University of Belize

Education Empowers a Nation

Institutional Review Board Manual

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Background and Purpose

Since its establishment through the University of Belize Act (2000), the University of Belize (UB) has sought to engage and deliver excellence in research that responds to Belize's national development needs. It is imperative that the university fulfils this research function responsibly and ethically, particularly as it relates to the protection of human participants in research. The *Institutional Review Board (IRB)* was established to ensure compliance with best practices and professional standards that guide the conduct of research involving humans. The purpose of the IRB review is to evaluate the procedures taken to minimize the risks to human participants in research. All research at the University of Belize that involves the collection of data or identifiable personal markers from human participants must be reviewed and approved by the IRB before the start of data collection.

Much of the information in this Manual is based on the US Code of Federal Regulations Title 45, Part 46, referred to as 45 CRF 46. This legal framework serves as the universal standard for research with human subjects. It ensures that all research conforms to the principles of respect, beneficence and justice, principles that are explained in the *Belmont Report* and. Detailed information can be accessed at the United States' based Office for Human Research Protections (OHRP) which provides international "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)" (https://www.hhs.gov/ohrp/index.html).

This Institutional Review Board (IRB) Manual has been developed to:

1. Establish the ethical principles that will regulate the conduct of research that involves human participants by researchers at the University of Belize.

2. Explain the composition, function, and operation of the IRB.

3. Explain the protocols by which the ethical compliance of research projects will be assured.

Scope

These IRB protocols apply to all research involving human participants, including clinical investigations and trials, conducted under the auspices of the University of Belize, whether conducted by academic staff, students, or affiliated researchers.

Definition of Terms

Academic staff	The term “academic staff” refers to academic professionals who are responsible for planning, directing, supporting, or undertaking academic teaching and research within the HE (Higher Education) institutions. They also include vice-Presidents, medical practitioners, and other health care professionals, laboratory and field technicians, and other qualified staff who may undertake lecturing or research activities.
Applied Research	Involves an original investigation to develop a new understanding of a specific practical aim or objective.
Basic Research	Also referred to as fundamental research, involves experimental or theoretical work undertaken to acquire new knowledge without a particular application.
Classroom-Based Research	Not all data collection by university students constitutes human research. Only classroom-based research designed to develop or produce “generalizable knowledge” should be submitted to the IRB. This includes all thesis-based research involving human subjects, as well as research done in a research methods-based course in which studies are designed to produce “generalizable knowledge.” Studies submitted to the IRB should result in an undergraduate or graduate-level thesis or public poster, or paper presentation.
Experimental Development Research	Refers to systematic work that draws from existing knowledge gained from research and/ or practical experience that is directed to produce new materials, products, and devices, install new processes, systems, and services, and substantially improve those already made or installed.
Honorary researcher	This term refers to persons who are recognized for their outstanding contribution to the University with particular reference to research activity. Evidence of outstanding ability, judged by research publications and the ability to attract external funding. Such an individual would have a high level of responsibility, a nationally recognized reputation in the research area, and a developing international reputation. The person may already hold or have held similar, substantive positions at recognized universities or organizations with distinguished Research and Development disposition. A doctoral degree will be required.

Human Subjects	This definition is adopted from 45 CFR 46, which is “laws set by the U.S. Department of Health and Human Services (DHHS) to protect a person from risks in research studies that any federal agency or department has a part in. They are also called 45 Code of Federal Regulations Part 46, human participant protection regulations, and Protection of Human Subjects.” According to 45 CFR 46, a human subject is "a living individual about whom an investigator (whether professional or student) conducting research: 1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."
Minimal risk	The term “minimal risk” is defined as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”
Research	Refers to “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities” (OHRP, 46.101. Section d)
Research Student	This is defined as one who conducts research under the supervision of academic staff. This may include undergraduate and graduate students.
Vulnerable Populations	This term refers to groups of people who may be subjected to coercion by researchers or who may be unable to provide informed consent. The list of vulnerable populations includes, but is not limited to, children under the age of 18, pregnant subjects, fetuses, prisoners, mentally impaired subjects, frail, elderly, or terminally ill persons, and socially and economically disadvantaged people are all considered to be vulnerable. The IRB is particularly concerned to review

research that proposes to use participants from any of these groups.

Ethical Principles Adopted from the Belmont Report

The involvement of human participants in research is a privilege for researchers, not a right. Therefore, researchers are responsible and obligated to protect the rights and well-being of research participants. The ethical principles that guide the ethics of research at UB are grounded in the Belmont Report and are as follows:

1. **Respect for persons**: "Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection." Respecting the autonomy of a person signifies that they have a right to self-determination in choosing to participate in the research in question and that this decision is made with adequate information, voluntarily, free of coercion or prejudice. It also indicates that persons with diminished autonomy, as in the case of children, prisoners, and persons with mental disabilities, must be assured special protection. Respect for persons also implies that individuals have rights that are enshrined in the Belizean Constitution and several international human rights instruments that must be respected.

2. **Beneficence**: The principle of beneficence speaks to doing no harm, maximizing possible benefits, and minimizing possible harm. While research has potential benefits for society, the well-being of the participants is paramount. Research must not harm individual participants. However, research may sometimes involve risks. When risks are involved, all measures must be taken to minimize these risks, and they must be weighed against potential benefits.

3. **Justice**: This principle addresses who benefits from the research and who bears the burden. Justice implies that no one should bear the entire burden or receive all the benefits—these should be distributed fairly. The selection of participants must be scrutinized to determine whether especially disadvantaged groups are being selected because they offer an easy route out.

IRB Mandate

1. To review, require modifications for approval, approve or disapprove all research activities conducted under the auspices of the University of Belize to safeguard the rights and welfare of human participants in research in keeping with the IRB policy and procedure manual.

2. To determine and recommend whether the research proposal requires any other review at the national level.

3. To require and review reports, conduct inspections, and conduct overall monitoring of research involving human subjects.

4. To suspend or terminate approval when research is not being carried out under the IRB requirements or when it poses an unexpected risk to subjects.

5. To carry out investigations of research ethics violations.

IRB Appointment and Composition

The Institutional Review Board members will be appointed by the President of the University on the recommendations of the Vice President. The Deans, the Graduate Studies and Research Committee, and the Academic Council may make nominations. Members will be appointed to serve for two years with the possibility for renewal. Members appointed to the IRB will be required to declare institutional affiliations, qualifications, experience, and expertise. At the completion of each term, the Chair of the Board will evaluate performance and will advise the President on re-appointments.

The composition of the IRB will ensure that the Board has the competence and credibility through the diversity, integrity, maturity, expertise, and experience of its membership to:

1. Review research carried out under the auspices of the University.

2. Review the ethical soundness of proposals regarding the university's commitments to national regulations and laws, professional standards, human rights standards, code of ethics (such as those articulated in the Belmont Report and Helsinki Declaration), and community attitudes.

3. Guarantee respect for its advice and decisions.

To this end, the composition will consist of six members and account for diversity of gender, profession, and diversity of representation, and will include:

Internal to the University

1. Two members whose primary concern is in the health/behavioral/social sciences.

2. One member whose concern is Non-Scientific.

External to the University

1. One member whose primary concern is in the health/behavioral/social sciences.

2. Two members whose concern is in non-scientific areas (human rights, community, legal).

3. Research Director of the University as an ex-officio member.

The Board will select a Chair and Vice-Chair from the University members on the Board. The Chair will be responsible for presiding over the meetings and speaking on behalf of the IRB. In the absence of the Chair, the Vice-Chair will assume the Chair's duties.

IRB Voting

1. At times, the IRB may not have the necessary expertise to review a particular proposal; in which case, it may seek expert advice from outside the IRB. Such an expert will not constitute a member of the IRB and will not have voting rights. Such an expert will be requested to disclose any conflict of interest.

2. For applications requiring Full and Continuing Review and other business requiring a vote, a quorum of the committee must be present. A quorum constitutes a simple majority of IRB membership.

3. An application approval from the IRB requires a majority vote by committee members when a quorum has been met.

4. When quorum cannot be met, for reasons such as loss of majority through recusal of members with conflicting interests or early departures, or absence of a non-scientist or community member, the IRB may conduct an electronic vote, and quorum is met electronically.

5. The Research Director is an ex-officio member and is a non-voting member unless necessary to make a quorum or to break a tie vote.

IRB Meetings

The IRB can host face-to-face or virtual meetings at least twice per semester, which shall be made available to the University community. For business of the IRB to be undertaken, a quorum, consisting of a simple majority of members, must be established. Approval of protocols shall require a majority vote. If at any time during the meeting quorum is lost, this must be noted down in the minutes, and no approval votes shall be taken.

Before the meeting, an agenda of protocols will be developed and circulated to IRB members. The IRB Chair will assign primary and secondary reviewers based on their expertise as it relates to the protocol in question and shall ensure that either the primary or secondary reviewer is present for the session. Researchers may be called to attend a meeting to make clarifications, but they shall leave the meeting during deliberations and decision-making.

IRB Meeting Minutes

The University of Belize IRB is a functional unit within the Research Office. The IRB shall maintain minutes that are detailed enough to allow a reconstruction of deliberations and decisions taken by the Board. Drafts of minutes will be circulated to Board members before a subsequent meeting at which they will be reviewed and accepted. IRBs must keep detailed documentation of meeting activities, including attendance, voting on actions, the basis for the actions, and a written summary of the IRB discussion of controverted issues and their resolution.

Minutes shall include:

1. The names of those in attendance and excuses or absences.

2. The agenda for the meeting.

3. A protocol summary and the deliberations for each protocol and the resulting IRB action.

4. The approval period for each initial review, continuing review, and amendment.

5. A record of attendance for each protocol, including the names of members who left the meeting due to a conflict of interest, and a notation of such

6. The voting record for each protocol reflects the number of members for, against, or abstaining from the vote.

7. The basis for requiring changes to a protocol, tabling, or disapproving of research.

8. A written summary of the discussion and resolution of controverted issues.

9. A list of all actions that were taken administratively during the previous month.

Conflict of Interest

To ensure the integrity and credibility of the IRB and safeguard the rights and welfare of human subjects participating in research, conflicts of interest shall be avoided. IRB members are required to declare any conflict of interest in a research protocol under review. At the start of the meeting, the Chair will request that the Board members declare any such conflicts. Where a member declares a conflict of interest with respect to a given protocol, such member shall be excluded from deliberations and voting, shall leave the room, and shall not count as quorum.

The IRB Review Submission Process

All research proposals involving human participants must be submitted for IRB review.

1. Complete the IRB Ethics Form at research.ub.edu.bz. Please note that students must secure approval from their research advisors before submission of ethics forms.

2. All submissions must include informed consent, consent documentation or waivers, recruitment materials, and research instruments. These will undergo preliminary review by the IRB Chair, who determines the level of review that each application will undergo. The Chair may request additional information about the proposed research project. The Chair may also invite ad hoc reviewers to assist in the review process when additional expertise is necessary; such reviewers serve as nonvoting consultants.

3. A response from the IRB will be provided within two weeks of submission for Expedited and Exempt reviews. The decisions for Full reviews will be provided five days after the sitting of the full IRB. The response from the IRB will include information on the type of review and details of any further action to be taken.

Types of IRB Review

There are three types of review for research involving human subjects:

1. Exempt from further review

2. Expedited Review

3. Full Board Review

The IRB Chair will review the application and determine the category of review.

Exempt Review

The classification of Exempt Review does not suggest that a proposal is exempt from submission for review. Rather, this level of review refers to an exemption from review by the full IRB and is reserved for research that involves minimal risk. The determination of exemption is made by the IRB Chair, coordinator, or such IRB member as determined by the IRB. Researchers must submit their protocols following the usual procedure and shall receive the official results of the IRB's determination in writing within five working days.

In determining the category of exemption, the IRB will be guided by the list of exemptions identified by the United States Code of Federal Regulations (46.101) quoted below:

1. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

    2.1 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

    2.2 Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

    2.3 The investigator records the information obtained in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and at least one of the following criteria is met:

    3.1 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

    3.2 Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

    3.3 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or

through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

4. For this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

5. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

6. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

    6.1 The identifiable private information or identifiable biospecimens are publicly available.

    6.2 Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

    6.3 The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

    6.4 The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable,

the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

7. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

    7.1 Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. [Reserved]

    7.2 Taste and food quality evaluation and consumer acceptance studies:
    If wholesome foods without additives are consumed, or If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

8. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 46.111(a)(8).

9. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

    9.1 Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

9.2 Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 46.117;

9.3 An IRB conducts a limited IRB review and makes the determination required by 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

9.4 The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Expedited Review

The expedited review is conducted by two members of the IRB, including the Chair or Vice-Chair and an experienced reviewer designated by the Chair, and is reserved for research that involves minimal risk. Researchers must submit their protocols using the standard procedure and will receive the results of the review in writing. Expedited Reviews excludes research on children, vulnerable populations, or sensitive content.

In making this determination, the IRB will be guided by the OHRP policy on categories of research that may be reviewed by the Institutional Review Board (IRB) through an

Expedited Review Procedure (1998) quoted below:

Applicability

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2. The categories in this list apply regardless of the age of subjects, except as noted.

3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable

and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

4. The expedited review procedure may not be used for classified research involving human subjects.

5. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

6. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices are only conducted when condition (1.1) or (1.2) is met.

   1.1 Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.

   1.2 Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel-stick, ear stick, or venipuncture as follows:

   2.1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in 8 weeks and collection may not occur more frequently than 2 times per week; or from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 mL or 3 mL per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

3.1 Hair and nail clippings in a non-disfiguring manner;

3.2 Deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction;

3.3 Permanent teeth if routine patient care indicates a need for extraction;

3.4 Excreta and external secretions (including sweat);

3.5 Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;

3.6 Placenta removed at delivery;

3.7 Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

3.8 Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

3.9 Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

3.10 Sputum collected after saline mist nebulization.

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. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.

Examples:

4.1 Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

4.2 Weighing or testing sensory acuity;

4.3 Magnetic resonance imaging;

4.4 Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

4.5 Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate, given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

   6.1 Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

7. Continuing review of research previously approved by the convened IRB as follows:

   7.1 The research is permanently closed to the enrollment of new subjects;

   7.2 All subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified, or the remaining research activities are limited to data analysis.

8. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Board Review

A Full Board Review is conducted when research procedures pose risks to participants or if the participants belong to a vulnerable population. Additionally, any research proposing risky procedures or harmful effects that may cause pain or harm to participants must be reviewed by the full board.

The full board review will be conducted at a convened IRB meeting, in which there is a quorum of IRB members. At least one member with a nonscientific background must be present. A majority of the IRB members present must approve the research.

Researchers will submit their protocols following standard procedures and will receive a reply in writing. Researcher proposals requiring full board review must be submitted at least two weeks prior to the scheduled meetings of the IRB. The IRB must notify (in writing) researchers and the organization of its decision to approve, modify, or disapprove the research.

Criteria for Approval

1. Approval will be granted to begin data collection for a research study based on whether such a study meets the criteria below at the time of initial review and is sustained throughout the life of the project. Any deviations from the IRB-approved protocol must be sought through a request for amendments.

    1.1 Human subjects are not exposed to unnecessary risk, and risks to participants are minimized using methodologies and research designs that are sound and, where possible, follow tested procedures.

    1.2 The risks to participants are reasonable and positively balanced against possible benefits to participants and the importance of knowledge.

2. The participants must be selected in an equitable manner, ensuring the principle of justice, that the costs of research are paid equitably, and that vulnerable populations are not being selected because of easy access.

3. Human rights of the subjects are not being violated.

4. Informed consent from each participant or his/her legally authorized representative has been received, the subject has been adequately informed, and this informed consent has been properly recorded. Where research involves persons, who are mentally and physically incapacitated to give consent, or procedures that might coerce subjects' informed consent, shall be supervised by a third party other than the Principal Investigator (PI).

5. The participant's rights to privacy are adequately protected, and confidentiality of data is maintained.

6. Where research involves medical or psychological procedures, the PI or personnel applying the procedures are qualified to do so, and this qualification is documented.

7. Researchers abide by any other known, required national research criteria.

8. Once approved, any changes in the research should be reported back to the IRB.

IRB Submissions from Honorary and/or External Researchers

Researchers who are not affiliated with the University of Belize may apply for IRB approval through the Ethics Form portal (research.ub.edu.bz).

Any external researcher wishing to recruit research subjects on any UB campus must apply for prior permission from the IRB Chair. Applicants must present evidence that their proposed research has received ethical clearance from a recognized IRB. The results of the application will be communicated to the researcher in writing within 10 working days.

Key Related Documents

Ethics Form

Amendment History

Revision #	Description of changes	Reason(s) for the change	Date of revisions
0	Initial Review	Not Applicable	Same as Initial Date