modified policies and to advise the IRB/ORC regarding policy decisions. At the discretion of the Institutional Official (IO) and the IRB Subcommittee, input may also be sought from other parties that would be affected by the policy. The IRB 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 ORC.

At a minimum, ORC will conduct a comprehensive review of institutional policies contained in this handbook at an interval does not exceed three years or whenever a change in federal regulations or 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 UTRGV polices and if there is a need for new policies to be developed. If an individual policy has been revised, ORC will announce the revision date on the IRB website. Revisions and last approval dates will be captured at the end of each policy.

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4.2.8.7 Review of IRB Policies and Procedures

IRB Internal Policies and Procedures will be reviewed no less than three years from the date of approval. The new review date is determined as three years from the last date of approval. The IRB Policies and Procedures will then be presented to the UTRGV IRB for input before approval. Areas of concern that arise will be addressed by the Office of Research Compliance in collaboration with the IRB Panels, Chairs, and Vice Chairs.

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4.2.8.8 IRB Interaction with Other Institutional Regulatory Committees

Research studies may be subject to review by one or more of the research regulatory committees (e.g., Institutional Animal Care and Use Committee (IACUC) and/or Institutional Biosafety Committee (IBC)) UTRGV's mission to protect human subjects research subjects is dependent upon open communication amongst these institutional components. These committees work together to exchange information and when necessary, assure that, in addition to IRB review, human subjects research receives all appropriate review prior to implementation. In most cases, reviews can be done concurrently. Human subjects research is not allowed to begin until all applicable reviews are complete, and notification of approval is received by the IRB.

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Section 5. Rules and Processes Related to IRB Meetings and Related Board Activities

5.1 IRB Convened Meetings

A convened meeting is a meeting of the IRB consisting of a quorum. The IRB meeting schedule can be viewed on the IRB website. Investigators may also contact the Office of Research Compliance for the dates of the monthly meetings.

The ORC staff is responsible for preparing the agenda, after it is determined by the IRB Chairs, and distributing it to the IRB prior to each meeting. All Members will have access to the meeting materials a week before the meeting to allow enough time to perform a substantive review.

Materials received by the IRB will be considered confidential and will be distributed only to meeting participants (voting Members, ex-officio Members, consultants, administrative staff) for the purpose of review. The Office of Research Compliance will provide the review materials to the IRB. All materials will be collected after the Board adjourns.

Quorum is defined as 51% of the voting members and at least one non-scientist voting member. A Member with a conflict of interest cannot contribute to a quorum. Quorum must be maintained during the entire meeting.

The IRB meeting may not convene until quorum is established. The Office of Research Compliance 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.

Consultants and visitors are invited to the IRB meeting by the Chair or Vice-Chairs. A visitor can be an Investigator whose study is being reviewed. A Primary Reviewer can submit a request for a consultant whenever necessary expertise for review is not represented on the Board. Consultants can be internal or external but cannot have a conflict of interest related to the study or item he/she is requested to consult on.

Consultants and visitors will be expected to sign the UTRGV IRB Confidentiality Statement and will receive a printed copy if necessary. The ORC staff is responsible to have each consultant or visitor sign the agreement prior to the start of the meeting. These agreements will be maintained the ORC.

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5.1.1 Unforeseen or Emergency Situations

An unforeseen event or emergency situation refers to the occurrence of natural disasters, riots, closures, pandemic situations, and other events outside the control of the UTRGV that affect the operations of the IRB or the human subject research that the IRB oversees.

In case of emergencies or unforeseen events that prevents the IRB from operating as usual, the IRB may:

1. Convene a meeting through alternative means of communication (e.g., conference calls and teleconferencing);
2. Call for emergency meetings outside of regularly scheduled meetings;
3. Recommend to the Institutional Official (IO) the issuance of institutional interim policies supporting the IRB in its endeavors.

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 mean used by each member. If institutional interim policies are issued by the IO, such policies will be annexed to this handbook as an appendix.

Appendix C: Interim Policies during Emergency Situations or Unforeseen Events

Originally approved: April 2020 Last Rev. (N/A)

5.2 Consultants

The IRB may request consultants in order to assist with a review that is beyond Members' scope of expertise. The consultant(s) may provide scientific and scholarly expertise about a topic or population. In addition, consultants may be used during the initial review, review of modifications, or continuing review of a study. Consultants, however, may not vote during IRB deliberations and his/her attendance cannot be used to establish quorum.

Identifying a Consultant:

1. A recommendation may be made to seek assistance from a consultant by the IRB Chair, Vice-Chair, or by any IRB reviewer, coordinator, manager, or administrator. Ultimately, the IRB Chair appoints the consultant.
2. Consultants internal to UTRGV may be identified through any form of communication with an IRB Member.
3. Consultants may also be external to UTRGV.
4. Consultants cannot be compensated except for expenses directly related to the review (e.g., parking).

5. Consultants must not have a conflict of interest and must be willing to abide by confidentiality rules.

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5.2.1 Consultant Participation in the Review of Research

The ORC should document in writing that the consultant has certified that he/she does not have a conflict of interest; this is typically done in the board minutes.

1. The consultant should have access to all documents required for IRB review.
2. The consultant is required to return all documents and/or relinquish access to all documents related to the project under review after the meeting.
3. Consultants must present their professional opinions by verbal or written presentation at the time of the IRB meeting.
4. If a consultant is present during IRB meeting, he/she should step out and not take part in the IRB determination (voting).

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

5.3.1 Conflicts of Interest for IRB Members or Chairs and Vice-Chairs

A conflict of interest occurs when an IRB member, chairperson, or consultant has a financial interest in research study or could potentially realize some other type of personal gain from the approval or disapproval of a study that could potentially bias their professional objectivity, and judgement. No IRB Members, chairpersons, or consultants should be present for deliberations or vote on any project for which they have a conflict of interest (except in the case where an individual involved in a project is asked to be present during deliberations to answer questions posed by the board).

Conflicts of Interest that would require recusal include but are not limited to:

1. When a board member (including a chairperson) or consultant participating in a study as an investigator or part of the research team that is under review by the IRB;
2. A board member (including a chairperson) or consultant is an immediate family member of an investigator whose study is being reviewed by the IRB. Immediate family includes a spouse or dependent children;
3. A board member (including a chairperson) or consultant that has a financial interest in a study or serves in a company who sponsors a study that is under review by the IRB;
4. A board member (including a chairperson) or consultant is a potential competitor to an investigator who is under review and is working on similar studies.

Managing Conflicts of Interest during the IRB Review and Convened Meetings:

1. IRB Members, chairperson, or consultants who may have a conflicting interest must disclose it to the Board and the Office of Research Compliance (ORC) prior to review.

2. IRB Members, chairperson, or consultants who have a conflicting interest must leave the room when a project is being reviewed.
3. The IRB chairperson may not chair the meeting during discussion of a study in which he/she has a conflicting interest.
4. Conflicted IRB Members may not be present for voting and must not be included in voting or counted towards quorum.
5. Designated reviewers who have a conflicting interest with a project under review must have the project reassigned to a different reviewer.
6. IRB chairperson checks if there are any conflicts of interest before starting a convened meeting.

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5.3.2 Conflicts of Interest for Investigators

All investigators and research personnel are required to disclose any outside affiliation according the University of Texas System policy on Conflicts of Interest, Conflicts of Commitment, and Outside Activities. Outside affiliations that might affect the protection of subjects must be managed. Management of a conflict of interest can be done through a management plan and/or through the study at the discretion of the Office of Research Compliance.

The term "Investigators" encompasses anyone who is involved in the research project. This includes the Principal Investigator, research staff, volunteers, and assistants. Investigators must also report any conflicting interest involving their immediate families.

Conflict of Interest Can Occur When a Research Investigator's Outside Interests:

1. Influence the way the PI performs his/her institutional responsibilities, or if the interest has been offered with the intent to influence the Investigator'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.

Managing Investigator's Conflicts of Interest:

Investigators who receive any type of salary or wages from UTRGV (e.g., work-study or graduate assistantship) must disclose their outside affiliation through the UT System Outside Activity Portal. For non-employee Investigators, the disclosure should be made by completing the "Outside Affiliation Disclosure Certification (OAD) Form" found on the UTRGV IRB website.

If a new financial interest is acquired that is related to the Investigator's current research project, then the Investigator must submit a new form and report this disclosure within 30 days of acquiring the new affiliation. A report of possible non-compliance will be investigated following the non-compliance procedures in this manual.

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5.4 IRB Meeting Minutes

Meeting minutes are recorded in writing and contain enough details to allow an outside observer to reconstruct the specific discussions and IRB actions taken during a convened meeting. The minutes at a minimum include a record of attendance; statement of quorum; a summary of all research activities reviewed; any vote taken by the IRB related to a proposed research activity; rationale for requiring changes or disapprovals; and, a summary of controverted issues and their resolutions.

The Office of Research Compliance staff is responsible for counting and documenting 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 Office of Research Compliance and will be retained for three years after the end of the research study. Meeting agendas and meeting minutes are not subject to public records requests.

The ORC staff is responsible for preparing a draft outline of meeting minutes prior to a convened meeting. After the meeting takes place, determination of quorum, determinations, stipulations, and discussions will be documented following the minutes template appended to this document (**APPENDIX B**).

The ORC staff is responsible for preparing the draft minutes and submitting them to the IRB Chair and Vice-Chair for pre-review within 3 business days. The draft minutes are then presented to the IRB for review and approval at the next subsequent convened meeting. Once approved by the Board, meeting minutes are filed electronically for future reference.

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5.5 Records Access, Location, and Retention

The ORC prepares and maintains adequate documentation of all IRB activities for at least 3 years after the study closes. These activities include:

1. Copies of research study applications;
2. IRB meeting minutes;
3. Research studies that are under continuing review;
4. Copies of any type of communication between the IRB and research Investigators;
5. A detailed list of all the Members of the IRB committee in accordance to 45 CFR 46.107 ;
6. Written procedures for the IRB (this handbook), these procedures should also be in accordance with federal regulation 45 CFR 46.108 ;
7. Documentation and statements of significant new findings provided to subjects, as required by 45 CFR 46.116 (b)(5).

IRB records are available and accessible for inspection and protected from unauthorized access. To ensure privacy but accessibility, documents are placed in a secure shared drive that backs ups every day and at the electronic routing system (Tick@Lab).

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Section 6. Training Requirements for IRB Members, Chairs, and the Office of Research Compliance

6.1 IRB Members and Chairs & Vice-Chairs

Prior to commencing service on the IRB, all Members must complete a new member orientation and the CITI IRB Member Course. The modules required for the CITI IRB Member Course are:

1. Belmont Report and Its Principles (ID 1127)
2. Populations in Research Requiring Additional Considerations and/or Protections (ID 16680)
3. Basic Institutional Review Board (IRB) Regulations and Review Process (ID 2)
4. Assessing Risk – SBE (ID 503)
5. Informed Consent (ID 3)
6. Privacy and Confidentiality – SBE (ID 505)
7. The IRB Member Module – 'What Every New IRB Member Needs to Know' (ID 816)
8. Research and HIPAA Privacy Protections (ID 14)

IRB Members receive additional training via their attendance at convened meetings, appropriate training conferences, courses, meetings, and professional memberships. Ongoing education of the IRB includes distribution, review, and discussion of relevant publications and annual trainings provided by the Office of Research Compliance (ORC).

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6.2 The Office of Research Compliance

ORC staff members must be familiar with pertinent federal regulations and IRB policies and procedures, including the ones contained in this handbook. Further training is provided by working in close interaction with fellow staff members. The ORC staff are encouraged to attend regional or national human subject protection meetings and to obtain/maintain professional certifications, such as the Certified IRB Professional (CIP) designation.

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6.3 Training Requirements for Investigators

The UTRGV IRB utilizes CITI (Collaborative Institutional Training Institute) as the primary program for required human subjects training. Instructions for how to register to complete training through the CITI program, or to add/change the affiliated institution can be found at the IRB webpage.

CITI courses must be passed with a score of 80% or above.

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6.3.1 Initial Training for All Researchers Involved in non-Exempt Human Subjects Research

All members of a research team that are involved in the conduct of non-exempt human subjects research (i.e.,: Expedited and Full Board level of reviews) must complete human subjects research training before submitting an application to the IRB. This requirement applies to all members of the research team that are responsible for the scientific oversight of study (including mentors for trainees) and/or who:

1. Recruit potential participants (this does not include individuals who only post study advertisement or provide potential participants with recruitment materials but do not answer questions or provide any study details);
2. Obtain informed consent;
3. Interact with participants to collect research data;
4. Analyze identifiable research data.

All researchers are required to complete the CITI Responsible Conduct of Research training. In addition, CITI has two courses related to working with human subjects – a biomedical course and a social-behavioral-educational (SBE) course; one of these courses is required, based on the type of research. Biomedical and SBE researchers must complete the five modules listed on their selected course (5.3.2 or 5.3.3) and two additional modules of their choosing before commencing research with human subjects. Additional training may be required depending on the specifics of the study submitted to the IRB and the research team's experience and training.

Biomedical Course

1. Belmont Report and CITI Course Introduction (1127)
2. History and Ethics of Human Subjects Research (ID 498)
3. Basic Institutional Review Board (IRB) Regulations and Review Process (ID 2)
4. Informed Consent (ID 3)
5. Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID 14777)

Social-Behavioral-Educational Course

1. Belmont Report and CITI Course Introduction (ID 1127)
2. History and Ethical Principles (ID 490)
3. The Federal Regulations
4. Informed Consent
5. Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID 14928)

Refresher Training

The Responsible Conduct of Research course is required every four years. The Social-Behavioral-Educational Refresher or Biomedical Refresher must also be completed every four years after completion of the initial training

6.3.2 Special Considerations for Researchers Conducting Clinical Trials

All Investigators and research study personnel conducting clinical trials, regardless of the source of funding, are required to complete either the CITI GCP training course or the Society of Behavioral Medicine GCP course before they participate in any research activities.

The NIH defines a clinical trial as: "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

NIH provides resources on their website to define these terms and to help researchers determine whether their research falls under this definition. For all NIH or FDA funded studies, the sponsor will make the final determination of whether a study is defined as a clinical trial. For all other studies, the ORC will make the final determination.

Originally approved: November 2019 Last Rev. April 2021

Section 7. Principal Investigators, Research Personnel, Trainees, and Faculty Advisors

For UTRGV IRB Purposes:

1. **Investigators** are defined as all persons who contribute significantly to the design and implementation of a study
2. **Principal Investigator** is the Investigator taking lead on the study
3. **Research study personnel (referred to as Other Study Personnel in Tick@Lab)** are all persons who contribute to the implementation of the study, including interaction with subjects and/or access to data, but do not participate in the design and development of the study
4. **Faculty Advisors –** investigator responsible for reviewing the scientific integrity of the project, including evaluating the scientific rigor and merit of the study

7.1 Principal Investigators

Principal investigators (PIs) at UTRGV are responsible for protecting the human subjects involved in their research in accordance with UTRGV policies, all applicable federal, state, and local regulations, as well as the code of ethics of their professions and this handbook. Additionally, PIs are responsible for:

1. Submitting adequately prepared applications and documentation to the IRB through the electronic routing system, Tick@Lab, managed by the Office of Research Compliance;

2. Requesting timely continuing review of any research that proposes to extend beyond the initial review period;
3. Notifying the IRB of adverse events or unanticipated problems in a prompt manner;
4. Maintaining adequate records, documents, and informed consent forms for at least (3) years following the completion of approved project or activity;
5. Staying current on required trainings;
6. Ensuring that all research study personnel receive complete training.

Although a PI may delegate some of these tasks, (e.g., notification of adverse events) the PI still maintains responsibilities for all aspects of the study.

7.2 Research Personnel

The PI is responsible to ensure that qualified research personnel are on the study to minimize risk. At a minimum, the following should be included in the study application for the IRB to determine the qualifications of the research personnel.

1. Role in the study
2. Responsibilities
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.)

7.3 Trainees as Principal Investigators

UTRGV students and medical residents may be designated as Principal Investigators for mentored research they conduct under the supervision of a Faculty Advisor. As such, they must comply with all the responsibilities of Principal Investigator. Faculty advisors must be included on all IRB applications as a Pre-Reviewer and Signer.

7.4 Faculty Advisors

Faculty advisors are responsible for the protection of human subjects involved in the research projects of their trainees/students in accordance with UTRGV policies, all applicable federal, state and local regulations, as well as code of ethics of their profession and this handbook. Faculty advisors are also responsible for knowing whether the trainee or student (1) is qualified to conduct the proposed research project; (2) have access to resources needed to adequately protect research participants and complete the proposed project within the agreed research period; (3) ensure the research has scientific merit; and (4) ensure all forms are submitted to the IRB on a timely manner.

7.4.1 Faculty Advisor Requirements for Medical Students and Residents

1. UTRGV-employee faculty are approved to serve as faculty advisors.
2. UTRGV non-paid (volunteer) faculty member can serve as faculty advisors and must have a UTRGV-employed faculty member as co-PI.

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Section 8. Studies Subject to IRB Review, Criteria for IRB Approval Under the Common Rule, Vulnerable Populations, Initial Review of Research, and Informed Consent

8.1 Studies Subject to IRB Review

The UTRGV IRB reviews and approves research projects meeting the regulatory definition of human subjects research as defined in the Federal regulations (45 CFR 46.102(e)(1)).

The Federal Regulations define a **Human Subject** as a living individual about whom a research investigator (faculty or student) obtains data through intervention or interaction with the individual or from individually identifiable information.

Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (l). Under FDA regulations, research (clinical investigation) means any study in which a drug is administered or dispensed to or used involving one or more human subjects.

Investigators are responsible for obtaining IRB approval before beginning any human subjects research that meet the definitions above. If the Principal Investigator is unsure of whether the study constitutes "human subjects research" he/she should contact the Office of Research Compliance for guidance and/ or to request a determination (Request for Determination Form).

Human Subjects Research Studies include:

1. Studies that utilize test subjects or their specimens for new devices, products, drugs, or materials;
2. Studies that collect data through intervention or interaction with individuals;
3. Studies using private information;
4. Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair or nail clippings, even if these materials are not collected for the study;
5. Studies that use human subjects to evaluate environmental alterations.

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8.1 Criteria for IRB Approval of Research Under the Common Rule

The U.S. Department of Health and Human Services (HHS) at 45 CFR 46.111 and FDA regulations at 21 CFR 56.111, delineate specific criteria for the approval of research.

The UTRGV IRB will determine that all the following requirements are satisfied before approving proposed research:

1. Risks are minimized using sound research design, and when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks are reasonable in relation to anticipated benefits.
3. The selection of subjects will be equitable.
4. The informed consent of subjects will be obtained.
5. The informed consent of subjects will be documented.
6. The research includes adequate provisions for monitoring data to ensure the safety of subjects.
7. The research includes adequate provisions to safeguard the confidentiality of data and the privacy of subjects.
8. The research includes adequate additional protections to safeguard the rights and welfare of subjects who may be vulnerable to coercion or undue influence.

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8.2 Special Requirements for Vulnerable Populations

There are special regulatory requirements for the approval of research that involves certain vulnerable populations:

1. Children: Federal regulations include requirements for parental permission (consent) and assent from children. 45 CFR Part 46, Subpart D
2. Pregnant women, fetuses, and neonates: Consent may be required from only the woman or the woman and the father. 45 CFR Part 46, Subpart B
3. Prisoners: There are several restrictions on research involving prisoners, and these studies require extra review time. 45 CFR Part 46, Subpart C
4. Individuals with cognitive impairments, legally blind, illiterate, or physically cannot talk or write: The consent process and/or documentation method may need to be altered for these individuals. 45 CFR 46.111(b)

The IRB may require additional safeguards to protect vulnerable populations. For example, the IRB may require that the Principal Investigator (PI) submit each signed informed consent form to the IRB, that someone from the IRB oversee the consent process, or that a waiting period be established between initial contact and enrollment to allow time for family discussion and questions.

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8.3 Initial Review of Research

For the IRB to conduct an initial review of research, it must have access to the following in the Tick@Lab application

1. Answers to the smart form questionnaire;
2. Informed consent and/or assent form(s), if applicable;

3. Recruitment materials;
4. Outside activity disclosure certifications;
5. Outside sites/supporting letters if, applicable;
6. Data collection materials

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8.4 Informed Consent

The informed consent process must be a dialogue of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits. The process of consenting is ongoing and must be made clear to the subject that it is his/her right to "withdraw" or "opt-out" of the study or procedure at any time, not just at the initial signing of the paperwork. The location where the consent is being discussed, and the subject's physical, emotional and psychological capability must be taken into consideration when consenting a human subject. The informed consent process should ultimately assure that the subject understands what he/she is signing up for.

Principal Investigators must obtain full informed consent in all non-Exempt research with human subjects unless a waiver or alteration is approved by the IRB. Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless a waiver of documentation of consent is approved by the IRB. A copy shall be given to the person signing the form.

In compliance with 45 CFR 46.116 (a) or 21 CFR 50.25 (a), the informed consent document should include at a minimum:

a) A statement that the study involves research, an explanation of the purposes of the research study and expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures which are experimental;
b) A description of any foreseeable risks or discomforts to the subject;
c) A description of benefits to the subject or others that may be reasonably expected from the research;
d) The disclosure of appropriate alternative procedures or course of treatment, if any, that may be advantageous to the subject;
e) A statement describing the extent to which confidentiality of records identifying the subject will be maintained;
f) For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if an injury occurs during study participation;
g) The identification of an individual who can be contacted by the subject for answers to questions related to research, research-related injury, or their rights as a research subject;
h) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may

discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled;

i) A statement on whether the investigator or study personnel has a financial interest in the outcomes of the research. A statement describing whether recordings (audio/visual) will be used, voluntary nature, and safeguards for protection of the data.

When a subject is not proficient in English, translated consent forms must be provided. A written consent should be written at an eighth-grade reading level. The UTRGV IRB accepts two methods of translation: 1) translation and back translation, and 2) professionally translated documents. The method chosen must be documented in the IRB application. The translated documents are not required at initial submission, however, must be submitted as attachments through an amendment to the approved research study.

Consent presented orally requires documentation through a written summary and a "short form written consent". A "short form written consent" states the components of informed consent as required by the regulations (45 CFR 46.116) are documented and a witness is required to sign this form. The witness and the research subject are required to sign a written summary of what was presented orally. However, the research subject is not required to sign the "short form written consent" document.

The IRB may waive any of the elements or the requirement of informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration and;
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB may waive the requirement (45 CFR 46.117) for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

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8.4.1 Waiver or Alteration of Informed Consent

The IRB will take into consideration the risks and potential harms involved in the research before granting a waiver of informed consent. Additionally, the IRB will consider the precautions investigators must take in order to protect vulnerable populations such as studies that involve pregnant women, human fetuses, and neonates.

If vulnerable populations are involved, additional safeguards are generally required. In the case of children, in the addition to the required parental/guardian consent, an 'assent' document should be prepared, written in the reading level and language the child will understand.

The consent form approved by the IRB is the official document that should be given to subjects, signed, and returned to the PI for safekeeping. The PI must retain signed consent forms for at least three years past completion of the research study and should store these documents according to the approved application.

The IRB approval of the informed consent document expires one year from the initial approval. It is the PI's responsibility to ensure a timely application for continuing IRB review and approval as necessary. The IRB has the authority to observe or have a third party observe the consent process.

Revisions to Informed Consent Form

When a revision to the informed consent form is made, regardless of whether any participants are enrolled, the PI will need to attach a copy of the IRB approved form and a copy of the revised informed consent form to the amendment application in the electronic routing system, Tick@Lab.

If participants have already signed an informed consent form and it becomes necessary to inform them of modifications or new information, an addendum informed consent document may be needed. An addendum will apply if:

1. The study is open for recruitment and enrollment.
2. Some participants are already enrolled and
3. The change might be related to the participants' willingness to continue their participation in the study;

Or

1. The study is closed to enrollment and
2. The change might be related to the participants' willingness to allow the continued use of data from their participation.

Changes to the informed consent form will be reviewed by the Full Board at a convened meeting unless the changes meet the IRB's requirements for Expedited review. Any IRB approval of a revised informed consent form that might relate to the subject's willingness to continue participation in the study will require the re-consent of all current subjects (active or follow-up) in the study. Subjects in follow-up

may be mailed a copy of the changes to the consent form. For minor changes to the consent form that will not change risk/benefit, re-consenting is generally not required.

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Section 9. Levels of Review, IRB Determinations, and Appeals

9.1 Levels of Review

There are 4 levels of review (Exempt, Exempt with limited IRB review, Expedited, and Full Board) defined by the Federal Regulations for Protection of Human Research Subjects (45 CFR 46).

An IRB Chair or a Member can elevate the level of review for any study if he/she believes there is cause to do so.

1. The specifics of the study may elevate the risk.
2. The specifics of the research team may elevate the risk (e.g., history of noncompliance or an inexperienced PI without any more experienced Investigators on team).

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9.1.1 Exempt Review

Department of Health and Human Services (DHHS) regulations in 45 CFR 46.104 (Common Rule) identify several different categories of minimal risk as being Exempt from the requirements of the federal regulations. This includes research involving minimal risk to participants. Minimal risk refers to risk that an individual may ordinarily encounter in daily life or during the performance of a routine physical or psychological examination or test (45 CFR 46.102 (j)).

In order to determine if a research study is Exempt from expedited and full-committee review, the Office of Research Compliance evaluates the study to determine whether it meets the criteria of 45 CFR 46.101.

Exempt Categories:

1. Research on normal educational practices.
2. Surveys, interviews, educational tests, or public observation.
    a. May only apply to children if the study involves educational tests or observation of public behavior when the Investigator (s) do not participate in the activities being observed.
3. Benign behavioral interventions.
4. Analysis of previously collected, identifiable info/specimens.
5. Federal research/demonstration projects.
6. Taste and food evaluation studies.
7. Storage or maintenance of identifiable private info/specimens for potential secondary research.
8. Use of identifiable private info/specimens for secondary research.

Materials Required for Review:

Exemption 1: If applicable, a letter of support or permission from the participating schools (only applies if research is taking place outside of UTRGV).

Exemption 2: If research is limited to observation of public behavior, no additional materials are required. If research is limited to educational tests, survey procedures, or interviews in which no identifiers are being collected, a copy of the data collection material(s) are required. For research involving educational tests, survey procedures, or interviews in which identifiers are being collected, a brief consent form and a copy of the data collection material(s) should be submitted, and information provided in the IRB application should provide a clear plan for protecting the privacy of subjects and maintaining the confidentiality of the data.

Exemption 3: A brief consent form or verbal consent script. If using a written consent form and no other identifiers are being collected, the signature of the subject is not required, the consent form should simply state that proceeding with the research procedures implies consent. If audiovisual recording is taking place, this fact should be included in the consent script/form.

If identifiers are being collected, the information provided in the IRB application should provide a clear plan for protecting the privacy of subjects and maintaining the confidentiality of the data.

Exemption 4: HIPAA authorization form or request for waiver of authorization in the IRB application should be requested, if applicable.

Exemption 5: A brief consent and/or assent form. The IRB application must provide the URL for Federal website listing the research or project.

Exemption 6: Verbal consent/assent script.

Exemption 7: Copy of consent/assent form used. The IRB application should provide a clear plan for protecting the privacy of subject, maintaining the confidentiality of the data and information on how refusals of broad consent are tracked.

Exemption 8: Copy of consent/assent form used. The IRB application should provide a clear plan for protecting the privacy of subjects and maintaining the confidentiality of the data and information on how refusals of broad consent are tracked.

Only the Office of Research Compliance (ORC) can determine whether a project is Exempt.
Exempt studies are still subject to institutional policy and this handbook.

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9.1.2 Limited IRB Review (Common Rule)

This category is appropriate for studies in which the only risk to subjects comes from the possibility that sensitive, identifiable information may be made public (Exempt Categories 2 and 3). For studies in this

category, the Chair or an experienced IRB member designated by the Chair, conducts a review related only to the provisions to safeguard sensitive and identifiable information. These reviews follow the procedures adopted for Expedited reviews.

Investigators conducting research in this category should complete the general information and appropriate sections of the IRB application, making sure to include enough information that ORC staff can confirm that the research meets the definition of exempt research in Category 2 or Category 3.

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9.1.3 Expedited Review

Research studies may fall under the Expedited review process if the research study includes minimal risk to participants but does not meet the criteria for Exemption. This can include studies that use deception or recruit from some vulnerable populations.

Research that falls under this category does not require review during a convened IRB meeting; expedited studies can be reviewed by the IRB Chair or a designee. In order to determine whether a research study qualifies as an to Expedited review, the research must meet the criteria from one or more categories listed at 45 CFR 46.110.

Expedited Categories:

1. Clinical studies of drugs and medical devices only when certain conditions are met.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.
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.

A Member conducting an Expedited review can take the following actions:

1. Approve the Study – The study can begin following the application and or study as written.
2. Approval Upon Meeting Stipulations – Stipulations must be met before final approval is granted. Stipulations that are not significant in nature (non-substantive) may be later reviewed by the professional staff at the Office of Research Compliance. Stipulations of a significant nature (substantive) will be reviewed by the designated IRB Member.

3. Deferred (Tabled) – The IRB reviewer needs more information from the Principal Investigator before making a final determination. This may include a consultation between the IRB reviewer and the Principal Investigator before the review can be finalized. Revisions required must be revisited by the designated reviewer before a determination can be made.
4. Refer the Study to Full Board – The reviewer has determined that the study represents more than minimal risk and needs to be visited by the Board in a convened meeting.

However, an expedited reviewer cannot disapprove a research study. Disapprovals are voted on at a convened IRB meeting.

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9.1.4 Full Board Review

A full board review is required for any study that does not meet the criteria of an Exempt or Expedited category.

Research projects that require full review are reviewed by all IRB Members and the IRB Chair at a convened meeting with quorum for discussion and a vote. Typically, research projects that require a full review include projects that put human subjects at more than minimal risk or include vulnerable populations.

The Office of Research Compliance assigns projects to an experienced IRB Member, known as the Primary Reviewer or Designated Member, prior to the convened meeting. Primary Reviewers are experienced IRB members that conduct a comprehensive review of all submitted materials for the assigned study, presents findings resulting from the review, provide an assessment of the criteria for approval, and recommend specific actions to the IRB. The Primary Reviewer leads the discussion of the assigned study during the convened meeting.

The deadline for submission of a study for full board review is approximately 3 weeks prior to each board meeting. Exact dates are published on the UTRGV IRB website .

Investigators must submit a complete and accurate application to meet the submission deadlines for the convened meetings. Inability to understand the project details can significantly delay processing of applications; oftentimes these applications will not be reviewed by the board until a complete application is submitted. Delays may result from unusual circumstances or academic-calendar issues such as breaks or final exams. Although every effort is made to review complete applications submitted on time, if a board receives more applications than can be feasibly discussed at a meeting, applications will generally be discussed in the order in which they were received.

The IRB Chair has the option of requiring the Principal Investigator(s)' presence at the review during a convened meeting. Some examples of Full Board review studies are:

1. Studies that are judged to involve more than minimal risk, including those originally submitted for Expedited review that are deemed by the IRB to involve more than minimal risk;
2. All clinical trials including any federally funded project deemed a clinical trial by the sponsor;
3. Studies that involve sensitive topics or vulnerable populations (e.g., prisoners, mentally or developmentally impaired individuals, children, terminally ill individuals, pregnant women, and fetuses, etc.).

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9.2 IRB Determinations

IRB can make one of the following determinations:

1. Approved. – the research activity, as submitted, meets the criteria for approval as defined in 45 CFR 46.111 (and 21 CFR 56.111 and/or 32 CFR 219.111, when applicable).
    a. The date of approval is the date on which the IRB reaches an approval determination.
    b. The Principal Investigator is not permitted to begin research activities until he/she has received the written notification of IRB approval.
2. Approved with stipulations - to be reviewed by a designated IRB Member or the Board's designee depending on the level of changes (substantive vs. non-substantive). Such changes must be clearly delineated by the IRB so the investigator may simply concur with the IRB's stipulations. The research study may proceed after the required changes are verified and the study is approved by the designated reviewer.
3. Deferred – the convened IRB requires significant changes in the research or other action(s) to be taken by the Principal Investigator (PI). The IRB will include the rationale for its decision and give the PI an opportunity to respond. The PI's responses to the deferral require review by the convened IRB.
4. Disapproved. The IRB has determined that the research study cannot be approved by the UTRGV IRB. The IRB meeting minutes will include the basis for disapproving research and will be provided to the investigator.

The IRB meeting minutes will include all the actions taken by the convened IRB and the votes underlying those actions. These actions will be provided electronically through the routing system (Tick@Lab) to investigators.

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9.3 Appeals

Only the PI can appeal a determination by an IRB. Appeals should include new information that would alter the IRB's assessment of risk or benefit. The IRB will provide the Principal Investigator (PI) a notification via the electronic routing system (Tick@Lab) describing the reasons for disapproving or

requiring modifications in the proposed research and will give the PI an opportunity to respond (15 days).

If a response is received, the IRB will carefully and fairly evaluate the PI's response in reaching its final determination. There is no limit to the number of times a research project can be revised and resubmitted to the IRB for determination; however, it is recommended that researchers plan and present a well thought out study with careful attention to minimization of potential risks to subjects that is designed in such a way to maximize benefits prior to submitting any IRB application.

Submission to the IRB should not be considered as method to receive feedback on design issues or consultation on HSPs; if consultation is required this should be done *prior* to submission of an IRB application.

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Section 10. Modifications, Amendments, Minor & Major Changes, and Review Types

10.1 Modifications and Amendments

Once a research study has been approved by the IRB, no substantive changes can be made without prior approval. The only exception to this requirement is when a change is required to eliminate immediate hazards to human subjects, in which case the IRB must be notified of the modification and the rationale for implementing the modification without prior approval within 5 business days.

Federal regulations require IRB approval of any change made to any human subjects research projects, including those under Exempt categories. No changes may be implemented before an IRB approval, unless the change is intended to eliminate apparent and immediate hazard to subjects.

This includes adjustments, modifications, or corrections to the following areas:

1. Recruitment materials
2. Research procedures
3. Population or inclusion criteria
4. Measures
5. Compensation
6. Consent/assent forms
7. Research sites
8. Funding
9. Personnel

Modification/Amendment submissions must be submitted through the electronic routing system, Tick@Lab, and include the following documents:

1. Completed modification application;

2. Modified application reflecting all proposed changes (e.g., updates to personnel, changes in project information). The most recent application in the electronic system should reflect the study procedures that are being proposed. It is not sufficient to simply note the requested changes in the modification application alone if the proposed modification is in conflict with an element on the initial application;
3. Documents impacted by the proposed research modification (e.g., consent forms, site letters);
4. New or revised documents that support the proposed research modification;
5. Other supporting documents (e.g., revised protocol document, certifications of trainings completed outside of the CITI program).

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10.2 Minor and Major Changes

Minor changes may include but are not limited to:

1. Addition or deletion of study team members, with the exception of the PI or an investigator whose expertise was required for approval of the study;
2. Addition of procedures that do not increase risk;
3. Removal of procedures which would result in reduced risk or does not decrease potential benefits to subjects;
4. Addition of non-sensitive survey or interview questions;
5. Document changes that do not modify the intent of the content (e.g., typographical error corrections, improvements for clarity);
6. Addition of, or changes to, recruitment strategies.

Major Changes may include but are not limited to:

1. Major changes to study design;
2. New/increased risks or benefits;
3. Change in the use of drugs;
4. Change in PI or personnel;
5. New vulnerable populations (when research is more than minimal risk);
6. New more than minimal risk procedures;
7. New/revised procedures involving general anesthesia or sedation, radiation, x-rays or microwaves;
8. Reducing/changing safety monitoring procedures.

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10.3 Review Types

The amendment's review type (e.g., full board, expedited, administrative) depends on the nature and level of the change.

1. Major changes to a project previously approved by the full IRB require full board approval and are subject to IRB submission deadlines and committee meeting dates.
2. Major changes to a project previously approved using the expedited process can be reviewed by the IRB Chairs.
3. Minor changes (as defined above) may be reviewed via an expedited or administrative (i.e., ORC staff) process.

A designated reviewer may not render a decision of disapproval. Amendment disapprovals may only be decided by the IRB at a convened meeting.

Once the IRB approves an amendment, the information, study, and documentation in the amendment becomes the record of the approved study. The end date of the approval period will remain the same as assigned at the initial or continuing review unless the IRB specifically shortens the current approval period (requiring continuing review earlier) as part of the motion voted on by the Board.

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Section 11. Continuation Review

The purpose for continuing review is to ensure that that the studies continue to meet the criteria for approval. As such, CR must be substantive and meaningful and includes an analysis of whether there is new evidence available, either in the scientific literature of gathered during the course of the conduct of the study that alters the potential benefits of the research and/or the risks to subjects.

The frequency of continuing review for a human subjects study is determined at the time of the initial approval if a continuation review is required. The Tick@Lab system notifies an Investigator with a frequency of reminders at 90, 60, and 30 days before expiration of approval. Notifications are sent well in advance of the submission deadline to give the Investigator enough time to submit the required materials. If the required documentation is not submitted in a timely manner, it may result in a lapse between the IRB expiration date and the continuation review approval. If the IRB does not approve a study to continue, all study-related activities must stop immediately. The PI is responsible for keeping track of the expiration date and initiating the continuing review process in the system.

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11.1 Studies Under the Old Common Rule

This policy applies to studies with an initial IRB approval date prior to January 21, 2019.

Continuing review of research approved through the expedited process or at a convened meeting is required under the following conditions:

1. New subjects are being enrolled or subject records accessed (in the case of a records review).

2. The research remains open to long-term follow-up of subjects, even if the study is permanently closed to new enrollment and all subjects have completed research-related interventions

3. Remaining research activities are limited to the collection of private identifiable information.

For research approved through the expedited process or at a convened meeting the IRB will determine a data for CR appropriate to the specifics of the study but at an interval no greater than 12 months. Studies must undergo continuing review in accordance with the criteria for approval stated above and until all data analysis of identifiable private information is complete.

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11.2 Studies Under the Revised Common Rule

This policy applies to studies with an initial approval date after January 21, 2019.

Continuing review is not required for:

1. Research that is eligible for expedited review,
2. Exempt research conditioned on limited IRB review,
3. Research approved through full-board procedures that has completed all interventions and only includes analyzing data, even if the information or biospecimens are identifiable
4. Research that has completed all interventions and only includes accessing follow-up clinical data from standard care procedures

The IRB can override this default and still choose to require continuing review, provided that the IRB documents the decision and its rationale. 45 CFR 46.109(f), 46.110, and 46.115(a)(8)

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11.3 Documentation

The following documents are required for continuing review submissions:

1. Continuing review application (submitted via Tick@Lab)
2. Consent form (latest approved version)

IRB reviewers will have access to these documents and can be provided with supporting materials if requested.

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11.4 Post-Approval Monitoring

The UTRGV IRB determines which projects require verification from sources (e.g., sponsor) other than the investigators to confirm that material changes have not occurred since the previous IRB review. The IRB uses the criteria below to make these determinations:

1. Complex studies involving unusual levels or risk to subjects

2. Studies that are conducted by investigators who have failed to comply with IRB determinations or requirements in the past
3. Studies where changes occurred without IRB approval and concern has been raised

The IRB may conduct random reviews as part of a regular post-approval monitoring cycle, occurrence of non-compliance, unanticipated problems, complaints, or requests by an Investigator to review their human subjects processes.

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Section 12. The Office of Research Compliance Administrative Procedures and Determination of Level of Review

The ORC staff is responsible for the pre-review all new studies, continuing reviews, and amendment/modifications submitted in the electronic routing system (Tick@Lab). During the pre-review, the professional staff at ORC determines completeness and accuracy of information provided and may request revisions or additional details from the Primary Investigator to ensure that there is enough information to make a determination on the criteria for approval. The ORC staff also ensures that all regulatory policies are followed.

The timeline for an administrative review will vary depending upon the quality and completeness of the initial study, and in some cases, the availability of the Office of Research Compliance staff and IRB Members with appropriate expertise. For this reason, Principal Investigators are strongly encouraged to submit a complete application for full Board review well ahead of the board meeting at which they would like the study to be reviewed.

Submissions are reviewed for the following:

1. Completion of required training.
2. Completion of required reporting (i.e., Financial Conflicts of Interest in Research).
3. Completeness and consistency of information provided in the application and attachments.
4. Adherence to federal regulations and institutional policies.
    a. HHS Regulations 45 CFR 46
    b. FDA Regulations (Drug and Device Research) 21 CFR 50, 56, 312, & 812, where applicable
    c. HIPAA Regulations, where applicable.
    d. This handbook.
5. Risk assessment to determine level of review.

The ORC staff is responsible for completing reviews within 5-7 business days from the time of submission. The Principal Investigator will be contacted at this point only if there are any changes or additional information that needs to be submitted for an IRB member to be able to complete a review.

After any missing information is collected, a determination on the level of review will be made. Applications that meet the criteria of an Exempt study will be reviewed by the ORC staff. Applications that meet the criteria for expedited and full board review will be referred to a Primary Reviewer (Board Member) for approval or confirmation that a full board review is needed.

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12.1 Study Completions and Close Out

The Principal Investigator must notify the IRB if he/she wants to close a research study. If the study is funded, the PI must also notify the funding agency and the Office of Sponsored Programs.

A study closure (known as project closure in Tick@Lab) is needed to close out a study and must be submitted to the IRB. If a study approval lapses (expires) the PI is still required to submit a study closure report to the IRB.

The UTRGV ORC will review study closure notifications, and if needed, request additional information from the Principal Investigator if questions arise.

The ORC may close projects without the Principal Investigator's approval in the following situations:

1. It is determined that the PI is no longer affiliated with UTRGV and no other approved Investigators will assume the lead on the study.
2. IRB approval has been terminated. This would only occur after IRB review and communication with the PI.

If the study is funded, ORC will notify the Office of Sponsored Programs of such termination. Termination of IRB approval is reportable to the appropriate sponsors and Institutional Officials. The IRB will notify the Principal Investigator if his/her study is closed.

Once a study is closed, the study records must be stored in accordance with the UTRGV data storage and retention policy.

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Section 13. Complaints, Non-Compliance, Continuing Non-Compliance, Documentation, and Research Misconduct

13.1 Complaints

A subject complaint is an expression of dissatisfaction by the subject that may or may not involve a breach in human rights or research ethics. Subjects may choose to report complaints to the research team or to the IRB. It is important that during the consent process, subjects receive consent forms and information sheets that include the Principal Investigator's and IRB contact information so that subjects have resources to ask questions about the study and report complaints.

Research subjects who have questions, concerns, complaints, suggestions, or feel that they have been subjected to coercion or under influence regarding aspects of human research may contact the Office of Research Compliance:

Office of Research Compliance
Edinburg – (956) 665-2889
Brownsville – (956) 882-7743
researchcompliance@utrgv.edu

Subjects who have concerns or complaints about the research or research staff and do not want to give his/her name, may call toll free at 1-877-882-3999. This is a 24-hour hotline used to report allegations of fraud, theft, waste, non-compliance, and abuse at UTRGV. The hotline is operated by an outside company. Anyone can call (student, faculty, staff, patient, research subject or visitor) and callers do not have to identify themselves.

Once a subject complaint is received, the Office of Research Compliance will review the complaint to make sure it is within the scope of human subjects' research. Complaints outside this scope will be referred to the appropriate office (if any). Once ORC confirms the complaint is within the scope, it is forwarded to the IRB Chairs for further investigation. This process involves reviewing the study in which the subject is enrolled to ensure that the study has received and maintains active IRB approval and ensure compliance with pertinent federal and state regulations. It is the PIs responsibility to report subject complaints to the IRB during the continuation review process or earlier if the issue is more serious.

The ORC/IRB may contact the Principal Investigator and research staff for additional information to assist with the validation and/or dismissal of the complaint. Once all information is received, IRB will determine if any further action is necessary. A written correspondence will be provided to the subject and PI with the determination and justification for actions taken.

If it is determined that there is potential non-compliance, the Office of Research Compliance will initiate the process as outlined in the policy on handling allegations of non-compliance.

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13.2 Noncompliance and Continuing Non-Compliance

Non-compliance occurs when there is a failure to adhere to federal regulations, laws, or policies and procedures that are mandated by the IRB in order to protect human subjects. Instances of non-compliance may be disclosed by an investigator, a member of the research team, a study participant, members of the UTRGV community or the public through the IRB Protocol Deviation/Possible Noncompliance Report Form. Instances of non-compliance may be also be discovered by the ORC or the IRB through post-approval monitoring of the study.

A continuing non-compliance occurs when there is a persistent pattern indicating failure to comply. Ultimately, this pattern adversely affects research subjects and the integrity of the research project.

Examples of non-compliance and continuing noncompliance may include, but are not limited to the following:

1. Failure (or repeated failures) to provide or review progress reports resulting in lapses of IRB approval.
2. Inadequate oversight of ongoing research.
3. Failure to respond to or resolve previous allegations or findings of noncompliance.

Non-compliance and continuing non-compliance issues are handled by the Office of Research Compliance through the following process:

1. If discovered by the ORC/IRB, the ORC will examine the approved protocol, including the level of review it was approved under, to determine among other things, whether the event has the potential to increase the level of review (for example, from Exempt to Expedited) and will determine if an IRB Protocol Deviation/Possible Noncompliance Report Form is required.
2. If discovered by the ORC/IRB and further reporting applies, the ORC will provide the IRB Protocol Deviation/Possible Noncompliance Report Form to be completed by the Principal Investigator and submitted via email to irb@utrgv.edu.
3. Upon receipt of the IRB Protocol Deviation/Possible Noncompliance Report form, the ORC will conduct a review to ensure completeness of the information provided and will make a preliminary determination of the seriousness and nature of the event reported:
    a. Not serious and not continuing non-compliance
    b. Serious and/or continuing non-compliance
    c. Not non-compliance
4. If determined to be non-compliance or continuing non-compliance, the form will then be submitted in writing via email to the IRB Chair and Vice Chair of the appropriate panel for their review. The ORC will provide a brief description of the event reported, the ORC's determination, and any corrective actions recommended.
5. The IRB Chairs will conduct a review and provide a response with their findings and corrective actions.
6. A letter will be issued by the IRB to the Principal Investigator notifying the outcome and required corrective actions (if needed).

Corrective action(s) will be based on the nature of the non-compliance, the degree to which research participants were placed at risk, occurrence of previous noncompliance, etc. The range of possible corrective actions that the IRB may consider includes, but is not limited to the following:

1. Modification(s) of the research study or procedures.
2. Modification(s) of the consent process or consent form.
3. Providing additional information to current research participants (required when such information may relate to their willingness to continue in the research).
4. Providing additional information to past research participants.
5. Reconfirming consent of current research participants.

6. Requiring additional follow-up/monitoring for current and/or past research participants.
7. Monitoring of the research (including audits) or consent process.
8. Education or mentoring for the Principal Investigator (PI) and/or research staff.
9. Additional reporting, including modifications of the continuing review schedule.
10. Requiring additional resources to support the PI's research activities.
11. Placing limitations (e.g., restriction to co-investigator status) on the PI's research activities or use of research data.
12. Suspension of IRB approval for one or more of the PI's studies.
13. Termination of IRB approval for one or more of the PI's studies.

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13.3 Documentation

Records relating to review and investigation of non-compliance or continuing non-compliance will be retained by the Office of Research Compliance for a minimum of three years after completion of research or any corrective actions (whichever is longer) in keeping with federal regulations, applicable state and local laws, and university policy.

13.4 Research Misconduct Involving Human Subjects

Researchers conducting human subjects research at UTRGV are expected to comply with the provisions of the IRB Internal Policies and Procedures in addition to federal regulations, University policies, and state and local regulations. If the UTRGV Research Integrity Officer (RIO) receives an allegation of research misconduct involving a human subjects' research study, then those allegations will be investigated in accordance with HOP ADM 07-102, *Misconduct in Research and Scholarly Activities* to determine if there is a basis in fact or not. The procedures for investigations and outcomes are the following:

1. If an allegation is made, the RIO will be responsible for conducting an initial inquiry into the allegation to determine if the allegations are related to human subject's research. Inquiries into allegations of research misconduct will proceed promptly and with due regard for the reputation and rights of all the individuals involved.
2. The expertise of an IRB Chair or outside consultant may be called upon when conducting this initial inquiry.
3. If the inquiry reveals enough evidence/information to sustain the allegations in a case of human subjects' research, then an investigation is initiated to include the chair and vice chair or the appropriate IRB Panel. Investigations should be conducted and concluded within 60 days, unless there are special circumstances, in which case an extension of an (equivalent number of days) can be granted.
4. The investigation involves an extensive review of study records, interviews with research personnel, interviews with the complainant, and may include correspondence to the PI or to the appropriate university employees to obtain additional information.

5. Correspondence to the PI or the appropriate research personnel within the University will provide the PI an opportunity to respond to the allegations of suspected non-compliance.
6. If appropriate, the RIO and the IRB will, in cooperation with the PI, develop an initial corrective action plan to accompany the reports of the investigation results.

Upon completion of the investigation, a report will be provided to the IRB Chair or Vice Chair of the appropriate panel for review. The report will describe the allegation and outcome and include a recommended corrective action plan if appropriate. The report and the outcome will be forwarded to the IO.

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Section 14. Collaborative Research Agreements, Permissions, and Research Conducted at External Sites

14.1 Studies Initiated by UTRGV

UTRGV employed faculty, staff, students and residents conducting research at off-campus sites must submit IRB applications to the UTRGV IRB. Applications must include signed site letter approvals (see IRB Templates) from authorized officials to indicate support for conducting research at the site. Approval of research by the UTRGV IRB indicates adequate protection of human subjects only. Additional site approvals may be required by the external site to determine feasibility of conducting research at their site.

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14.2 Material and Data Transfer Agreements

Policy in Development.

14.3 Non-FWA Holding Sites

Policy in Development.

14.4 Multiple External Collaborative Partners

The UTRGV IRB has reciprocity agreements in place with many local, regional and state partners in which UTRGV acts as the IRB of record for multi-site studies initiated here, or likewise accepts IRB approvals from outside institutions for which we have agreements in place. Contact the Office of Research Compliance to discuss all certifications of approvals from external IRBs.

Section 15. Reliance Agreements, Transfer of IRB Oversight and Single IRB Review

15.1 Reliance Agreements

UTRGV may, at the discretion of the Office of Research Compliance, permit reliance on a non-UTRGV IRB. The UTGV IRB may also agree to serve as the reviewing IRB for multi-site projects in which UTRGV faculty, staff, or students are engaged. All instances of such reliance for non-Exempt research will be documented in a reliance agreement that describes the responsibilities of both the reviewing and the relying IRBs. Reliance agreements will be signed by the Institutional Official (IO) or his/her designee.

A reliance agreement is needed if a UTRGV Investigator is engaged in human subjects research at another institution and the intent is for the research to be reviewed and monitored by the IRB of that institution. A reliance agreement must be in place before any research personnel at UTRGV commences their participation.

A reliance agreement is not needed in cases in which a UTRGV researcher(s) is collaborating on a human subjects research project but is not considered to be engaged in research (e.g., the researcher's role is limited to the analysis of de-identified data) or contribution to presentations or manuscripts.

Reliance agreements, at a minimum, must document the following responsibilities:

1. Initial and continuing review of research.
2. Review of unanticipated problems involving risk to subjects or others.
3. Review of serious and/or continuing non-compliance.
4. Preparation, review, and submission of reports to federal agencies.
5. Conflict of interest review.
6. Post approval monitoring and access to research records.
7. Maintenance of IRB records.

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15.2 Reliance on a Non-UTRGV IRB

All research in which UTRGV faculty, staff, or students are engaged must be submitted to the Office of Research Compliance even if another IRB will be named as the reviewing IRB. The instructions for submitting to the Office of Research Compliance are located on the IRB website. The Office of Research Compliance will review the submission to ensure the study activities and documents adhere to UTRGV policies and procedures. The review includes:

1. Verification of the Principal Investigator's qualifications to conduct the study
2. Verification of completion of required trainings by research personnel
3. Completion of conflict of interest reviews
4. Verification of other compliance committee approvals, if needed
5. Inclusion of required informed consent language, as necessary

The Office of Research Compliance will evaluate requests to rely on a non-UTRGV IRB to assess whether comparable standards are upheld by the reviewing IRB. The evaluation may include the following depending on the risk of the proposed research:

1. Verifying accreditation
2. Determining that the reviewing IRB has engaged in quality self-evaluations
3. Verifying active FWA
4. Reviewing policies and procedures
5. Reviewing meeting minutes pertaining to the study

Reliance agreements will only be signed when the review conducted by the Office of Research Compliance is complete, and all other conditions are satisfied. The Office of Research Compliance will work with Investigators to prepare materials requested by reviewing IRBs. Principal Investigators are responsible for being aware of and adhering to the policies and procedures of the reviewing IRB.

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15.3 Transfer of IRB Oversight

An IRB transfer happens when a study that has been approved by another IRB is transferred to UTRGV. Transfers can happen if the Principal Investigator decides to change his/her primary affiliation for some reason, if a local IRB is closing, or if the study is at an institution that has recently signed a contract with UTRGV.

Transfers are accomplished in an orderly way that assures continuous IRB oversight with no lapse in either IRB approval or monitoring, and with minimal disruption of research activities.

To start the transfer of IRB oversight to UTRGV, the Principal Investigator must submit a new study application through the electronic routing system (Tick@Lab). The study will then go through the oversight transfer review and if approved, the PI will be given an approval letter to submit to the original IRB. The original IRB may then inactivate oversight of the study as of the date of UTRGV IRB of approval of the study. The ORC may deviate from this procedure if otherwise agreed upon in a contractual agreement.

If appropriate, when transferring IRB review and oversight of research projects from one IRB to another IRB, UTRGV follows the transfer process documented in a written agreement between the original and receiving IRBs. The agreement should address the following eight actions, as appropriate. Additional actions may be necessary, if applicable.

1. Identifying those studies for which IRB oversight is being transferred;
2. Ensuring the availability and retention of pertinent records;
3. Establishing an effective date for transfer of oversight, including records, for the research project(s);
4. Conducting a review of the study(ies) by the receiving IRB, where appropriate, before it accepts responsibility for the study(ies);

5. Confirming or establishing the date for the next continuing review;
6. Determining whether the consent form needs to be revised;
7. Notifying the key parties; and
8. Addressing IRB regulatory issues.

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15.4 Single IRB Review

Policy in Development.

Section 16. Health Insurance Policy and Accountability Act (HIPAA) Regulations

Under the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security and Privacy Rule, Investigators must meet certain requirements before using or disclosing Protected Health Information (PHI) for research.

HIPAA's Privacy Rule went into effect April 14, 2003. The law generally prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from using or disclosing PHI without written authorization from the research subject (HIPAA Authorization).

At UTRGV, the IRB serves as the Privacy Board and acts upon requests for a waiver or alteration of Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study. As the Privacy Board, the IRB may waive or alter all or part of the Authorization requirements for a specified research project or study. A covered entity may use and disclose PHI without an Authorization, or with an altered Authorization, if it receives the proper documentation of approval of such alteration or waiver from a Privacy Board.

The UTRGV, the IRB is charged with ensuring that all Investigators accessing protected health information are HIPAA compliant. In this capacity, the IRB will determine whether:

1. The subject must sign a UTRGV HIPAA Authorization Form, in addition to the Informed Consent Form from the covered entity, to obtain their authorization for research use or disclosure of PHI;
2. A Waiver of HIPAA Authorization, either for being a research subject and/or for screening/recruiting subjects will be granted.

Even if some research projects involving human subjects may meet the Exempt (from IRB review) category, they may still require HIPAA authorization or waiver.

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16.1 Protected Health Information

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. 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 HHS has adopted standards), it is likely to be protected health information. The HIPAA rule governs the use of individually identifiable health information when it is protected health information (PHI). HIPAA defined categories of PHI include:

1. Patient names;
2. Dates (except year) directly related to an individual (e.g., DOB, 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.

The IRB requires all Investigators who are part of the UTRGV or Affiliated Covered Entity (ACE) or collaborating with someone within UTRGV or ACE and who are using or disclosing protected health information (PHI) to obtain written permission (i.e., an authorization) from subjects for the use of PHI or obtain a waiver or alteration of authorization from the IRB.

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16.2 Required Elements for Authorization

1. A description of the information to be used or disclosed presented in a specific and meaningful fashion.;
2. The name or other specific identification of the person(s), or class of persons, to whom the use or disclosure will be made;
3. A description of each purpose of the requested use or disclosure;

4. An expiration date or event that relates to the individual or the purpose of the use or disclosure;
5. 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;
6. A statement indicating when the authorization for use and disclosure occurs; e.g., at the end of the research;
7. 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.

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16.3 Waiver of Authorization for Use and Disclosure of PHI

In order to use or disclose 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. This provision of the rule might be used for example, to conduct records research when Investigators are unable to use de-identified information; or
2. 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; or

3. 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.

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16.4 HIPAA Limited Data Set and User Agreement

Limited data sets are not fully de-identified data and must not include direct or facial identifiers like name, social security number, full-face photos, or medical record number.

Limited data sets 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 limited data set 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 limited data set recipient enter into a data use agreement.

This data use agreement is the means by which covered entities obtain satisfactory assurances that the recipient of the limited data set will only use or disclose the PHI in the data set for specified purposes.

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Section 17. FDA-Regulated Research

UTRGV requires its researchers and its IRB to comply with all applicable regulations of the Food and Drug Administration (FDA) when conducting research with drugs, devices, supplements, botanicals, or biologics (collectively referred to as “items”) that are regulated by the FDA. This includes the research use of items that have already received FDA approval as well as the research use of investigational items.

The FDA has its own definitions of “human subject” and “research” (called “clinical investigation” by the FDA), which the UTRGV IRB applies when it considers whether a proposed activity requires IRB review. Researchers who have the roles of both “investigator” and “sponsor”, as defined by the FDA, have additional FDA-specified responsibilities, which the UTRGV IRB expects them to fulfill. Additional guidance is included in the sections below.

For FDA information on the IND process, see their guidance here.

For FDA information on medical devices, see their guidance here.

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17.1 Criteria for Determination

Under FDA regulations, UTRGV becomes engaged in human subjects research when it undertakes a clinical investigation on individuals who are or become subjects in the investigation, either as recipients of a test article or as controls and may be either patients or healthy non-patients. Research that is regulated by the FDA must adhere to its regulations for the protection of human subjects and other relevant FDA regulations (e.g., 21 CFR 50, 54, 56, 312, 314, 812, and 814).

The UTRGV IRB is responsible for evaluating the use of a drug in research involving human subjects (DHHS) or a clinical investigation (FDA) to determine if prior submission to the FDA is required or if the use of the drug is exempt from such prior submission to the FDA. If prior submission is required, the IRB must determine whether an Investigational New Drug application (IND) has been obtained.

It is the policy of the UTRGV IRB that research involving a drug, other than the use of a marketed drug in the course of medical practice, must have an investigational new drug (IND) number provided by the FDA, unless the drug meets the FDA IND Exemption criteria listed in the procedure below. This policy does not apply to Emergency use and use under a Treatment IND as both are covered in the section 'Reporting of Emergency Use of an FDA-Regulated Test Article to the IRB' of this policy manual.

The IRB evaluates:

1. If the use of the drug is considered research and involves human subjects (DHHS – 45 CFR 46.101), and;
2. If the drug used is considered an investigational drug and involves human subjects (FDA – 21 CFR 56.102)

If the IRB determines neither of the above are true, the activity that includes a drug may still be reviewed. In this case, if the activity is not considered to be research (non-research) or research not involving human subjects under DHHS rules the activity is reviewed following guidance in the section, 4.1 Studies Subject to IRB Review (Exempt Research) of this policy manual.

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17.2 Clinical Investigations

If the activity is considered Exempt research (DHHS) not constituting a clinical investigation (FDA) then it is reviewed following guidance in the section, 4.1 Studies Subject to IRB Review, of this policy manual.

Clinical investigations are evaluated by the IRB to determine whether:

1. Submission to the FDA for an IND is required, and if required has been completed (as indicated by documentation provided by the sponsor) or;
2. The use of the drug is exempt from prior submission to the FDA.

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17.3 IND Exempt Categories

Research which meets one or more of the following Exemption categories does not require prior submission to the FDA for an IND.

Exemption 1 - the clinical investigation is for a drug product that is lawfully marketed in the U.S. and all the following apply:

1. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
2. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
3. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
4. The investigation will be conducted in compliance with 21 CFR 50 and 56.
5. The investigation will be conducted in compliance with the requirements of 21 CFR 312.7.

Exemption 2 – the clinical investigation is for an in vitro diagnostic biological product that involves one or more of the following:

1. Blood grouping serum, reagent red blood cells, and/or anti-human globulin; AND
2. The diagnostic test was intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure, AND
3. The diagnostic test will be shipped in compliance with 21 CFR 312.160.

Exemption 3 – the clinical investigation is for a drug intended solely for tests in vitro or in laboratory research animals if shipped in accordance with 21 CRF 312.160.

Exemption 4 – the clinical investigation involves the use of a placebo and the investigation does not otherwise require submission of an IND.

Exemption 5 – dietary supplements, botanicals, or other substances designated as generally recognized as safe (GRAS) for use in food if study does NOT evaluate product's ability to diagnose, cure, mitigate, treat or prevent disease (see FDA guidance for required conditions).

Exemption 6 – radioactive drug or biological product (see FDA guidance) if:

1. It involves basic research not intended for immediate therapeutic, diagnostic, or similar purposes, or otherwise to determine the safety and efficacy of the product,

2. The use in humans is approved by an Institutional Biosafety Committee (IBC) that is composed and approved by FDA,
3. The dose to be administered is known not to cause any clinically detectable pharmacological effect in humans, and
4. The total amount of radiation to be administered as part of the study is the smallest radiation dose practical to perform the study without jeopardizing the benefits of the study and is within specified limits.

When a clinical investigation (i.e., research study) is received involving a drug with an IND number the Office of Research Compliance documents a valid IND has been received as evidenced by:

1. A document from the sponsor indicating the IND number or;
2. A letter from the FDA indicating the IND number or;
3. Other IRB approved method of validation.

When a study involving an investigational drug is submitted to the IRB for review without an IND number:

1. The ORC staff pre-reviewer considers the justification for Exemption provided by the Principal Investigator in the Tick@Lab application. Based on this review, the ORC staff pre-reviewer determines whether an IND is needed or whether the use in the clinical investigation can be exempt from the IND requirements.
2. The IRB agrees with the justification for Exemption, then this decision is documented in the IRB files and the research is reviewed in accordance with Section IV of this policy manual. The IRB agreement with this determination is documented in the meeting minutes (see Section X).
3. If the ORC staff pre-reviewer determines that an IND is required and the IRB agrees with this determination, the ORC staff will communicate this decision to the Principal Investigator and approval will not be granted until an IND number is submitted to the IRB or the FDA determines that an IND is unneeded for the study.

If prior submission to the FDA is required but has not yet been received, the IRB may approve the study with stipulations under the condition that valid proof or receipt of an IND has been obtained prior to starting the study.

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17. 4 Documenting Risks

For research studies with an investigational device, the convened IRB must determine whether the use of the device involves “significant risk” or “non-significant risk”. The risk determination is specific to the use of the device in the proposed study. The researcher is responsible for providing the IRB with any information relevant to this determination, including:

1. A copy of the FDA’s determination (if one has been made).

2. Risk determination documents if other IRBs have reviewed the proposed study.
3. Correspondence from the sponsor and/or FDA supporting the determination that the proposed use of the device is Non-Significant risk (NSR) or the IDE approval letter or conditional approval letter from the FDA for Significant Risk Devices.
4. IDE number (for Significant Risk devices).
5. A description of the device.
6. Reports of prior investigations with the device.
7. The investigational plan/study/research project proposal.
8. A description of the subject selection criteria.
9. A description of the planned monitoring procedures.
10. Proposed consent form(s).
11. IDE Exemption criteria, if applicable.
12. Any other information that the IRB requires in order to conduct its review and make a determination.

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17.5 Requests for Expanded Access or Treatment

Expanded access, sometimes called "compassionate use," is the use of an investigational test article outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or a condition that has no comparable or satisfactory alternative treatment options.

The compassionate use provision allows access for patients who do not meet the requirements for inclusion in the clinical investigation but for whom the treating physician believes the test article may provide a benefit in treating and/or diagnosing their disease or condition.

Investigators can request approval for one of the following categories of expanded access:

1. Individual patient IND (investigational new drug application) – including emergency use IND (21 CFR 312.310) commonly held by treating physician or investigator for treatment of an individual patient.
2. Intermediate population treatment IND (21 CFR 312.315) commonly held by the sponsor (manufacturer) for use in a population smaller than a typical treatment IND or treatment study . The investigational drug for intermediate population treatment INDs may be in active development or may be an FDA approved drug that is unavailable or in limited supply.
3. Large population treatment IND or treatment study (21 CFR 312.320) commonly held by the sponsor for widespread treatment use. For a large population treatment INDs, the sponsor must be pursuing marketing approval.

Before submitting an Individual Patient IND to FDA, the PI must confirm the manufacturer will provide the drug. If a large or intermediate scale expanded access is available through the manufacturer, the PI

may coordinate access to the drug through the manufacturer's approved Treatment IND rather than filing a separate Individual Patient IND. FDA regulation require prospective review by the convened IRB.

FDA policy states that "the provision for emergency use would rarely apply to a treatment study or treatment IND because these are planned uses of the test article and sufficient time is available to obtain IRB review and approval." In rare cases in which emergency use does apply for individual patients, procedures will be taken according to federal regulations (21 CFR 56.104).

The FDA identifies special considerations when a patient is to be treated under expanded access:

1. Drug development – FDA stipulates that expanded access use should not compromise enrollment or interfere with active clinical investigations that could support approval of the drug.
2. Informed consent – the PI must ensure that potential subjects are fully aware of the risks involved because subjects may be ill and particularly vulnerable. Medications received have not been proven either safe or effective in a clinical setting.
3. Charging treatment for INDs – the FDA permits charging for the drug, agent, or biologic when used through expanded access when regulatory criteria are met. Charging for participation may preclude economically disadvantaged persons from receiving access to test articles. The IRB must balance this interest against the possibility that unless the sponsor can charge for the drug, it will not be available for treatment until it receives full FDA approval.
4. Regulatory responsibilities – per FDA regulations, a licensed physician administering investigational drugs for expanded access use is considered an investigator and assumes regulatory responsibilities. Individuals that submit an IND for expanded access are considered a sponsor-investigator and will assume the applicable responsibilities for sponsors and investigators. (21 CFR 312.305 (c)).

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17.6 Reporting of Emergency Use of an FDA-Regulated Test Article to the IRB

Situations may arise when a physician finds it is in the best interest of the patient who is in a life-threatening situation to administer an investigational product prior to receiving IRB approval. Such a use is deemed an emergency use.

In accordance with FDA regulations, the IRB may allow for the emergency use of an investigational drug or device if the situation meets the definition of Emergency Use (21 CFR 56.102 (d) and if the emergency use is reported to the IRB within 5 working days of the actual use of the drug or device. The Emergency Use criteria are:

1. The patient is in a life-threatening or severely debilitating situation,
2. No standard acceptable treatment is available and,
3. There is not enough time to obtain IRB approval.

The PI should make every effort to notify the IRB prior to an emergency use of an investigational drug device. Notification may occur by phone or email. Acknowledgement of receipt of the notification is not necessary prior to proceeding with the emergency use procedure. Regardless of whether a pre-notification has occurred, the PI must submit a report of the use to the IRB within 5 working days of the use. The use report will be reviewed and acknowledged by the IRB Chair.

Emergency use of unapproved drugs or biologics is research according to FDA regulations. As such, the emergency use of a test article, other than a medical device, is considered a clinical investigation by the FDA, and the patient is considered a research subject. If the research involves an investigational drug, the FDA must issue an Investigational New Drug Application (IND) prior to the use. The FDA may require data from an emergency use to be reported in a marketing application.

Conversely, DHHS regulations do not permit data obtained by patients to be classified as human subjects research, nor permit the outcome of such care to be included in any report or a research activity subject to DHHS regulations.

21 CFR 50 and 21 CFR 50.27 from the subject or the subject's legally authorized representative is expected, unless before the use of the test article, both the Principal Investigator (PI) and a physician who is not otherwise participating in the clinical investigation certify in writing that:

1. The patient is confronted by a life-threatening situation necessitating the use of the test article.
2. Informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.
3. Time is not enough to obtain consent from the patient's legal representative.
4. There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

The above written certification must be submitted to the IRB within 5 working days after the use of the test article. If time is not enough to obtain the independent determination in advance of using the test article, the use must be reviewed, and the above criteria evaluated in writing by a physician who is not participating in the clinical investigation.

Any subsequent use of the test article at UTRGV requires prior IRB approval. However, the FDA and the IRB acknowledge that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had enough time to convene to review the proposed one. In instances when the IRB has received more than one request for emergency treatment (multiple request from the same researcher or isolated requests from more than one researcher), the IRB will review the request but will ask the researcher to submit a study for review by the convened IRB for subsequent use. In instances where a second researcher requests approval for an identical use, the IRB will suggest that he/she collaborate with the PI who made the initial request.

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Section 18. Policies Regarding Reportable Events

Federal regulations require prompt reporting to appropriate institutional officials or agency head when any unanticipated problems involving risk to human subjects occurs. In addition, federal regulations mandate reporting any instance of serious or continuing noncompliance with the applicable officials [45 CRF 46.103 (a) , 21 CFR 56.108 (b)] *

18.1 Unanticipated Problems

Unanticipated problems involving risks to subject or others, in other words events that meet the three criteria in the definition presented below, always need to be reported to the IRB

An unanticipated problem involving risk to subjects or others is any incident, experience, or outcome that meets all the following criteria:

1. The event is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the study -related documents, such as the IRB-approved research study and informed consent document; and (b) the characteristics of the subject population being studied;
2. The event is related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. The event suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

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18.2 Adverse Events

An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporarily associated with the subject's participation in research.

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

Most adverse events occurring in the context of research are expected considering (1) the known toxicities and side effects of the research procedures; (2) the expected natural progression of subjects' underlying diseases, disorders, and conditions; and (3) subjects' predisposing risk factor profiles for the adverse events. Thus, most individual adverse events do not meet the first criterion for an unanticipated problem and do not need to be reported under the HHS regulations 45 CFR part 46.103 (b)(5)

OHRP defines serious adverse event as any adverse event that:

1. Results in death;
2. Is life threatening (places the subject at immediate risk of death from the event as it occurred);
3. Results in inpatient hospitalization or prolongation of existing hospitalization;
4. Results in persistent or significant disability/incapacity;
5. Results in congenital anomaly/birth defect; or
6. Based upon appropriate medical judgement, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Serious adverse events must always be reported!

The PI also must ensure that the adverse event is reported to a monitoring entity (e.g., the research sponsor, a coordinating or statistical center, an independent medical monitor, or a Data Safety Monitoring Board (DSMB) if required under the monitoring provisions described in the IRB-approved study or by the sponsor.

Additionally, if an Investigator determines that an adverse event is not an unanticipated problem but is later notified by a monitoring entity that they have determined the event to be an unanticipated problem, the investigator must report the event to the IRB.

Reporting Reportable Events to the IRB and Possible Outcomes

If the Principal Investigator determines that the incident, experience, or outcome represents an unanticipated problem, the Investigator must report it promptly to the IRB. The PI can designate someone on the research team to report reportable events, but the PI always retains the responsibility for making sure reports are made and are timely. Events not meeting the definition of a serious adverse event must be reported within 5 business days. Events meeting the definition of a serious adverse event must be reported within 24 hours. All reports should be made to the IRB Chair and Vice-Chair, by emailing the Unanticipated Problem/Adverse Event Reporting Form located on the IRB website to the Office of Research Compliance.

When the IRB Chairs and Vice-Chairs of the relevant Board receive a report, they have the option of reviewing the report or bringing it to a convened meeting. This determination will be made based on required expertise of review and whether the events suggest that immediate action is required.

The first step in any review will be to determine whether the incident meets the criteria for a reportable event. When reviewing an incident, experience, or outcome reported as an unanticipated problem by the investigator, the reviewing body (the IRB Chairs or the Full Board) may determine that the incident, experience, or outcome does not meet all three criteria for an unanticipated problem. In such cases, the case will be closed, and the investigators will be notified.

If the incident meets the criteria for a reportable event, the reviewing body will then determine whether the affected study still satisfies the requirements for IRB approval under 45 CFR 46.111. The reviewing body will consider whether risks to subjects are still minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result. Based on this assessment, the IRB may require action ranging from continued monitoring by the investigatory team up to and including termination of all study procedures. Examples of actions that will be considered are:

1. Suspension or termination of the research;
2. Requiring notification and reconsenting of current participants, when such information might be related to their willingness to continue to take part in the study;
3. Requiring modifications to the study and/or consent documents;
4. Increase in frequency of continuing review;
5. Imposition of additional monitoring requirements;
6. Requiring additional training of some or all members of the research team.

All determinations and any/all requirements for continuing the research will be reported to the Primary Investigator in writing.

All incidents, experiences, or outcomes determined to be unanticipated problems involving risk to subjects or others will be reported to the IRB Administrative Director within 1 month. The Office of Research Compliance is responsible for the reporting of events, incidents, or outcomes to OHRP and, if applicable, the supporting HHS agency head (or designee). For multicenter trials, only events occurring at the UTRGV site will be reported by the Office of Research Compliance and only if a central monitoring agency has not been designated for this purpose.

Originally approved: November 2019 Last Rev. (N/A)

18.3 Documenting Reportable Events

Records and documents relating to adverse events and unanticipated problems will be retained by the Office of Research Compliance for a minimum of three years after completion of research or any corrective actions (whichever is longer) in keeping with federal regulations, applicable state and local laws, and university policy.

Section 19. Suspension, Termination, and Reinstatement

A noncompliance can result in a suspension or termination. An IRB can suspend or terminate approval of a research project that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to human subjects

Any suspension or termination of IRB approval shall include a statement of the reasons for the IRB's action and shall be reported within 48 hours of the suspension or termination to the PI. Any suspension

or termination of IRB approval will be reported to appropriate institutional and governmental officials in accordance to federal regulations.

19.1 Qualifications for Suspension or Termination

The IRB may suspend or terminate a study if it finds:

1. Inappropriate involvement of human subjects in research;
2. Violation of the rights or welfare of human subjects or others;
3. Serious or continuing non-compliance with Federal regulations, IRB policies or institutional policies; or
4. New information regarding increased risk to human subjects or others.

Originally approved: November 2019 Last Rev. (N/A)

19.2 Notification to Principal Investigators and Research Personnel

The Office of Research Compliance (ORC) will prepare a notification letter. In this letter, the IRB may request information on the status of existing subjects, how the existing subjects will be notified of the suspension, and what impact the suspension or termination will have on the care or participation of the existing subjects.

Once an Investigator receives a written notice about a suspension or termination, they must immediately:

1. Cease research activities as specified in the IRB suspension notification until notified that the IRB has granted approval for resumption of the research activities, or in the case of termination, cease all activities;
2. Notify subjects of the suspension or termination as directed by the IRB;
3. Report to the IRB any adverse event or unanticipated problems involving risk to subjects or others that occur while the research activities are suspended;
4. Comply with all corrective action(s) as directed by the IRB;
5. Consider actions to protect the rights and welfare of study subjects, for example, arranging for medical care outside of the study or transferring subjects to another study.

Originally approved: November 2019 Last Rev. (N/A)

19.3 Consideration of Subjects in Case of Suspension or Termination

In the event that the suspension or termination of the study would result in harm to the subjects, the IRB will work with the PI to devise other methods to protect the welfare of subjects such as:

1. Requiring the PI to submit a corrective plan.
2. Requiring the PI to submit proposed procedures for withdrawing currently enrolled subjects that takes into consideration their rights and welfare. The IRB will review the proposed procedures

and may mandate oversight or transfer responsibility to another PI to ensure implementation of these procedures.
3. Requiring the PI to submit to the IRB a proposed script or letter notifying all currently enrolled participants that are affected by the suspension or termination.

Originally approved: November 2019 Last Rev. (N/A)

19.4 Reinstatement

To reinstate IRB approval for a suspended research study, the PI must submit a written request to the IRB. The reinstatement request will be reviewed at a convened meeting. The possible actions that the IRB may take include, but are not limited to:

1. Reinstate approval;
2. Reinstate approval with stipulations or additional restrictions; or
3. Continue suspension.

Originally approved: November 2019 Last Rev. (N/A)

Section 20. Department of Defense (DoD) Regulations

Human subjects research supported by the Department of Defense (DoD) must comply with additional requirements established by DoD in order to be approved the UTRGV IRB.

Research supported by the Department of Defense includes:

1. Research that is funded by a DoD component, including when UTRGV is the recipient of a subaward from the direct recipient of DoD funds;
2. Research that involves cooperation, collaboration or other type of agreement with a DoD component;
3. Research that uses property, facilities, or assets of a DoD component;
4. Research subject population that includes personnel (military and/or civilian) from a DoD component. DoD requirements do not apply when DoD personnel incidentally participate as research subjects where they are not the intended research population or where the project is not otherwise DoD supported.

The Office of Research Compliance will notify Investigators of relevant DoD regulations, if applicable.

When following DoD regulations, the definition of minimal risk based on the phrase, “ordinarily encountered in daily life during the performance of routine physical or physiological examination or tests” shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

As a practice, UTRGV does not currently conduct non-Exempt, classified, human subjects research. In case of a change in practice, UTRGV will follow the requirements of DoD Directive 3216.02 when conducting such research.

Originally approved: November 2019 Last Rev. (N/A)

20.1 Additional Protections for Vulnerable Subjects

Research involving pregnant women, prisoners, and children are subject to 45 CFR 46, Subparts B, C, and D.

1. For the purposes of Subpart B, the phrase "biomedical knowledge" shall be replaced with "generalizable knowledge".
2. The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.
3. Fetal research must comply with US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
4. Research involving prisoners cannot be reviewed by the expedited procedure.
5. IRB review of research involving prisoners requires at least one prisoner representative to be present for quorum.
6. If consent is obtained from experimental subjects' legal representative, the research must intend to benefit the individual subject. The determination that the research is intended to be beneficial to the individual experimental subject must be made by the IRB.
7. In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:
    a. The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
    b. The research presents no more than minimal risk.
8. If a participant becomes a prisoner and if the researcher asserts to the IRB that is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-participant may continue to participate until the convened IRB can review the request to approve a change in the research study and until the organizational official and DoD Component office review the IRB's approval to change the research study. Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the study. The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, shall promptly re-review the research study to ensure that the rights and well-being of the human participant, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert, having the expertise of a prisoner representative if the IRB reviewing the research study does not have a prisoner representative. The convened IRB may approve the prisoner-participant to continue when it is determined that:

a. The prisoner-participant can continue to consent to participate and is capable of meeting the research study requirements.
b. The terms of the prisoner-participant's confinement do not inhibit the ethical conduct of the research and;
c. There are no significant issues preventing the research involving human participants from continuing as approved.
d. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants.

9. Research involving any person captured, detained, held or otherwise under the control of DoD personnel (military and civilian, or contractor employee) is prohibited.

    a. This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.

10. Research involving prisoners of war is prohibited. In order to make this determination, the IRB must be made aware of the definition of "prisoner of war" applicable to the specific DoD component granting the addendum.

Originally approved: November 2019 Last Rev. (N/A)

20.2 International Research

Investigators have additional responsibilities while conducting research that involves subjects in international settings:

1. Investigators must obtain permission to conduct research in that country by certification or a local ethics review.
2. Investigators must follow all local laws, regulations, customs, and practices.
3. Originally approved: November 2019 Last Rev. (N/A)

Originally approved: November 2019 Last Rev. (N/A)

20.3 Consent by a Legally Authorized Representative

If consent is to be obtained from the experimental subject's legal representative, the research must intend to benefit the individual participant. The determination that research is intended to be beneficial to the individual experimental subject must be made by the IRB.

Originally approved: November 2019 Last Rev. (N/A)

20.4 Scientific Review

The Department of Defense requires scientific review prior to IRB review for all new, non-Exempt DoD supported human research and subsequent substantive amendments. The requirement may be met by

scientific review by an ad hoc departmental committee or scientific review conducted by appropriately qualified IRB as part of the IRB review process.

When research is limited to the review of medical records or existing data sets, the DoD review of the study will be accepted as the scientific review.

Originally approved: November 2019 Last Rev. (N/A)

20.5 Education Requirements

The Department of Defense requires that all individuals involved in the "design, conduct, or approval of human subjects research" complete human subjects research training. UTRGV's requirements for mandatory and continuing education meet the requirements. The DoD component may evaluate UTRGV's education policies to ensure the research personnel are qualified to perform the research, based on the complexity and risk of the research.

The Office of Research Compliance staff will ensure that training requirements for research team members are current at the time of review of studies funded by the DoD.

Originally approved: November 2019 Last Rev. (N/A)

20.6 Research Monitor Required: More than Minimal Risk Studies

For DoD funded research involving greater than minimal risk to subjects, appointment of an independent research monitor is required, although the IRB or Institutional Official can require this for a portion of the research or studies involving no more than minimal risk, if appropriate. The following are additional IRB considerations:

1. The monitor will be appointed by name and shall be independent of the team conducting research.
2. There may be more than one research monitor if different skills or experience are needed.
3. The monitor may be an ombudsman or a member of the data and safety monitoring board.
4. The IRB must approve a written summary of the monitors' duties, authorities and responsibilities and the IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities and responsibilities.
5. The duties of the research monitor are determined on the basis of specific risks or concerns about the research such as:

    a. Perform oversight functions such as observing recruitment and enrollment procedures, observing the consent process, observing study interventions and interactions, reviewing monitoring plans and reports of unanticipated problems involving risks to participants or others, reviewing aspects of data matching, collection and analysis.
    b. Discuss the research study with researchers, interview participants and consult with others outside the study.
    c. Report observations and findings to the IRB or other designated official.

The research monitor has the authority to:

1. Stop a research study in progress.
2. Remove individuals from the study.
3. Take any steps to protect the safety and well-being of subjects until the IRB can assess the research monitor's report.

The Investigator may identify a candidate for the position of research monitor, taking into account the nature and disciplinary focus of the study and the likely type of expertise required. The IRB will consider the nomination along with ensuring the that the research monitor has the appropriate experience and expertise and is independent of the research team. The monitor should be named in the research study application and the informed consent document in the Privacy and Confidential section (the monitor will have access to individually identifiable data) in the electronic routing system, Tick@Lab.

Originally approved: November 2019 Last Rev. (N/A)

20.7 Waiver of Consent and Exemption from Informed Consent in Emergency Medicine

If a subject meets the definition of "experimental subject", (An activity, for research purposes where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.), DoD regulations prohibit a waiver of consent unless the Investigator obtains a waiver from the Assistant Secretary of Defense for Research and Engineering. The Assistant Secretary of Defense for Research and Engineering may waive the requirements for obtaining informed consent when all of the following are met:

1. The research is necessary to advance the development of a medical product for the military services;
2. The research might directly benefit the individual experimental subject;
3. The research is conducted in compliance with all other applicable laws and regulations.

The IRB may waive the consent process if the research does not meet the definition of "experimental subject." DoD regulations prohibit an exception from informed consent in emergency medicine research unless the Investigator obtains a waiver from the Assistant Secretary of Defense for Research and Engineering.

Originally approved: November 2019 Last Rev. (N/A)

20.8 Collaborative or Multi-Site Research Requirements

Any Investigator developing a proposal for DoD funding or other support that involves collaborating institutions needs to consult the sponsoring DoD component to identify additional requirements for multi-site research. When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party.

Originally approved: November 2019 Last Rev. (N/A)

20.9 Research Related Injuries

Investigators are responsible for informing the IRB if there are any additional requirements from the DoD Component regarding the provision of care in the case of a research-related injury. If the DoD Component has stricter requirements that the Common Rule or UTRGV's policies, the verbiage will need to be discussed with UTRGV's Legal Affairs Office and the Executive Director of Research Compliance and Export Controls. These requirements will also need to be disclosed in the informed consent document.

Originally approved: November 2019 Last Rev. (N/A)

20.10 US Military Personnel as Research Subjects

If any research includes U.S. military personnel as subjects:

1. Officers are not permitted to influence the decision of their subordinates;
2. Officers and non-commissioned officers may not be present at the time of recruitment;
3. Officers and senior non-commissioned officers have a separate opportunity to participate;
4. When recruitment involves a percentage of a unit, an independent ombudsman must be present;
5. Federal employees while on duty and non-federal persons may be compensated for blood draws for research up to $50 for each blood collection;
6. Unless military personnel who are research subjects are on leave status during their participation, they may not receive compensation for their participation;
7. Non-federal personnel may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

The study must include a plan for subject recruitment that incorporates additional safeguards to minimize undue influence from individuals within a potential subject's chain of command. The Investigator is required to consult with the sponsoring DoD component to determine appropriate recruitment plans.

Originally approved: November 2019 Last Rev. (N/A)

20.11 Additional DoD Review Prior to Initiation of Study

After the IRB completes its review and issues approval, the Investigator will need to submit documentation of IRB approval, the risk level, and the expiration date of the research to the DoD component funding or otherwise supporting the study. The DoD may also request additional documentation to verify compliance with federal and DoD policies, including minutes related to the research.

Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research study is reviewed and approved by the IRB.

Investigators may not initiate the study until the human research protection officer within the sponsoring DoD Component reviews and approves the study.

Originally approved: November 2019 Last Rev. (N/A)

20.12 Reporting Requirements

The Investigator is responsible for promptly reporting to the DoD-specific component's human research protection official or office (30 days or less):

1. When significant changes to the research are approved by the IRB
2. Results of continuing IRB review
3. Change(s) in reviewing IRB

The Office of Research Compliance is responsible for promptly reporting to the DoD-specific component's human research protection official or office (30 days or less):

1. Notification by any federal department, agency, or national organization that may be part of the HRPP that is under a "for-cause" investigation involving DoD-supported research
2. Serious and/or continuing noncompliance
3. Any unanticipated problem involving risks to subjects or others for DoD-supported research
4. Any suspension or termination of DoD-supported research

Originally approved: November 2019 Last Rev. (N/A)

20.13 Access to Records

Study records documenting compliance (or non-compliance) with DoD regulations will be made accessible for inspection and copying by DoD representatives at reasonable times and in a reasonable manner.

Originally approved: November 2019 Last Rev. (N/A)

Section 21. Appendices

21.1 Appendix A: UTRGV Federalwide Assurance

Submission#: 339219 OMB No. 0990-0278

FWA#: FWA00000805 Approved for use through July 31, 2020

Name#: The University of Texas Rio Grande Valley

Federalwide Assurance (FWA)
for the Protection of Human Subjects

Update or Renewal for FWA Number: FWA00000805

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 all components 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 components listed below.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)	Status

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

The Belmont Report

4. Applicability

(a) 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.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance

5. Assurance of Compliance with the Terms of the Federalwide Assurance

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

6. Designation of 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. This institution (a) designates the following internal IRB(s) for review of research under this Assurance; or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

HHS IRB Registration Number	Name of IRB as Registered with HHS	External to the Institution?
IRB00000076	U of Texas at Dallas (The) IRB #1	E
IRB00000121	U of Texas M.D. Anderson Cancer Ctr IRB #1 - Clinical	E
IRB00000130	U Texas Austin IRB #1	E
IRB00000232	U of Texas Med Branch at Galveston IRB #1	E
IRB00000308	U of Texas Hlth Science Ctr at Houston IRB #1	E
IRB00000311	U of Texas at El Paso IRB #1	E
IRB00000553	U of Texas Hlth Sciences Ctr at San Antonio IRB #1	E
IRB00000627	U Texas Hlth Ctr @Tyler IRB #1	E
IRB00000672	U of Nebraska-Lincoln IRB #1	E
IRB00000757	U of Texas Med Branch at Galveston IRB #2	E
IRB00000974	U of Texas Southwestern Med Ctr at Dallas IRB #1	E
IRB00000975	U of Texas Southwestern Med Ctr at Dallas IRB #2	E
IRB00000976	U of Texas Southwestern Med Ctr at Dallas IRB #3	E
IRB00002203	U of Texas M.D. Anderson Cancer Ctr IRB #2 - Clinical	E
IRB00002691	U of Texas Hlth Sciences Ctr at San Antonio IRB #2	E
IRB00002692	U of Texas Hlth Sciences Ctr at San Antonio IRB #3	E
IRB00002921	UTexas Hlth Ctr @ Tyler IRB #2	E
IRB00003048	U Texas San Antonio IRB #1	E

IRB00003142	U of Texas Southwestern Med Ctr at Dallas IRB #4	E
IRB00003763	U of Texas Hlth Science Ctr at Houston IRB #2	E
IRB00003869	U of Texas M.D. Anderson Cancer Ctr IRB #3 - Executive Session	E
IRB00004604	U of Texas Hlth Science Ctr at Houston IRB #3	E
IRB00005015	U of Texas M.D. Anderson Cancer Ctr IRB #4 - Psychosocial/Behavioral	E
IRB00005292	U of Texas at Tyler (The) IRB #1	E
IRB00005768	U of Texas at Arlington IRB #2 - UTA	E
IRB00006023	U of Texas M.D. Anderson Cancer Ctr IRB #5 - Clinical	E
IRB00010253	The University of Texas Rio Grande Valley IRB #3	I
IRB00010709	Doctors Hospital at Renaissance IRB #1	E
IRB00011868	The University of Texas Rio Grande Valley IRB #2	I

7. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Glorimar Middle Initial: Last Name: Colon

Degrees or Suffix: J.D. Institutional Title: Interim Director of Research Compliance

Institution: The University of Texas Rio Grande Valley

Telephone: 956 665-3008 FAX: 000 000-0000 E-Mail: glorimar.colon@utrgv.edu

Address: 1201 W University Drive, ELIBR 1.120F

City: Edinburg State/Province: TX Country: USA

8. 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 subject 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. The IRB(s) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

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: Parwinder S Grewal Ph.D.

Date: 01/17/2019

First Name: Parwinder Middle Initial: S Last Name: Grewal

Degrees or Suffix: Ph.D. Institutional Title: EVP for Research, Graduate Studies and New Program Development

Institution: The University of Texas Rio Grande Valley

Telephone: 956-665-3883 FAX: 000-000-0000 E-Mail: parwinder.grewal@utrgv.edu

Address: 1201 West University Drive, SSBL 5.101

City: Edinburg State/Province: TX Country: USA

9. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number: Expiration Date:

HHS Approving Official: Date:

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 30 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.

21.2 Appendix B: IRB Meeting Minutes Template

INSTITUTIONAL REVIEW BOARD
PANEL [#] – [NAME OF THE PANEL]
Meeting Minutes
[Meeting Date]

ATTENDANCE

Voting Members Present:

	IRB Position	*Area or Department*
[Name]	*[Chair, Vice-Chair, Scientist, Non-Scientist, Non-Affiliated Community Member]*	*[Academic/administrative department or Community Member]*

Voting Members Absent:
(Without Representation)

	IRB Position	*Area 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 or Department*
[Name]	Ex-Officio, [Scientist or Non-Scientist]	*[Academic/administrative department or Community Member]*

Ex-Officio Non-Voting Members Absent:

	IRB Position	*Area 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.

QUORUM

The quorum requirement for this meeting was [#] voting members (more than 50% of the [#] total voting members). Upon quorum being assembled and at least one non-scientist member being present, the meeting was called to order by the [Chair/Vice Chair] at [Time]. 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. [Add the following when FDA-regulated studies are included: At least one physician was present for FDA-regulated studies.]

WELCOME [AND INTRODUCTIONS]

The [Chair/Vice Chair] welcomed the Board Members. [Optional: The group then introduced themselves to the new members and Research Compliance staff in attendance.]

STATEMENT OF CONFIDENTIALITY

The [Chair/Vice Chair] reminded Board Members to hold in confidence the information revealed and/or discussed during the meeting and not disclose the information to any third parties including investigators and research personnel. 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; however, Members should not disclose to investigators study-related deliberations and discussions of the Board in convened meetings.

REVIEW AND APPROVAL OF PREVIOUS IRB MEETING MINUTES

[Indicate whether the IRB met on previous month(s).]

1. Review of meeting minutes dated **[insert date]**.

    a. The Board noted the following correction(s): [describe. NOTE: If no corrections were noted remove the statement].
    b. A motion was made and seconded to approve the minutes [as drafted or with noted corrections].
    c. All were in favor of approval.
    d. [Name of voting member not present at current meeting] was not present, and therefore did not vote. [Name of person not present at the meeting which minutes are

voted on] was not present during the [date of the meeting] meeting and abstained from voting.

e. Total Voting = [#]; Vote: For = [#], Against = [#], Abstained = [3]

REPORTS TO THE IRB:

1. Approvals Report for the month of [name of the 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.]

UPDATES AND ANNOUNCEMENTS:

1. [Describe any updates and announcements made].

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.]

OLD BUSINESS

None. [Or in the alternative, list the studies using the format under New Business]

NEW BUSINESS

1. **IRB# [Insert Number]**
   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]
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 has 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 are 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 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).

OPTION #2 DISAPPROVALS:

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]

Adjournment

The meeting was adjourned at ____.

----APPROVAL OF MINUTES ----

These minutes were approved by the IRB on _____.

21.3 Appendix C: Interim Policies during Emergency Situations or Unforeseen Events

21.3.1 Actions for Human Subject Research during COVID-19 Outbreak

URGENT: Actions for Human Subject Research during COVID-19 Outbreak

Saturday, March 21, 2020: Office of the Executive Vice President for Research, Graduate Studies, & New Program Development

Notice to Researchers

Today, President Bailey and I are issuing an interim policy to temporarily pause all research procedures with human participants involving in-person interactions/interventions under Institutional Review Board (IRB) oversight, with limited exceptions. These restrictions are expected to last until April 15, 2020 and at that time, UTRGV will reevaluate this decision on an ongoing basis, while sharing additional updates or modifications as more information becomes available.

1. Except as noted on number 3 below, any research procedures that involve in-person interactions/interventions with participants must be immediately paused. Research procedures involving no direct in-person interaction/intervention with participants may continue (e.g. data analysis, online surveys, telephone interviews). This applies to both exempt and non-exempt research studies.
2. During this pause, Investigators should consider whether it is feasible to modify their in-person research procedures to use alternative methods for data gathering (e.g. telephone, online, Zoom, Skype, or other means). If alternative methods to in-person participation are feasible and desired, Investigators should submit a modification/amendment to the study and secure IRB approval prior to the implementation of changes. Keep in mind that it is possible for the Office of Research Compliance and the IRB to experience a high volume of requests during this time.

   If the study cannot be conducted without the in-person participant interaction/intervention, then new participant enrollment and any ongoing in-person participant interactions/interventions must be immediately paused.

   An investigator may implement changes to approved research prior to obtaining IRB approval if such changes are necessary to eliminate apparent immediate hazards to the participants as provided for in federal regulations (45 CFR 46.108(a)(3)(iii) under the 2018 Rule and 45 CFR 46.103(b)(4)(iii) under the pre-2018 Rule). In such cases, the Principal Investigator must promptly notify the IRB via the IRB Protocol Deviation/Possible Non-Compliance Report Form and submit the corresponding modification/amendment via Tick@Lab as soon as it is feasible.

3. Exception to the in-person interaction/intervention pause:
    1. Projects in which a pause of the in-person interaction/intervention will have the potential for direct harm to participants. These studies may continue subject to the following: any in-person participant interactions/interventions must be minimized and alternatives for in-person data collection should be considered if feasible. Investigators should consider their

ability to continue with the research based on current and future staffing resources, facility restrictions, and any other factors specific to the study. Investigators should also consider the rapidly evolving environment and plan for research continuity, such as planning for facility restrictions or closures, illness or absence of research team, drug or device shortage, or lack of required personal protective equipment. New participants should not be enrolled without prior permission from the IRB.

2. Projects actively studying influenza and COVID-19 in collaboration with the CDC or the NIH.
3. Projects where the in-person interaction/intervention with participants is conducted by international partners or by UTRGV researchers in another country in compliance with governmental and UTRGV's COVID-19 restrictions. Investigators must consult with the country's local IRB/ethics board regarding the continuation of the research. If the local IRB determines that it is safe for the work to continue, then the project may proceed. Principal Investigators must provide documentation of this determination to the UTRGV IRB via irb@utrgv.edu prior to the continuation of the research. Modified procedures to eliminate or minimize the need for in-person contact are recommended and the investigator must continue to monitor the changing COVID-19 situation.
4. Investigators and their research personnel should work with their study sponsors and others to evaluate impacted studies and develop a plan appropriate to their research procedures, including financial considerations. For questions on how to contact a study sponsor and other considerations related to sponsored projects, please email the Office of Sponsored Programs.

A list of Frequently Asked Questions (FAQs) [is] posted on the IRB webpage. If there are other questions or you need assistance, please email the Office of Research Compliance.

Thank you for your continued support and assistance in protecting human subjects research and research personnel.

Parwinder S. Grewal, Ph.D.
Executive Vice President
Research, Graduate Studied, and New Program Development

Extended: Actions for Human Subject Research during COVID-19 Outbreak

Thursday, April 16, 2020: Office of the Executive Vice President for Research, Graduate Studies, & New Program Development

Notice to Researchers

The University of Texas Rio Grande Valley has extended the Interim Policy on Human Subjects Research based on the rapidly evolving circumstances regarding COVID-19, and the University's focus on social distancing and the health and well-being of the community. **The Interim Policy has been extended to May 30, 2020.** At that time, UTRGV will reevaluate this decision on an ongoing basis, while sharing additional updates or modifications as more information becomes available.

1. Except as noted on number 3 below, any research procedures that involve in-person interactions/interventions with participants must be immediately paused. Research procedures involving no direct in-person interaction/intervention with participants may continue (e.g. data analysis, online surveys, telephone interviews). This applies to both exempt and non-exempt research studies.
2. During this pause, Investigators should consider whether it is feasible to modify their in-person research procedures to use alternative methods for data gathering (e.g. telephone, online, Zoom, Skype, or other means). If alternative methods to in-person participation are feasible and desired, Investigators should submit a modification/amendment to the study and secure IRB approval prior to the implementation of changes. Keep in mind that it is possible for the Office of Research Compliance and the IRB to experience a high volume of requests during this time.

   If the study cannot be conducted without the in-person participant interaction/intervention, then new participant enrollment and any ongoing in-person participant interactions/interventions must be immediately paused.

   An investigator may implement changes to approved research prior to obtaining IRB approval if such changes are necessary to eliminate apparent immediate hazards to the participants as provided for in federal regulations (45 CFR 46.108(a)(3)(iii) under the 2018 Rule and 45 CFR 46.103(b)(4)(iii) under the pre-2018 Rule). In such cases, the Principal Investigator must promptly notify the IRB via the IRB Protocol Deviation/Possible Non-Compliance Report Form and submit the corresponding modification/amendment via Tick@Lab as soon as it is feasible.

3. Exception to the in-person interaction/intervention pause:
   1. Projects in which a pause of the in-person interaction/intervention will have the potential for direct harm to participants. These studies may continue subject to the following: any in-person participant interactions/interventions must be minimized and alternatives for in-

person data collection should be considered if feasible. Investigators should consider their ability to continue with the research based on current and future staffing resources, facility restrictions, and any other factors specific to the study. Investigators should also consider the rapidly evolving environment and plan for research continuity, such as planning for facility restrictions or closures, illness or absence of research team, drug or device shortage, or lack of required personal protective equipment. New participants should not be enrolled without prior permission from the IRB.

2. Projects actively studying influenza and COVID-19 in collaboration with the CDC or the NIH.
3. Projects where the in-person interaction/intervention with participants is conducted by international partners or by UTRGV researchers in another country in compliance with governmental and UTRGV's COVID-19 restrictions. Investigators must consult with the country's local IRB/ethics board regarding the continuation of the research. If the local IRB determines that it is safe for the work to continue, then the project may proceed. Principal Investigators must provide documentation of this determination to the UTRGV IRB via irb@utrgv.edu prior to the continuation of the research. Modified procedures to eliminate or minimize the need for in-person contact are recommended and the investigator must continue to monitor the changing COVID-19 situation.
4. Investigators and their research personnel should work with their study sponsors and others to evaluate impacted studies and develop a plan appropriate to their research procedures, including financial considerations. For questions on how to contact a study sponsor and other considerations related to sponsored projects, please email the Office of Sponsored Programs.

A list of Frequently Asked Questions (FAQs) [is] posted on the IRB webpage. If there are other questions or you need assistance, please email the Office of Research Compliance.

Thank you for your continued support and assistance in protecting human subjects research and research personnel.

Parwinder S. Grewal, Ph.D.
Executive Vice President
Research, Graduate Studied, and New Program Development

Interim Policy for the Continuation of Human Subjects Research with In-Person Component through the COVID-19 Outbreak

Monday, June 1, 2020: Office of the Executive Vice President for Research, Graduate Studies, & New Program Development

Notice to Researchers

On March 21, 2020, UTRGV issued an interim policy to temporarily pause all research procedures with human participants involving in-person interactions/interventions under IRB oversight (with limited exception) in response to the public emergency resulting from the COVID-19 outbreak. The interim policy was extended through May 30, 2020.

Today, UTRGV is issuing a new interim policy to support the continuation of human subjects' studies that were paused as a result of the previous policy. This new interim policy, which will be implemented immediately, is intended to remain in effect for the duration of the public health emergency related to COVID-19 as declared by the Secretary of Health and Human Services (HHS).

UTRGV recognizes that the current public health emergency has affected the conduct of the research involving human subjects and impacted the risk/benefit analysis for participants of studies with research procedures requiring an in-person interaction/intervention.

Consistent with FDA and OHRP guidance and recommendations, UTRGV supports the continuation of human subjects' research by minimizing risks and ensuring the safety of research participants. This policy applies to approved studies regardless of their level of review (Exempt, Expedited, Full Board) and where UTRGV's IRB is responsible for providing oversight to the research. Investigators wishing to continue their paused studies must comply with the following conditions:

- Develop a risk mitigation plan specific to the study that describes the measures that will be
- implemented to reduce the risk of COVID-19 exposure through the in-person procedures.
- Mitigation plans will be submitted for the consideration and approval by an Emergency IRB specifically impaneled to evaluate human subjects' studies in an expeditious manner during emergency situations. This panel will evaluate risk mitigation plans with the assistance of consultants, as deemed necessary. This Emergency IRB will meet as often as needed to ensure prompt determinations on the adequacy of the mitigating measures proposed. For information on how to submit the risk mitigations plans to the Emergency IRB panel, please refer to this document.
- Obtain approval of the study risk mitigation plan by the Emergency IRB prior to resuming the in person interaction/intervention activities.

For collaborative studies in which the UTRGV IRB is relying on another entity's IRB for oversight of the research, investigators must:

- Request a statement from the overseeing IRB certifying that risk mitigating measures have been implemented consistent with Centers for Disease Controls' (CDC) recommendations and state/local government restrictions
- Submit the statements to irb@utrgv.edu and wait for acknowledgement by the IRB prior to resuming in-person study activities.

For a list of recommended risk mitigating measures and Frequently Asked Questions, please refer to the IRB webpage. For questions about PPE or sanitizing supplies and procedures for on-campus research, please email the Office of Environmental Health, Safety & Risk Management.

For other questions or assistance, please email the Office of Research Compliance.

Thank you for your continued support in protecting human subjects and advancing UTRGV research during these unprecedented times.

Parwinder S. Grewal, Ph.D.
Executive Vice President
Research, Graduate Studied, and New Program Development

UTRGV Reiterates Pause on Research Procedures with Human Subjects; Pause to Apply to Studies Approved to Continue under Risk Mitigations Plans

Wednesday, August 12, 2020: Office of the Executive Vice President for Research, Graduate Studies, & New Program Development

UTRGV is reiterating the pause on all research procedures with human participants, with limited exceptions as indicated below. This policy applies to studies (Exempt, Expedited, Full Board, Reliance) where UTRGV is the lead institution conducting research or where UTRGV IRB provides oversight.

Exceptions to the Pause:

1. Studies in which the research procedures do not involve direct in-person interaction/intervention with participants (e.g., data analysis, online surveys, telephone interviews).
2. Studies in which the pause to the in-person interaction/intervention will have the potential for direct harm to participants. These studies may continue provided the in-person contact is minimized and alternatives for in-person data collection have been considered, if feasible. Investigators should consider their ability to continue with the research based on current and future staffing resources, facility restrictions and any other factors specific to the study. Investigators should also consider the rapidly evolving environment and plan for research continuity, such as planning for facility restrictions or closures, illness or absence of research team, drug or device shortage, or lack of required personal protective equipment. New participants should not be enrolled without prior permission from the IRB.
3. Projects actively studying influenza and COVID-19.
4. Projects where the in-person interaction/intervention with participants is conducted by international partners or by UTRGV researchers in another country in compliance with governmental and UTRGV's COVID-19 restrictions. Investigators must consult with the country's local IRB/ethics board regarding the continuation of the research. If the local IRB determines that it is safe for the work to continue, then the project may proceed. Principal Investigators must provide documentation of this determination to the UTRGV IRB via irb@utrgv.edu prior to the continuation of the research. Modified procedures to eliminate or minimize the need for in-person contact are recommended and the investigator must continue to monitor the changing COVID-19 situation.

What's new? Research procedures of studies that were approved to continue under Risk Mitigation Plans, as per the previous interim policy (published on June 1st, 2020), are now to be paused immediately. No new Risk Mitigation Plans will be approved until further notice.

This decision is in response to the alarming number of active coronavirus cases in our community and State and the fact that hospitals have reached full capacity in the Rio Grande Valley. We apologize for the multiple communications on this matter. This is a fluid situation and our priority continues to be the safety of individuals who participate in our research studies as well as our students, employees, and the community we serve.

For questions please contact the Office of Research Compliance at researchcompliance@utrgv.edu.

For your convenience, below is a summary of the Interim Policies that have been published related to Human Subjects Research (in chronological order) during the pandemic.

Interim Policies on Human Subjects Research during the COVID-19 Outbreak

March 21, 2020:

UTRGV Announces Actions for Human Subjects Research during COVID-19 Outbreak. This Interim Policy paused all research procedures with human participants, with limited exceptions, through April 15, 2020.

April 15, 2020:

UTRGV Extends the Interim Policy on Actions for Human Subjects Research during COVID-19 Outbreak. UTRGV extended the pause on research procedures through May 30, 2020.

May 30, 2020 (Published on June 1, 2020):

UTRGV Announces New Interim Policy for the Continuation of Human Subjects Research with In-Person Component through the COVID-19 Outbreak. This new Interim Policy allowed for the continuation of studies with in-person interventions/interactions that were paused under the March 21, 2020 policy, provided IRB approved a Risk Mitigation Plan.

August 12, 2020:

UTRGV Reiterates Pause on Research Procedures with Human Subjects; Pause to Apply to Studies Approved to Continue under Risk Mitigations Plans. This Policy restated the pause of all research procedures with human participants, with limited exceptions, until further notice. The pause will also apply to projects that were approved to continue by the IRB under Risk Mitigation Plans in accordance to the previous interim policy.

21.3.5 UTRGV to Continue Human Subjects Research Procedures under approved Risk Mitigations Plans

UTRGV to Continue Human Subjects Research Procedures under approved Risk Mitigations Plans

Effective immediately, UTRGV will allow human subjects studies that are paused under previous interim policies to continue under IRB-approved Risk Mitigation Plans.

This decision responds to the decrease in the number of hospitalizations, including the number of COVID patients in intensive care units (ICU). We continue monitoring the COVID Risk Levels in the Rio Grande Valley (Key Metrics for COVID Supression) as we review interim policies from time to time. This is a fluid situation and our priority continues to be the safety of individuals who participate in our research studies as well as our students, employees, and the community we serve.

As a reminder, all research procedures with human participants were paused on March 21, 2020, with limited exceptions as indicated below. This pause applies to studies (Exempt, Expedited, Full Board, Reliance) where UTRGV is the lead institution conducting research or where UTRGV IRB provides oversight.

Exceptions to the Pause:

1. Studies in which the research procedures do not involve direct in-person interaction/intervention with participats (e.g., data analysis, online surveys, telephone interviews).
2. Studies in which the pause to the in-person interaction/intervention will have the potential for direct harm to participants. These studies may continue provided the in-person contact is minimized and alternatives for in-person data collection have been considered, if feasible. Investigators should consider their ability to continue with the research based on current and future staffing resources, facility restrictions and any other factors specific to the study. Investigators should also consider the rapidly evolving environment and plan for research continuity, such as planning for facility restrictions or closures, illness or absence of research team, drug or device shortage, or lack of required personal protective equipment. New participants should not be enrolled without prior permission from the IRB.
3. Projects actively studying influenza and COVID-19.
4. Projects where the in-person interaction/intervention with participants is conducted by international partners or by UTRGV researchers in another country in compliance with governmental and UTRGV's COVID-19 restrictions. Investigators must consult with the country's local IRB/ethics board regarding the continuation of the research. If the local IRB determines that it is safe for the work to continue, then the project may proceed. Principal Investigators must provide documentation of this determination to the UTRGV IRB via irb@utrgv.edu prior to the continuation of the research. Modified procedures to eliminate or minimize the need for in-person contact are recommended and the investigator must continue to monitor the changing COVID-19 situation.

Studies that were paused are now allowed to continue provided a Risk Mitigation Plan is approved by the IRB. For information on how to submit a Risk Mitigation Plan, please visit the IRB webpage.

Research studies with already approved Risk Mitigation Plans may continue without further actions.

For questions please contact the Office of Research Compliance at researchcompliance@utrgv.edu.

For your convenience, below is a summary of the Interim Policies that have been published related to Human Subjects Research (in chronological order) during the pandemic.

Interim Policies on Human Subjects Research during the COVID-19 Outbreak

March 21, 2020:

UTRGV Announces Actions for Human Subjects Research during COVID-19 Outbreak. This Interim Policy paused all research procedures with human participants, with limited exceptions, through April 15, 2020.

April 15, 2020:

UTRGV Extends the Interim Policy on Actions for Human Subjects Research during COVID-19 Outbreak. UTRGV extended the pause on research procedures through May 30, 2020.

May 30, 2020 (Published on June 1, 2020):

UTRGV Announces New Interim Policy for the Continuation of Human Subjects Research with In-Person Component through the COVID-19 Outbreak. This new Interim Policy allowed for the continuation of studies with in-person interventions/interactions that were paused under the March 21, 2020 policy, provided IRB approved a Risk Mitigation Plan.

August 12, 2020:

UTRGV Reiterates Pause on Research Procedures with Human Subjects; Pause to Apply to Studies Approved to Continue under Risk Mitigations Plans. This Policy restated the pause of all research procedures with human participants, with limited exeptions, until further notice. The pause will also apply to projects that were approved to continue by the IRB under Risk Mitigation Plans in accordance to the previous interim policy.

October 23, 2020

UTRGV to Continue In-Person Research Procedures with Risk Mitigations Plans

This Policy allows for the continuation of studies with in-person interventions/interactions that were paused under the March 21, 2020 policy, provided IRB approve a Risk Mitigation Plan. It also authorizes studies that have already approved Risk Mitigation Plans to continue without further actions.