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INTRODUCTION

BACKGROUND

Beirut Arab University has established its Institutional Review Board (IRB) to review and approve the increasing number of research projects involving humans and animals conducted at/by BAU and the Affiliated University Hospitals.

All projects in which a university academic staff member or student investigates humans or animals for research purposes must be reviewed by the Institutional Review Board (IRB) prior to initiation of the project. It is the responsibility of the investigator to seek review of any study involving humans and animals.

The IRB is in charge of the institutional responsibility for assurance of protection of humans and animals involved in research or related activities.

RESPONSIBILITIES, AUTHORITIES, AND OBJECTIVES

Beirut Arab University’s Institutional Review Board (IRB) is a formally designated committee to review, approve, and monitor biomedical and behavioral research involving human subjects conducted by academic staff and students at BAU and/or its affiliates. BAU Institutional Review Board is also concerned in safeguarding animal rights. BAU’s IRB has the right to approve, require modifications in planned research prior to approval, or disapprove research. The IRB has the right to regularly monitor compliance to the ethical guidelines of the approved protocols at intervals of at least once per year until the research is completed.

The IRB reviews any research performed within the University premises or in collaboration with other institutes or hospitals either within the University or at other locations.

The IRB provides independent and timely decisions based on adherence to the guidelines in compliance with international declarations including Nuremberg, Helsinki, and Belmont declarations.
MISSION
The IRB aims to safeguard the protection of the dignity, rights, safety, and welfare of all actual or potential research subjects.

VISION
The IRB is looking towards modern approaches and concepts and practical and ethical scientific research to ensure the strengthening of the quality of scientific research in accordance with international standards for the service of society and the requirements of the labour market.

MEMBERSHIP
The Institutional Review Board (IRB) chairperson, coordinator and members are appointed by BAU administration at the beginning of each academic year; the duration of appointment lasts one year. The IRB has the freedom to work independently and decide on the merits of proposals without interference within the institutional framework.

The BAU Institutional Review Board is composed of at least eight members based on these criteria:
- The members must have enough collective experience, expertise, and diversity to make informed decisions on whether the research is ethical, informed consent is sufficient, and appropriate safeguards have been put in place.
- If the IRB works with studies that include vulnerable populations, the IRB should have members who are familiar with these groups.
- The IRB includes:
  - A physician, dentist, pharmacist, health sciences field member, and social behavioural science expert
  - A law expert
  - A “Community Member” familiar with social values, who is not affiliated with the institution or in the immediate family of a person affiliated with the institution.

Whenever there is a possibility of conflict of interest, members are asked to declare their association with the proposal and withdraw from the reviewing process. IRB members may not vote on their own projects.
ETHICAL GUIDELINES

International Instruments and Guidelines

The first international instrument on the ethics of medical research, the Nuremberg Code, was published in 1947 as a consequence of the trial of physicians (the Doctors’ Trial) who had conducted atrocious experiments on un-consenting prisoners and detainees during the Second World War. The Code, designed to protect the integrity of the research subject, set out conditions for the ethical conduct of research involving human subjects, emphasizing their voluntary consent to research.


The Covenant in “Article 7” states that “no one shall be subjected without his/her free consent to medical or scientific experimentation”. It is through this statement that society expresses the fundamental human value that is held to govern all research involving human subjects and the protection of the rights and welfare of all human subjects of scientific experimentation. The Declaration of Helsinki, issued by the World Medical Association in 1964, is the fundamental international document in the field of ethics in biomedical research; it has influenced the formulation of international, regional and national legislation and codes of conduct. The Declaration, amended several times, most recently in 2000, is a comprehensive statement of the ethics of research involving human subjects. It sets out ethical guidelines for researchers engaged in both clinical and nonclinical biomedical research.

After the publication of the Council for International Organizations of Medical Sciences’ (CIOMS) in 1993, many ethical guidelines on clinical trials have been published by several international organizations. This has included publications by the World Health Organization in 1995 entitled Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products and a publication by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), in 1996 entitled, Guideline on Good Clinical Practice, designed to ensure that data generated from clinical trials are mutually acceptable to regulatory authorities in the European Union, Japan and the United States of America. The Joint United Nations program on HIV/AIDS published the UNAIDS Guidance Document Ethical Considerations in HIV Preventive Vaccine Research in 2000. On the other hand, UNESCO adopted the Universal Declaration on Bioethics and Human Rights in 19 October 2005.

When dealing with biomedical research involving human subjects, the international Human Rights instruments should be considered. The Universal Declaration of Human Rights, which, particularly in its scientific provisions, was highly influenced by the Nuremberg Code; the International Covenant on Civil and Political Rights; and the International Covenant on Economic, Social and Cultural Rights. Since the Nuremberg experience, Human Rights Law has expanded to include the protection of women (Convention on the Elimination of all Forms of Discrimination against Women) and Children (Convention on the Rights of the Child).

General Ethical Principles

The three basic ethical principles, namely respect for persons, beneficence, and justice should guide all research involving human subjects. These principles, which in concept have equal moral force, guide the conscientious preparation of proposals for scientific studies. They may be expressed differently in varying circumstances and given different moral weight and their application may lead to different decisions or courses of action.

Two fundamental ethical considerations are assimilated in “Respect” for persons, namely:

- Autonomy, respect for the capacity of self-determination in treating those who are capable of deliberation about their personal choices.
- Persons with impaired or diminished autonomy should be offered security against harm or abuse.

“Beneficence” refers to the ethical obligation to maximize benefit and minimize harm. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and safeguard the welfare of research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, no maleficence (no harm).

“Justice” refers to the ethical obligation to treat each person in accordance with what is morally right and proper and to give each person what is due to him or her. In the ethics of research involving human subjects, the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and benefits of participation in research. Differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons; one such distinction is vulnerability.

“Vulnerability” refers to a substantial incapacity to protect one’s own interests, owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons.

WORKING PROCEDURES

Meeting Procedures

- The IRB will meet four times per academic year and review applications. Approved applications will be valid for up to three years.
- The IRB meeting is called to order when a quorum of more than half of the members is present. Approval of an action requires a majority vote when a quorum is present. IRB members with conflicting interests cannot count towards quorum. The meeting ends when business is finished. The meeting agenda should be arranged and sent electronically one week before to all the members.
Voting System

1- Voting at a convened meeting takes place under the following conditions:
   - A quorum of the members must be present for all reviews/actions voted on at a convened meeting.
   - A passing vote must consist of a majority of members present voting in favour of the motion.
   - External consultant do not hold a voting right in the IRB.
   - Community members must always be present for a vote.
   - A physician must be present to vote on human subject regulated research.

2- If the outcome of the IRB vote is that modifications and/or additional information is required, the
   IRB chairperson or the coordinator may review and approve the PI’s response on behalf of the IRB.

Issuing and Reporting the Final Decision

Investigators will be notified electronically and/or by a formal letter of the decision of the IRB and any
changes required. If minor specific changes are required, the changes, once returned, may be reviewed
and approved by the chairperson or coordinator. The IRB chairperson or the coordinator may approve
minor specific changes without return to the full board for review (e.g. address change, addition or deletion
of study personnel, change in number of subjects to be recruited, etc.) The IRB shall notify investigators
and the institution electronically via email of its decision to disapprove the proposed research activity or of
modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a
research activity, the reasons for its decision will be sent electronically to give the investigator an opportunity
to respond. Any Suspension or Termination of approval shall include a statement of the reasons for the IRB’s
action and shall be reported to the investigator.

Documentation Archival and Duration

The IRB, through its administrative staff, shall prepare and maintain adequate documentation of IRB
activities, including the following:

1- Copies of all research proposals reviewed and any associated documentation or materials, including:
   - scientific evaluations, sample consent documents, progress reports, amendments or extensions
   - submitted by investigators, reports of incidents or injuries to subjects, and copies of all correspondences
   - between the IRB and the investigators.
   - FDA has specified record-keeping and record retention requirements; generally, FDA regulated research records must be kept for 2 years. Accordingly, BAU IRB regulations, research records are archived for 3 years after completion of all its activities
   - while digital records are kept for more than 5 years.

2- Minutes of IRB meetings show attendance at the meetings, actions taken by the IRB, the vote on
   these actions including the number of members voting for, against and abstaining, the name of
   any person with a conflict of interest and reason for conflict, the basis for requiring changes in
   disapproved research proposals, and a written summary of the discussion of controversial issues and
   their resolution.

3- Listing of continuing review activities and research proposals that have been approved under the
   expedited and exempt review procedures.

4- A list of IRB members and working procedures guidelines.

Records required by this policy and those relating to conducted research shall be retained for at least three
years after completion of the research. The records of the IRB pertaining to individual research activities will
not be accessible outside the IRB and the individual researcher except for purposes of audit or inspection by
federal agencies to assure compliance.

Funding Resources

BAU is the main and only source of funding for BAU Institutional Review Board. The IRB does not charge
any fees for review of research studies involving human and animal subjects.

TYPES OF REVIEW

Exempt Research

Research that presents no more than minimal risks to non-vulnerable participants is exempt from the IRB’s
review and approval process. The IRB chairperson or coordinator determines that a research project proposal
qualifies as exempt from Expedited or Full Review. Research that falls into one of the categories below may
be exempted from IRB review:

- Research conducted in established or commonly accepted educational settings, involving normal
  educational practices, such as:
  - Research on regular and special education instructional strategies.
  - Research on the effectiveness of or the comparison among instructional techniques, curricula, or
    classroom management methods.
  - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), or
    observation of public behavior, unless:
    - Information obtained is recorded in such a manner that human subjects can be identified, directly or
      through identifiers linked to the subjects.
  - Any disclosure of human subject responses outside the research could reasonably place the subjects at
    risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or
    reputation.
  - Research involving watching public behavior of children, where the investigator does not take part in the
    activities.
  - Research involving data, documents, pathological specimens, or diagnostic specimens publicly available
    or if the information is recorded by the investigator in such a manner that subjects cannot be identified,
    directly or through identifiers linked to the subjects.
• Research and demonstration projects which are conducted by or subjected to the approval of department or agency heads and which are designed to study, evaluate, or otherwise examine:
  • Public benefit or service programs.
  • Procedures for obtaining benefits or services under those programs.
  • Possible changes in or alternatives to those programs or procedures.
  • Possible changes in methods or levels of payment for benefits or services under those programs.
  • Taste and food quality evaluation and consumer acceptance studies.
  • If wholesome foods without additives are consumed.
  • If consumed food containing a food ingredient at or below the level of toxicity is found to be safe or if agricultural chemicals or environmental contaminants at or below the level of toxicity are 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 regulatory bodies.

Expedited Review

In some circumstances, if there is no more than minimal risk, expedited review can be conducted even on studies involving minors. Categories for expedited review are:

• Surveys/interviewing of children or observation of public behavior involving children when the researcher participates in the activity being observed.
• Surveys requesting information that expose the informant to criminal or civil liability or are extremely personal in nature in which the likelihood of associating the individual with the responses is very big.
• Collection of blood samples by finger stick, heel stick, ear stick, or veni-puncture not exceeding 50 ml or 3 ml per kg (whichever is less) in an eight week period, and collection may not occur more frequently than two times per week.
• Collection of hair and nail clippings in a non-disfiguring manner or of deciduous teeth and permanent teeth if patient care indicates a need for extraction.
• Collection of excreta, external secretions including sweat or un-cannulated saliva.
• Collection of both supra-and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth, and the process is accomplished with accepted prophylactic techniques.
• Recording of data from subjects using non-invasive procedures routinely employed in clinical practice, excluding X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for the market. Examples include the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or invasion of the subject’s privacy in regard to sensitive aspects of his/her behavior (e.g. illegal conduct, drug use, sexual behavior, alcohol use) when there is a possibility that the subject could be identified.
• Research involving prisoners.
• Research involving physically intrusive procedures.
• Research which previous experience (by the particular investigator or other investigators) has shown to create a potential of risk to subjects.
• Research that materially affects the pregnancy of a woman or the health/well-being of fetuses in utero.

Continuing Review

Continuing review of research conducted on human subjects by academic staff and students must be done in accordance with the policies and procedures outlined in this manual at intervals appropriate to the degree of risk but not less than once per year. The IRB cannot approve a research project for more than 12 months. All reviews for continuation will be conducted by expedited review if no changes have been made to the research protocol and no adverse or unexpected reactions or side effects have occurred or are expected. (However, the full IRB will be given the opportunity to review the continuation/renewal report). In all other instances, continuing the review will be conducted by the full IRB.
Revisions
If the investigator, during the course of conducting the research, revises the research protocol (e.g., makes changes to the informed consent form, survey instruments used, or number and nature of subjects), the principal investigator will notify the IRB chairperson immediately. The chairperson will determine the need for additional review and the type of review (Expedited or Full) and will notify the IRB members.

Suspension or Termination of Research
The IRB shall have authority to suspend or terminate research that is not being conducted in accordance with the IRB’s requirements and other institutional and governmental requirements or has been associated with any serious harm to subjects. Concerns regarding the conduct of research must be reported immediately to the chairperson of the IRB by any individual having such knowledge. Any Suspension or Termination of research must include a statement of the IRB’s action, and the chairperson must report its decision promptly to the principal investigator, the Dean and the funding agency in the case of a sponsored project.

Unintentional
In the event of research conducted without the intention of involving human subjects, which subsequently involves human subjects (by intention of the researcher), the research must be reviewed by the IRB in accordance with the policies and procedures outlined in this manual.

CRITERIA FOR IRB APPROVAL OF RESEARCH
Risks to Subjects
Risks to subjects are minimized:
- By using procedures that are consistent with a sound research design and which do not unnecessarily expose subjects to risk.
- Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

1. Have the rationale and base for the study hypothesis been provided in the background information?
2. Has the research been preceded by adequate laboratory and/or animal studies?
3. Are the design of the research and the proposed research procedures adequate to answer the research questions?
4. Can data from procedures or tests being performed for diagnostic or treatment purposes be used in lieu of procedures or tests being performed solely for research purposes?
5. Could procedures that involve less risk be used to answer the research question?
6. Is the sample size (number of subjects) adequate?
7. Is the method proposed for selecting and assigning subjects to treatment groups unbiased?
8. Are the study endpoints and methods of data analysis appropriate for the study?

Risk/Benefit Ratio
Risks to subjects are reasonable in relation to the anticipated benefits to subjects and importance of knowledge that may be reasonably expected to result.

1. What are the anticipated physical, psychological, social, legal, or economic risks to individual subjects?
2. What are the potential benefits, if any, to individual subjects?
3. What information is likely to result from the research and what impact, if any, will the information have on furthering the understanding of human physiology, diagnosis, or treatment of the disease or condition being studied?
4. Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research? Are the procedures for identifying such individuals adequate?
5. Are there adequate plans to exclude subjects who are vulnerable to injury during the period of withdrawal of active and effective therapy, if that is part of the research design?

Selection of Subjects
Selection of subjects is equitable.

1. Does the nature of the research require or justify using the proposed study population?
2. Will the solicitation of subjects avoid placing a disproportionate share of the risks and discomfort as well as inconvenience of the research on any single group of individuals?
3. Are women of childbearing potential eligible for participation or, if not eligible, has their exclusion been justified?
4. Has the selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?
5. Are any payments to subjects reasonable based upon the complexities and inconveniences of the study and the particular subject population?

INFORMED CONSENT [8.11]
General Requirements
No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive
or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the
sponsor, the institution or its agents from liability for negligence.
1- Basic elements of informed consent, except as provided in paragraph (3) of this section, shall be
provided for each subject according to the following:
   - A statement that the study involves research, an explanation of the purpose of the research and
the expected duration of the subject’s participation, a description of the procedures to be followed,
and identification of any procedures that are experimental.
   - A description of any reasonably foreseeable risks or discomforts.
   - A description of any benefits to the subject or to others which may be reasonably expected from the
research.
   - A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be
advantageous to the subject.
   - A statement describing the extent, if any, to which confidentiality of records identifying the subject will
be maintained.
   - An explanation for research involving more than minimal risk, as to whether any compensation is
provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
   - An explanation of whom to contact for answers to pertinent questions about the research and subjects’
rights and whom to contact in the event of a research-related injury to the subject.
   - A statement that participation is voluntary-refusal to participate will involve no penalty or loss of
rights and whom to contact in the event of a research-related injury to the subject.
   - A statement that significant new findings developed during the course of the research, which may
relate to the subjects’ willingness to continue in participation, will be provided to the subject.
   - The consequences of the subject’s decision to withdraw from the research and procedures for orderly
termination of participation by the subject.
   - A statement that new findings developed during the course of the research, which may relate to the
subjects’ willingness to continue in participation, will be provided to the subject.
   - The approximate number of subjects involved in the study.
2- Additional elements of informed consent, when appropriate, one or more of the following elements of
information shall also be provided to each subject:
   - A statement that the particular treatment or procedure may involve risks to the subject (or to the
embryo or fetus, if the subject is or may become pregnant), which are currently unexpected.
   - Anticipated circumstances under which the subject’s participation may be terminated by the
investigator without regard to the subjects’ consent.
   - Any additional costs to the subject that may result from participation in the research.
   - The consequences of the subject’s decision to withdraw from the research and procedures for orderly
termination of participation by the subject.
   - A statement that significant new findings developed during the course of the research, which may
relate to the subjects’ willingness to continue in participation, will be provided to the subject.
   - The approximate number of subjects involved in the study.
3- The IRB may approve a consent procedure which does not include, or which alters, some or all of the
elements of informed consent set forth above or waive the requirements to obtain informed consent
provided the IRB finds and documents that:
   - The research could not practically be carried out without the waiver or alteration.
   - The subject will be provided with additional pertinent information after participation, when appropriate.
   - The researcher project demonstration is to be conducted by or subject to the approval of government
officials and is designed to study, evaluate, or otherwise examine:
      - Programs under public benefit or service.
      - Procedures for obtaining benefits or services under those programs.
      - Possible changes in or alternatives to those programs or procedures.
      - Possible changes in methods or levels of payment for benefits or services under those programs.

Documentation
1- The IRB may waive the requirement for the investigator to obtain a signed consent form for some or
all subjects, if it finds either:
   - That the only record linking the subject and the research would be the consent document and the
principal risk would be potential harm resulting from a breach of confidentiality.
   - 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.
In documentation where the signed consent is waived, the IRB may require the investigator to
provide subjects with a written statement regarding the research.
2- Except as provided in item (1) of this section, 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. A copy shall be given to the person signing the form.
3- Except as provided in item (1) of this section, the consent form may be one of the following:
   - A written consent document that embodies the elements of informed consent. This form may be
read to the subject or the subject’s legally authorized representative, but in any event, the investigator
shall give either the subject or the representative adequate opportunity to read it before it is signed.
   - A ‘short form’ written consent document stating that the elements of informed consent have been
presented orally to the subject or representative. When this method is used, there shall be a witness
to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the
subject or the representative. Only the short form itself is to be signed by the subject or the
representative. However, the witness shall sign both the short form and a copy of the summary,
and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary
shall be given to the subject or the representative in addition to a copy of the ‘short form’.

IRB SUBMISSION AND REVIEW PROCESS
1- If you are sure that your project qualifies as a Human Subject Research, complete the Human Subject
Research Determination Form and submit it to the IRB coordinator. If you are instructed to apply for IRB
exemption or approval, proceed to step (2).
2. To apply for exemption (review the categories for exemption) from IRB approval, complete a request for exemption form. If your research is not exempt, complete an IRB application and attach evidence and required signatures and mail them to the committee. Alternately, you may e-mail pdf files with signature pages scanned to the e-site. Be sure to provide certification that you have completed the required training to conduct Human Subject Research.

3. Your application will be reviewed to determine if it is complete. Incomplete applications will be rejected and returned to the investigator. Completed applications will be evaluated to determine if they fall within one or more of the specified categories of exempt research or if they should have either an expedited (review the categories for expedited review) or full board review.

4. Exempt requests will be reviewed by the IRB coordinator and/or the designated IRB member. Once it is determined if an application is exempt, the investigator will be informed of the decision. Denials will be forwarded to the IRB chairperson for expedited review.

5. Expedited requests will be reviewed by the IRB chairperson or the designated IRB member and/or coordinator. Approvals will be valid for up to one year. Denials for expedited review will be forwarded for full board review by the IRB. The investigator will be informed of the decision.

6. Work on a project cannot extend beyond the date approved by the IRB. If it is necessary for work to extend beyond this date, a Continuation/Termination Request must be submitted.

7. Work on a project cannot be modified from the approved protocol. If any changes are to be made, a Modification Request Form must be submitted.

8. No research can be conducted until the investigator has received confirmation from the IRB coordinator that the application is either exempt or approved, or in the case of renewals and modifications, until they are approved.

Meeting Procedure

The IRB will meet four times per academic year to review applications. Approved applications will be valid for up to three years.

Submission Material

- A Complete Application Form signed by both the Primary Investigator (PI) and/or the Scientific Department Chairperson.
- When appropriate, any and all necessary appendices required by the Application Form.
- English or Arabic consent forms, unless a waiver of documentation of informed consent is being requested by the PI.
- Participant/Subject recruitment materials and samples (e.g. advertisements, brochures, flyers, video tapes or letters to potential subjects) that will be used to inform people about the study (if applicable).
- Questionnaires, tests and/or surveys that will be used in the research study. If this is a pilot study and the final survey(s)/questionnaire(s) is/are still under development, provide examples of the types, content and general subject matter to be covered.
- Curriculum vitae of the PI and co-investigators.
- Clinical Investigator Brochure in case of a sponsored clinical trial (if applicable).
- Insurance Certificate from sponsor or Clinical Trial Agreement, which documents that subject injury medical expenses are covered by sponsor (if applicable).

Estimated Review Schedule

The review schedule dates are calculated from the time of submitting a complete application. Some applications may be reviewed and approved before or after the stated timings based on the complexity of the study and reviewer concerns.

- Exempt Research Studies: announced within 3-4 weeks of review and approval.
- Expedited Review requires approximately 6-8 weeks for review and approval.
- Full Committee Review should be submitted at least four weeks prior to the IRB meeting date; review and approval by the IRB may require from 1-3 months after initial IRB review at a convened meeting.
BAU Institutional Animal Care and Use Guidelines (IACUG) are intended to facilitate the IRB review of research concerning animals.

This is to ensure that animal care and handling for the research proposed are performed in accordance with the regulations and guidelines stipulated by the BAU Institutional Review Board (IRB).

IRB has the right to regularly monitor compliance to the ethical guidelines of the approved protocols until the research is completed.

In the words of Gandhi:

“The greatness of a nation and its moral progress can be judged by the way its animals are treated.”

**ROLE OF IACUG**

Institutional Animal Care and Use Guidelines (IACUG) are established to prove safety and welfare of experimental animals used for research and ensure that the experiments will be performed to safeguard the rights, safety and wellbeing of the animals. IACUG should ensure the full review and evaluation of all ethical aspects of the research proposals it receives before they are carried out to make sure they follow ethical guidelines. The tasks of the review are performed free of bias and influence.

The IRB provides independent and timed decisions based on adherence to the guidelines detailed hereafter. These guidelines are based on the Animal Welfare Act and the Canadian Council on Animal Care’s (CCAC) Guide to the Care and Use of Experimental Animals.

The IACUG are to be also involved in the on-going monitoring of the approved research.

The IACUG take into account the interests and needs of researchers and the requirements of relevant regulatory and applicable laws.

The IACUG herein provide applicants with all the terms of references that set out the work expected of the committee in a standard operating procedure (SOP). The nature of the research determines what is required; it may include format sheets for applications (Form A-I, A-III).

The IACUG is willing to extend its role as an authority in ethical issues concerning research conducted on animals by participating in:

1. Cooperating, advising, and supporting other relevant committees, such as the Faculty Research Committee, in matters of common interest.
2. Promoting community awareness and consulting with individuals, communities, and the government on ethical issues related to research on animals.
3. Keeping up-to-date with international developments in relation to animal care and handling issues and communicating with relevant international organisations and individuals.
COMMUNICATION WITH IACUG

All communications and submitted applications are performed directly and sent through e-mail or regular mail to the committee. Online applications are accepted for review, but the final decision is withheld until a hard copy is submitted with the signature of the applicant.

The application file should include:
1. Before starting the project, Project Information-Research Involving Animals Form (Form A-I) should be submitted for approval.
2. After completing the research, a Project Completion Form (Form A-III) should be submitted to get a final approval letter (Form A-IV).

APPROVAL CONDITIONS AND DECISION MAKING

Submitted research proposals would be ideal if they have been previously reviewed by a relevant scientific committee and found to be scientifically valid. However, where there is no such separate review, the IRB needs to consider the scientific value and validity justification, methodology, proposed analytical methods, etc. as well as ethical issues stated hereafter.

Communications and decisions are given in a written form under the signature of the IRB chairperson or coordinator in the relevant form (Form A-II).

Positive Decision
The approval decision is subject to the adherence of the researcher to the qualification criteria. Any non-adherence leads to withdrawal or suspension of the approval.

Final approval and letter to publishing editors (Form A-IV) is granted according to the follow-up and submission of the research completion sheet.

Conditional Positive Decision
A conditional approval may be granted based on the researcher’s compliance with the conditions stipulated by IRB. The applicant may be asked to submit the required amendments in new sheets. A period of validity of the approval may be stated. The decision is stated in the final decision form (Form A-II).

Negative Decision
In case of a negative decision, a clear statement of the reasons for the negative decision is communicated to the researcher in a special standard format (Form A-II). This involves reasons for refusal and includes whether it may be submitted as a new proposal with appropriate changes. The right to appeal should be submitted only to the IRB.

Ethical Review and Guidelines for Research Using Animals

The IRB believes that the use of animals in research is acceptable only if it promises to contribute to understanding of fundamental biological principles or to the development of knowledge that can reasonably be expected to benefit humans or animals. Animals should be used only if the researcher’s best efforts to find an alternative have failed. Individuals using animals should employ the most humane methods on the smallest number of appropriate animals required to obtain valid information.

The following guidelines and principles should be applied in conjunction with the Animal Welfare Act and Canadian Council on Animal Care’s (CCAC) Guide to the Care and Use of Experimental Animals.

1. If animals must be used, it should be maintained in a manner that provides for their physical comfort and psychological well-being, according to CCAC’s policy statement on: social and behavioral requirements of experimental animals.
2. Animals must not be subjected to unnecessary pain or distress. The experimental design must offer them every practicable safeguard. Cost and convenience must not take priority over the animal’s physical and mental well-being.
3. Expert opinion must show the potential value of studies with animals. The following procedures, which are restricted, require independent external evaluation to justify their use in burns, freezing injuries, fractures, and other types of trauma investigation in anesthetized animals. All this must be in concomitant to acceptable veterinary practices for the relief of pain, including adequate analgesia during the recovery period.
4. If pain or distress is a necessary concomitant to the study, it must be minimized both in intensity and duration. Investigators, animal care committees, grant review committees and referees must be especially cautious in evaluating the proposed use of the following procedures:
   - Experiments involving withholding pre and post-operative pain-relieving medication.
   - Paralyzing and immobilizing experiments where there is no reduction in the sensation of pain.
   - Electric shock as negative reinforcement.
   - Extreme environmental conditions such as low or high temperatures, high humidity, modified atmospheres, or sudden changes therein.
   - Experiments studying stress and pain.
   - Experiments requiring withholding of food and water for periods incompatible with the species-specific physiological needs; such experiments should have no detrimental effect on the health of the animal.
   - Injection of Freund’s Complete Adjuvant must be carried out in accordance with CCAC guidelines on acceptable immunological procedures.
5. An animal observed to be experiencing severe un-relievable pain or discomfort should immediately be humanely killed using a method providing initial rapid unconsciousness.
6. While non-recovery procedures involving anaesthetized animals, and studies involving no pain or distress are considered acceptable, the following experimental procedures inflict excessive pain and are thus unacceptable:
- Utilization of muscle relaxants or paralytics (curare and curare-like) alone, without anaesthetics during surgical procedures.
- Traumatizing procedures involving crushing, burning, striking, or beating in un-anaesthetized animals.
- Studies such as toxicological and biological testing, cancer research and infectious disease investigation may, in the past, have required continuation until the death of the animal. However, in the face of distinct signs that such processes are causing irreversible pain or distress, alternative endpoints should be thought to satisfy both the requirements of the study and the needs of the animal.
- Physical restraint should only be used after alternative procedures have been fully considered and found inadequate. Restrained animals must receive exceptional care and attention in compliance with species-specific and general requirements.
- Painful experiments or multiple invasive procedures on animals should be done without pain using adequate anaesthesia.
- Waste disposal should be in compliance with BAU waste handling procedures that meet local environmental requirements. This is essential to ensure the safe transport and disposal of waste, especially animal waste. Bags and containers for medical waste are colour-coded (yellow) and labelled as biohazard or medical waste. Such waste is placed in appropriate leak-resistant bags and then yellow containers bearing the international black biohazard symbol and clearly marked medical waste. Medical waste and sharp containers are stored securely before being periodically collected by licensed waste contractors for final disposal using approved technology by licensed/accredited contractors (for detailed procedures, please contact +961 1300110 Ext: 2554).

**FOLLOW-UP**

Institutional Animal Care and Use Guidelines (IACUG) consider the advisability of monitoring progress of research approved by them.

**Submission of Progress Reports**

The IRB may call for reports at predetermined intervals every twelve months. On the conduct of the research during projects and on completion to help the IRB in formulating its guidance, reports should be submitted so that the IRB can be assured that projects continue to conform to the approved ethical standards. A final report should be followed at the end of the project.

“This will not in any way reduce the responsibility of the researcher to ensure such conformity.”

**Publication of Results**

The IRB will maintain a record of all proposed research projects and may require a formal report on completion of the project in order to review the outcome of the research and its contribution to knowledge.

Publication confirmation of results together with a reprint may be requested.
FORMS

Human Forms
1. IRB Face Page (Form H-I)
2. Protocol Application Checklist (Form H-II)
3. Protocol Application Checklist (Form H-III)
4. Protocol Application Checklist (Form H-IV)
5. Protocol Application Checklist (Form H-V)
6. Informed Consent Form (English Version) (Form H-VI)
7. Informed Consent Form (Arabic Version) (Form H-VII)
8. Parental Permission Form (English Version) (Form H-VIII)
9. Parental Permission Form (Arabic Version) (Form H-IX)
10. Assent Form (English Version) (Form H-X)
11. Assent Form (Arabic Version) (Form H-XI)
12. Research Project Final Approval Letter (Form H-XII)

Animal Forms
1. Project Information - Research Involving Animals (Form A-I)
2. Project Information - Final Decision (Form A-II)
3. Project Information - Completion of Research (Form A-III)
4. Research Project Final Approval Letter (Form A-IV)

Institutional Review Board Face Page (Form H-I)

Pl Name:
Correspondent Name:
Faculty:
Department/Division:
Protocol Title:

Instructions: When submitting documents to the Institutional Review Board, please check off all that apply for this submission. Be sure to include the protocol number and all attachments as noted in this sheet.

Please indicate whether this submission is for an expedited or full review and check all submitted documents. Be sure to include the correct number of copies with each submission as indicated and all applicable documentation. If incomplete, the documents will be returned to you.

☐ New Protocol Application - Signed (H-I)
☐ Expeditied Review
☐ Original (required)
☐ One Copy (required)
☐ Consent Form(s)/Information Sheet(s) (required)
☐ Full Review
☐ Original (required)
☐ Eight Copies (required) + Soft
☐ Consent Form(s)/Information Sheet(s) (required)

Please note: Complete documentation must be provided at the time of continuing review or study termination. If your protocol has been modified since your last IRB review, please provide a comprehensive protocol inclusive of all modifications and an Amendment Review Form (H-III).

☐ Re-approval - Signed (H-II)
Protocol Number:

☐ Protocol Application (H-I) (2) (Current Copies)
☐ Consent Form/Information Sheet / Assent Form (Clean Copy)
☐ Consent Form/Assent Form (Submit 4 signed with last names blacked out)

Please note: Any change to an existing protocol must be approved by the IRB prior to its implementation. Please submit a complete document.
Protocol Application Checklist (Form H-II)

PI Last Name:
Protocol Number:
Date of Meeting/Review:

SECTION I
General Information
Nature of Study/Specialty: Other Investigators:
Study Title: Collaborating Institutions:
Study Objectives: Study Location:
PI: Correspondent:
Notes:

SECTION II
Human Subjects
Anticipated Total Enrollment: Recruitment:
Subject Population: Special Population(s):
BAU Students or Employees:

Inclusion/Exclusion Criteria
Are the inclusion/exclusion criteria clearly stated and reasonable? Yes No N/A
Are the selection of subjects appropriate and equitable? Yes No N/A
Are minorities, women, children or other vulnerable populations included? Yes No N/A
Is the inclusion or exclusion of minorities, women, children and other vulnerable populations justified? Yes No N/A
Are additional safeguards in place to protect subjects who may be vulnerable to coercion or undue influence? Yes No N/A

Recruitment
Are recruitment methods for all subjects groups well defined? Yes No N/A
Are the location, setting, and timing of recruitment acceptable? Yes No N/A
Are all recruitment materials submitted? Yes No N/A
<table>
<thead>
<tr>
<th>Forms</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

**BAU Institutional Review Board**

**Research Plan**

- **Purpose:**
- **Benefits:**
- **Introduction:**
- **Risk/Benefit Analysis:**
- **Design, Procedures, Materials, and Methods:**
- **Economic Considerations:**
- **Data Analysis/Justification of Sample Size:**
- **Data and Safety Monitoring:**
- **Inclusion/Exclusion Criteria:**
- **Confidentiality:**
- **Risks and Inconveniences:**

<table>
<thead>
<tr>
<th>Specific Aims, Background, and Significance</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

- Are the study aims/objectives clearly specified?
- Adequate preliminary data to justify research?
- Are adequate references provided?
- Is there appropriate justification for this research protocol?

<table>
<thead>
<tr>
<th>Scientific Design</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

- Is the rationale for the proposed number of subjects reasonable?
- Is the scientific design adequate to answer the study's question(s)?
- Is the scientific design adequately described and justified?
- Are the study aims/objectives likely to be achieved within the given time period?
- Are there adequate plans for data safety and monitoring?
- Are the plans for data and statistical analysis defined and justified?

<table>
<thead>
<tr>
<th>Research Procedures</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

- Are the rationale and details of research procedures adequately described?
- For treatment studies, is there a clear differentiation between research procedures and standards of care and evaluation?
- Are there adequate plans to inform subjects about research results?

<table>
<thead>
<tr>
<th>Resources</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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</thead>
</table>

- Are there appropriate resources to conduct this research (e.g. equipment, space, lab, staff)?
- Is appropriate monitoring of subjects during and after the research assured?
- Will counseling or support services be provided, if applicable?
- Are provisions included for research related injuries, if applicable?

<table>
<thead>
<tr>
<th>Economic Considerations</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

- Is compensation to subjects reasonable, not coercive?
- If the subject does not complete the study, will compensation be pro-rated?
- For student participants, is experimental credit offered and clearly defined?

<table>
<thead>
<tr>
<th>Risks and Benefits</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

- Are the risks and benefits adequately identified, evaluated and described?
- Are the risks reasonable in relation to the benefits?
- Are the risks reasonable in relation to importance of knowledge to be gained?
- Are the risks minimized to the least extent possible?

<table>
<thead>
<tr>
<th>Subject Privacy and Confidentiality</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

- Are there adequate provisions to protect the privacy of subjects?
- Are there adequate provisions to protect the confidentiality of data during and after research?
- Are there adequate provisions for storage, coding, and use of identifiers?

**Notes:**

**Notes (if any):**
SECTION IV
Informed Consent

Consent Setting:
Requesting Waiver or Alteration of Consent:
Capacity to Consent:
Requesting Waiver of Signed Consent:
Parental Permission and Assent:
Documentation of Consent:

Process of Obtaining Consent/Assent

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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</table>

Is the process well defined?
Does this process provide sufficient time, privacy and adequate setting for the subject to consider?
Is the individual(s) obtaining consent/assent suitable?
Are issues of the subject’s comprehension and autonomy considered?

Notes (if any):

Signature
PI:
Department Chairperson:

Other Study Materials

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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</table>

Are all applicable materials attached to the submission (e.g., recruitment flyers, questionnaires, medical history forms, etc.)?
Should the protocol be reviewed more often than once per year?
Are there any notable conflicts of interest?
For studies that involve collaborating institutions or investigators, has the correct paperwork been submitted?

REVIEWER’S FINAL ASSESSMENT/OPINION

Approval
☐ No changes: there is an acceptable risk/benefit ratio and protocol is acceptable as submitted.

Conditional Approval
☐ Minor changes needed for the informed consent document, protocol or other study materials.
☐ Minor clarification(s) concerning specific aspects of study or additional information requested from PI.

Deferral
☐ There is an unacceptable risk/benefit ratio.
☐ Protocol is poorly written or lacking significant amounts of information regarding scientific justification, study procedures, risk reduction, etc.
☐ It is possible that a response from the investigator could alter the risk/benefit ratio.
☐ There are ethical concerns which can be addressed by obtaining more information or requiring changes in study design and procedures.

Disapproval
☐ Risks significantly outweigh the benefit or value of the knowledge to be gained.
☐ There are significant ethical concerns or questions that deem the study unacceptable.
Protocol Application Checklist (Form H-III)

PI:
IRB No:
Project Title:

Check current status below and complete the appropriate section for that option.
☐ This research is still active and being conducted according to the currently approved procedures. I wish to renew the IRB Approval for this study.

Complete SECTION A and SECTION C, sign and return this form.
☐ The research has never been initiated, but will be conducted according to the currently approved procedures. I wish to renew the IRB Approval for this study.

Complete SECTION B and SECTION C, sign and return this form.

IMPORTANT
This form is for renewal of the IRB approval of Human Subjects Research without revision. If the research has been revised since its most recent approval, or you intend to revise the research, submit a Request for Amendment Form to the IRB in addition to the Continuing Review.

SECTION A (for researches in progress).
1. Activity Status (choose only one)
   ☐ The research involves pre-existing records or samples only and no interaction/intervention with participants (skip to point 5).
   ☐ New participant recruitment is still in progress.
   ☐ Enrollment is closed, but participants are still undergoing study procedures.
   ☐ Enrollment is closed; participants have completed study procedures but are still in follow-up.
   ☐ Remaining study activity is limited to analysis only with no further contact with participants.
2. Describe any adverse events or participant complaints related to study procedures and show how you handled each.

3. Were any of these events unexpected or more serious than expected?
   ☐ Yes ☐ No

4. Describe any additional risks or benefits observed during the course of the study.

5. Participant/Numbers
   ☐ Number of participants actively enrolled or records/samples being reviewed (at present).
   ☐ Number of participants enrolled or records/samples reviewed since most recent approval.
   ☐ Number of participants enrolled or records/samples reviewed since original approval (Total).
   ☐ Number of additional participants to be recruited or records/samples needed to complete the study.

6. Provide a summary of your progress to date.

7. When do you expect the research to be completed?

SECTION B (For studies that have never been initiated).
1. Provide an explanation of why the research was never initiated.
2. List any additional risks that have been identified since the most recent approval.

SECTION C (for all research).
1. Informed Consent Procedures (choose only one)
   ☐ The remaining research procedures do not involve interaction or intervention with human participants and/or no participants will be recruited.
   ☐ I will continue to use the IRB stamped consent/permission/assent form(s) to recruit participants without revision.

Attach an electronic copy of the approved consent/permission/assent form(s) with IRB approval stamp.
**Protocol Application Checklist (Form H-IV)**

**PI Last Name:**
**Protocol Number:**
**Date of Meeting/Review:**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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</table>

- For each proposed amendment, does the PI provide a rationale for why the amendment is being made?
- For each proposed amendment, does the PI address whether the proposed amendment increases the level of risk to participants?

**SECTION I - GENERAL INFORMATION**

- **Key Personnel**
  - Any changes to Key Personnel!
  - If so, are changes, including the new researcher’s roles/responsibilities, properly documented?
  - Do the changes raise any human subjects training issues?
  - Is the amendment significant enough to require a change to the study title… or to the Study Objective?

**Notes (if any):**

**SECTION II - COLLABORATING INSTITUTIONS/FACILITIES AND OTHER IRB REVIEWS**

- If new personnel are added from other institutions, is IRB approval from that institution needed?

**Notes (if any):**
SECTION III- FUNDING
If the protocol was amended to include a new funding source...

Are the study procedures described in the protocol the same as those described in the new grant?  
☐  ☐  ☐
If applicable, is there adequate funding in the budget to compensate subjects as described in the protocol?  
☐  ☐  ☐
In case of new funding, is review of the source and consideration whether an IRB Authorization Agreement, Individual Investigator Agreement, or other IRB review needed?  
☐  ☐  ☐
Are any investigators on this protocol required to submit the supplemental significant Financial Interest Review Form?  
☐  ☐  ☐
If Yes, identify the individual(s):

Notes (if any):

SECTION IV- HUMAN SUBJECTS

Will the number of participants change?  
☐  ☐  ☐
If so, is this reflected properly here and in the Justification of Sample Size/Data Analysis Section?  
☐  ☐  ☐
Is there adequate justification for the increase?  
☐  ☐  ☐
Does participant selection remain equitable?  
☐  ☐  ☐
Are recruitment procedures amended?  
☐  ☐  ☐
If so, does recruitment material meet current standards?  
☐  ☐  ☐
Is permission from off-campus site required?  
☐  ☐  ☐
Are there concerns about coercion because of the changes?  
☐  ☐  ☐
Are special/vulnerable populations currently being recruited?  
☐  ☐  ☐
If so, are consent procedures still adequate?  
☐  ☐  ☐
Do study documents need to be translated?  
☐  ☐  ☐
Does the recruitment material/process meet current standards?  
☐  ☐  ☐

Notes (if any):

SECTION V- DRUGS/DEVICES, GENETIC TESTING, RADIATION, AND BIOLOGICAL SAMPLES

Are biological samples currently being collected?  
☐  ☐  ☐
If so, was approval from the biosafety office submitted?  
☐  ☐  ☐
If changes were made to the amount of samples collected, is this reflected in the study procedures and consent form?  
☐  ☐  ☐
Are procedures involving use of radiation currently being used?  
☐  ☐  ☐
If so, was approval from the radiation safety office submitted?  
☐  ☐  ☐
Are the new procedures adequately documented in the procedures section and risks identified in the risk section and reflected in the consent form?  
☐  ☐  ☐

Notes (if any):

SECTION VI- RESEARCH PLAN

Design, Procedures, Materials, and Methods

Were changes made to the research design and procedures?  
☐  ☐  ☐
If so, does the change impact the scientific integrity of the study?  
☐  ☐  ☐
Does the amendment increase the amount of time for the participants?  
☐  ☐  ☐
If so, was the consent form revised?  
☐  ☐  ☐

Notes (if any):

Justification of Sample Size/Data Analysis

Does the amendment require a change in sample size?  
☐  ☐  ☐
Do data analysis procedures need to be changed as a result of the amendment?  
☐  ☐  ☐
Is the sample size still adequate to achieve meaningful results?  
☐  ☐  ☐
Is there an increased likelihood of attrition?  
☐  ☐  ☐

Notes (if any):
### Inclusion/Exclusion Criteria

<table>
<thead>
<tr>
<th>Should the criteria be changed as a result of the amendment?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>If so, were the screening procedures and consent form revised?</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Is exclusion of certain participants still justified?</td>
<td>☐</td>
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</tbody>
</table>

**Notes (if any):**

### Risks and Inconveniences

<table>
<thead>
<tr>
<th>Does the level of risk change?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>If so, are the risks and procedures to minimize risk adequately addressed?</td>
<td>☐</td>
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<tr>
<td>If so, is risk greater than minimal requiring review by the full board?</td>
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<tr>
<td>If so, does the risk/benefit ratio change?</td>
<td>☐</td>
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</tr>
<tr>
<td>If so, was the consent form appropriately revised?</td>
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<tr>
<td>Are the risks still reasonable in relation to the benefits?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are the risks still reasonable in relation to importance of knowledge to be gained?</td>
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</table>

**Notes (if any):**

### Data Safety Monitoring

<table>
<thead>
<tr>
<th>Does the Data Safety Monitoring plan need to be changed because of the amendment?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

**Notes (if any):**

### Privacy/Confidentiality

<table>
<thead>
<tr>
<th>Are procedures to protect privacy and confidentiality still adequate?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>If not, are changes required?</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Were appropriate changes made to the consent form?</td>
<td>☐</td>
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</tbody>
</table>

**Notes (if any):**

### SECTION VII- INFORMED CONSENT

<table>
<thead>
<tr>
<th>Are appropriate changes as a result of the amendment reflected in the revised consent form?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there an increased need to assess capacity to consent?</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Should currently enrolled participants be re-consented?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Should previously enrolled participants be re-consented?</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Is the consent process still appropriate for all populations?</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Does the consent form/process meet current standards?</td>
<td>☐</td>
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</tr>
<tr>
<td>Should participants be afforded an increased level of privacy during consent?</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>Are previously granted waivers of consent/signed consent still appropriate?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Can a waiver of consent/signed consent be granted now?</td>
<td>☐</td>
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</table>

**Notes (if any):**

**REVIEWER RECOMMENDATIONS SUMMARY**

**Level of Risk**

- ☐ Remains...
- ☐ Has changed to...

**Minimal risk** (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)

- ☐ Greater than minimal risk

**Are the risks still reasonable in relation to anticipated benefits?** | Yes | No | N/A |
|------------------------------------------------------------------|-----|----|-----|
**Are the risks minimized through sound research design?** | ☐   | ☐  | ☐   |

**Recommended IRB Determination (check one):**

- ☐ Approve as submitted
- ☐ Requires Modifications to Secure Approval (summarize below)
- ☐ Defer (summarize below)
- ☐ Disapprove (summarize below)
LENGTH OF APPROVAL PERIOD
Continuing review of research should be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year.

If applicable, does the amendment increase risks such that the protocol should be reviewed more frequently?

☐ Yes  ☐ No  ☐ N/A

Are there concerns that warrant continuing review at 6 months or other time frame?

☐ Yes  ☐ No  ☐ N/A

If so, what time frame is appropriate?

Protocol Application Checklist (Form H-V)

PI Last Name: 
Protocol Number: 

SECTION I- GENERAL INFORMATION
Nature of Study: Other Investigators: 
Study Title: Other IRB Reviews: 
Study Objectives: Collaborating Institutions: 
Principal Investigator: Study Location:

SECTION II- ABSTRACT
Provide an abstract of the proposed research. The abstract should summarize the objectives of this project and the procedures to be used with an emphasis on what will happen to the participants.

SECTION III- RISK CLASSIFICATION
What is the overall risk classification of the research?
Minimal: If the classification is minimal risk, please justify why that category is appropriate.
Greater than minimal: If the research involves greater than minimal risk, then it is not eligible for exemption.

SECTION IV- PARTICIPANTS
Describe the participants who will be included in this research. Identify the location(s) in which participants will be recruited.

- Indicate if any of the following will be included in this research:
  - Children
  - Cognitively Impaired
  - Institutionalized Persons
  - Prisoners
  - Students
  - Employees
  - Pregnant Women/Fetuses/Neonates
  - Handicapped
SECTION V- INSTRUMENTS
Describe the instruments, if any, to be used to collect data in this study:
Attach copies of all questionnaires, surveys, interview questions, etc. If the research involves interviews that could evolve as the research progresses, include a list of discussion topics and any "starter" questions for each topic that are reasonably expected to be covered. If a draft of a written questionnaire or survey is attached, it should be clearly labeled as such, and a final version must be submitted before data collection begins.

SECTION VI- CONFIDENTIALITY
Describe what identifiers will be collected for the participants. If participants will be identified, describe the procedures in place to protect their confidentiality.

SECTION VII- PRIVACY
Explain provisions to protect privacy interests of participants. This refers to how investigators will contact participants and/or access private information from or about participants during and after their involvement in the research (e.g. time, place, etc. of research procedures).

SECTION VIII- CONSENT
a- Will consent be obtained from participants?
   Yes. If yes, describe how consent will be obtained and documented.
   No. If no, explain why this is justified.
b- If consent will be obtained, will consent be documented?
   Yes. If yes, describe how consent will be documented.
   No. If no, explain why this is justified.

Note: All of the data or materials must exist prior to proposing the research.
Please submit a signed application along with initialled supplements to the IRB office.
PRINCIPAL INVESTIGATOR: I will conduct the study identified above in the manner described. If I decide to make any changes in the procedure, or if a participant is injured, or if any problems occur which involve risk or the possibility of risk to participants or others, I will immediately report such occurrences or contemplated changes to BAU Institutional Review Board.
Please print your name:
Date:

THIS SECTION IS FOR IRB OFFICE USE ONLY
IRB Protocol Number:
Reviewed by:

Informed Consent Form (English Version) (Form H-VI)

Title: [Title of the research study as it appears on the IRB application. If multiple consent forms will be used, add subtitles to clarify the target population].
PI: [Name and BAU affiliation].
Date: [Date the form was prepared].

Purpose of Research Study
- Begin as follows:
  The purpose of this research study is [describe the purpose in a way that makes the potential value of the study clear].
- Include the following statement or an appropriate paraphrase:
  We anticipate that approximately [insert number] people will participate in this study.

Procedures
- Briefly describe what the participant will be asked to do and identify any procedures that are experimental (e.g. non-standard instructional methods).
- Give the expected duration of the participant’s participation, indicating the expected number and duration of each session.

Risks/Discomforts
- Describe any reasonably foreseeable risks and discomforts to the participant.
- If appropriate, include the following statement:
  Participation in this study may involve risks that cannot be foreseen at this time.
- For studies involving minimal risk, use the following statement, including or excluding the material in brackets as appropriate:
  The risks associated with participation in this study are no greater than those encountered in daily life [or during the performance of routine physical or psychological examinations or tests].

Benefits
- Describe any benefits to the participant that may be reasonably expected from the research.
  The description should be clear and not overstated.
- If there are no benefits to the participant, include the following statement:
  There are no direct benefits to you from participating in this study.
- Describe benefits to others that may be reasonably expected from the research, such as benefits to other people suffering from a disorder being studied or benefits to the general public or society. For example, in the case of general benefits accruing from advances in knowledge about the topic under investigation, a statement such as the following might be included: This study may benefit society if the results lead to a better understanding of [insert topic].

Voluntary Participation and Right to Withdraw

Begin with the following statements:
Your participation in this study is entirely voluntary: You choose whether to participate. If you decide not to participate, there are no penalties and you will not lose any benefits to which you would otherwise be entitled.

If you choose to participate in the study, you can discontinue your participation at any time without any penalty or loss of benefits. If you want to withdraw from the study, please [explain what the participant should do to withdraw].
- If a decision to withdraw from the study would have any significant consequences for the participant, explain these consequences.
- If any special procedures are required for the participant’s safe withdrawal from the study, describe these procedures.
- Include this statement, if appropriate:

Circumstances that Could Lead Us to End Your Participation

Include this section if there are specific circumstances that could lead to the participant being taken out of the study.

Begin with these statements:
Under certain circumstances, we may decide to end your participation before you have completed the study. Specifically, we may discontinue your participation, if [describe possible reasons for terminating the participant’s participation (e.g. we determine that it would be unsafe for you to continue in the study)].
- If the list of reasons is not exhaustive, add this sentence:

Alternatives to Participation

Include this section when (a) the participant may benefit from participating in the study and (b) the same or similar benefits may be obtained in some other way. For example, in the case of an educational study that provides special tutoring to participants, include this section if the same or similar tutoring is also available to students not taking part in the study.

Describe the alternatives to participation that may confer the same or similar benefits.

Confidentiality

- Describe to what extent the confidentiality of records identifying the participant will be maintained. For most studies, the following statement will be appropriate: Any study records that identify you will be kept confidential. The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the BAU Institutional Review Board. (All of these people are required to keep your identity confidential). Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.
- Describe how the study records will be created, stored, and maintained to protect confidential information (e.g. use of code numbers rather than participants’ names on data sheets, or keeping records in a locked file cabinet). Some studies may require disclosure of information to other parties. For such studies, explain what information will (or may) be disclosed and to whom.

Compensation

Describe all payments or other compensation.

If no compensation is provided, include the following statement:
You will not receive any payment or other compensation for participating in this study.

If You Have Questions or Concerns

You can ask questions about this research study now or at any time during the study, by talking to the researcher(s) working with you or by calling [insert name and role] at [insert phone number].

If you have questions about your rights as a research participant or feel that you have not been treated fairly, please call the BAU Institutional Review Board at 00961 1 300110 Ext. 2743.

If You are Harmed by Participating in the Study

Include this section if the research is of greater than minimal risk and research-related harm (physical, psychological, social, financial, or other) to the participant is possible.
If you feel that you have been harmed in any way by participating in this study, please call [insert name and role] at [insert phone number]. Please also notify the BAU Institutional Review Board at 00961 1 300110 Ext. 2743.

Then state whether any compensation and/or treatment is available to participants who have been harmed and, if so, describe the compensation/treatment or indicate where further information may be obtained. Make clear whether treatment will be provided without cost to the participant or, instead, the participant will be required to pay.

If no compensation or treatment is available, include the following statement:

This study does not have any program for compensating or treating you for harm you may suffer as a result of your participation.

What Your Signature Means:
Your signature below means that you understand the information in this consent form. Your signature also means that you agree to participate in the study.

Participant's Signature:
Date:
Signature of Person Obtaining Consent:
الفوائد

- صف الفوائد المتوقعة من البحث والتي تعود على المشاركين وصفاً واضحاً.
- في حال عدم وجود أية فائدة، أذكر العبارة التالية:

لا توجد فوائد مباشرة تعود عليكم من خلال المشاركة في هذه الدراسة.

- صف الفوائد المتوقعة من البحث والتي تعود على الآخرين. ومنها الفوائد التي قد تعود على من يعانون من اضطرابات تتعلق بموضوع البحث أو فوائد تعود على العامة أو المجتمع، على سبيل المثال، في حالة الفوائد العامة الناتجة عن إجراء نسخة من البحث يمكن إضافة عبارة مثل:

هيئة هذه الدراسة يمكن أن تفيد المجتمع إذا ما أدت نتائجها إلى فهم أفضل لـ (تحديد الموضوع).

المشاركة التطوعية وحق الانسحاب

- إبدأ بالعبارة التالية.

إن مشاركتكم في هذه الدراسة هي مشاركة طوعية بالكامل. فإن قرار المشاركة قراركم. وفي حال قررتم عدم المشاركة فلن يكون هناك أية عواقب كما أنكم لن تخسروا أياً من الامتيازات التي تحق لكم. وفي حال اختيار المشاركة في الدراسة، يمكنكم التوقف عن المشاركة في أي وقت بدون أية عواقب أو فقد لأية امتيازات مستحقة. برجاء (أشرح ما يتوجب على المشارك القيام به لإتمام الانسحاب).

- إذا كان قرار الانسحاب من الدراسة سيكون له أية عواقب للمشارك، اشرح تلك العواقب.

- إذا اقتضى الأمر، أضف الجملة التالية في نهاية هذا الجزء:

إذا ما توصلنا إلى أية معلومات جديدة خلال الدراسة والتي قد تؤثر في قراركم بالاستمرار في المشاركة، فإننا سوف نناقش هذه المعلومات معكم.

الظروف التي قد تؤدي إلى إنهاء مشاركتكم

أضف هذا الجزء إذا ما كانت هناك ظروف بعينها قد تؤدي إلى إنهاء المشاركة عن الدراسة.

إذا كانت تطوعي في هذه الدراسة هي مشتركة طوعية بالكامل، فإن قرار المشاركة قراركم. وفي حال قررتم عدم المشاركة فلن تكون أية عواقب. وفي حال قررتم المشاركة في الدراسة، فإنه يمكن أن يؤدي إلى بعض الإجراءات المطلوبة، مثل:

- إذا كان هناك إجراءات خاصة بخصوص المشارك الذي سيؤثر في قراركم، يمكنك الإشارة إلى هذه الإجراءات.

- إذا كانت هناك إجراءات خاصة بخصوص المشارك الذي سيؤثر في قراركم، يمكنك الإشارة إلى هذه الإجراءات.

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Purpose of Research Study
- Begin as follows:
  The purpose of this research study is [describe the purpose in a way that makes the potential value of the study clear].
- Include the following statement or an appropriate paraphrase:
  We anticipate that approximately [insert number] children will participate in this study.

Procedures
- Briefly describe what the participant will be asked to do, and identify any procedures that are experimental (e.g. non-standard instructional methods).
- Give the expected duration of the participant's involvement in the research, indicating the expected number and duration of each session.

Risks/Discomforts
- Describe any reasonably foreseeable risks and discomforts to the participant.
- If appropriate, include the following statement:
  Participation in this study may involve risks that cannot be foreseen at this time.
- For studies involving minimal risk, use the following statement, including or excluding the material in brackets as appropriate:
  The risks associated with participation in this study are not greater than those encountered in daily life (or during the performance of routine physical or psychological examinations or tests).

Benefits
- Describe any benefits to the participant that may be reasonably expected from the research.
  The description should be clear and not overstated.
- If there are no benefits to the participant, include the following statement:
  There are no direct benefits to your child from participating in this study.
- Describe benefits to others that may be reasonably expected from the research, such as benefits to other people suffering from a disorder being studied or benefits to the general public or society.
Voluntary Participation and Right to Withdraw
- Begin with the statements below. Include the material in brackets when appropriate given the participants’ age and mental status.
  
  Your child’s participation in this study is entirely voluntary: You choose whether to allow your child to participate, [and we will also ask your child whether he or she agrees to take part in the study]. If you decide not to allow your child to participate, [or your child chooses not to participate], there are no penalties, and neither you nor your child will lose any benefits to which you would otherwise be entitled.
  
  If you [and your child] choose to participate in the study, you [or your child] can discontinue participation at any time without any penalty or loss of benefits. If you want to withdraw your child from the study [or your child wants to discontinue participating], please [explain what the parent or child should do to withdraw].
  
  - If a decision to withdraw from the study would have any significant consequences for the participant, explain these consequences.
  
  - If any special procedures are required for the participant’s safe withdrawal from the study, describe these procedures.
  
  - Include this statement if appropriate:
    
    If we learn any new information during the study that could affect whether you [or your child] want to continue participating, we will discuss this information with you [and your child].

Circumstances that Could Lead Us to End Your Participation
Include this section if there are specific circumstances that could lead to the participant being taken out of the study.

- Begin with these statements:
  
  Under certain circumstances, we may decide to end your child’s participation before he or she has completed the study. Specifically, we may stop your child’s participation if [describe possible reasons for terminating the participant’s participation (e.g., we determine that it would be unsafe for your child to continue in the study)].
  
  - If the list of reasons is not exhaustive, add this sentence:
    
    There may also be other circumstances that would lead us to end your child’s participation.
If you [or your child] have questions about your child's rights as a research participant or feel that your child has not been treated fairly, please call the BAU Institutional Review Board at 00961 1 300110 Ext. 2743.

If You are Harmed by Participating in the Study
Include this section if the research is of greater than minimal risk and research-related harm (physical, psychological, social, financial, or other) to the participant is possible.
If you feel that your child has been harmed in any way by participating in this study, please call [insert name and role] at [insert phone number]. Please also notify the BAU Institutional Review Board at 00961 1 300110 Ext. 2743.
Then state whether any compensation and/or treatment is available to participants who have been harmed and, if so, describe the compensation/treatment or indicate where further information may be obtained. Make clear whether treatment will be provided without cost to the participant or, instead, the participant will be required to pay.
If no compensation or treatment is available, include the following statement:
This study does not have any program for compensating or treating your child for harm he or she may suffer as a result of his or her participation.

What Your Signature Means
Your signature below means that you understand the information in this consent form. Your signature also means that you agree to allow your child to participate in the study. [Your child's signature indicates that he or she agrees to participate in the study]. By signing this consent form, you [and your child] have not waived any legal rights your child otherwise would have as a participant in a research study.

Child's Name: Date:
Child's Signature (if applicable): Date:
Signature of Parent: Date:
Signature of Second Parent (if required): Date:
Signature of Legal Guardian (if applicable): Date:
Signature of Person Obtaining Consent: Date:
(Investigator or IRB-Approved Designee)
Witness to Consent Procedures (if required by IRB): Date:
الفوائد
- صف الفوائد المتوقعة من البحث والتي تعود على المشاركين وفصاً ووضعاً.
- في حال عدم وجود أي فوائد، أذكر العبارة التالية: لا توجد فوائد مباشرة تعود على طفلكم من خلال المشاركة في هذه الدراسة.
- صف الفوائد المتوقعة من البحث والتي تعود على الآخرين، ومنها الفوائد التي قد تعود على من يعانون
- من اضطرابات موضوع البحث أو فوائد تعود على العامة أو المجتمع، على سبيل المثال: في حالة
- الفوائد العامة الناتجة عن إجراء تقدم في البحث يمكن إضافة عبارة مثل ما يلي:
- هذه الدراسة يمكن أن تفيد المجتمع إذا ما أدت نتائجها إلى فهم أفضل لـ (تحديد الموضوع).
- إذا ما توصلنا إلى أي معلومات جديدة خلال الدراسة والتي قد تؤثر في قراركم أو قرار (طفلكم) بالاستمرار
- في المشاركة، فإننا سوف نناقش هذه المعلومات معكم (ومع طفلكم).
- إذا كانت قائمة الأسباب غير واضحة:
- قد تطرأ ظروف أخرى قد تؤدي إلى إنهاء مشاركتكم.
- إذا اقتضى الأمر، أضف الجملة التالية في نهاية هذا الجزء:
- في حال أنهينا مشاركتكم قبل نهاية الدراسة، سوف نوفر التعويض عن مشاركته/ مشاركتها
- حتى تاريخه.
- بعض الدراسات تتطلب الكشف عن المعلومات لأطراف أخرى وفي مثل هذه الدراسة اشرح ماهية
- المعلومات التي سوف يتم أو قد يتم الكشف عنها وفقاً للمعاهدات بين مستEnjoy Arabic font pre-trained model.
Assent Form (English Version) (Form H-X)
(Under the age of 18 years in social/behavioral studies)

Title: [Title of the research study, as it appears on the IRB application. If multiple consent forms will be used, add subtitiles to clarify the target population].

PI: [Name and BAU affiliation].

Date: [Date the form was prepared].

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about [insert topic and describe goals in simple language]. You are being asked to join the study because [insert name of condition or other reason(s) for inclusion].

If you agree to join this study, you will be asked to [describe procedures, (e.g. questionnaires, activities) in words a child would know and understand. Also, include number of visits and time frame in words easily understood by a child].

Describe possible risks (e.g., discomforts) in simple language. Use any of the following statements that are appropriate: We do not know if being in this study will help you. We expect that the study will help you by [describe how]. We may learn something that will help other children with [insert name of condition or topic under investigation] someday. This study will help us learn more about [topic under investigation].

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop.

Before you say yes or no to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you want to be in this study, please sign your name. You will get a copy of this form to keep.

Sign your name here:

Date:
بروف. إندي م. و. نورث

استمارة موافقة (لمذهم دون 28 عاماً والمشاركون في الدراسات الاجتماعية/السلوكية)

العنوان: عنوان الدراسة كما هو مبين على طلب مجلس أخلاقات البحث العلمي (IRB) في حال استلام استمارات مختلفة. أضف العناوين الفرعية للوضوح (اللغة المستهدفة)

الباحث الرئيسي: (الاسم، والعمل، والعولمة) بروت العرية

ال التاريخ: (تاريخ إعداد الاستمارة)

نود أن نفيدك عن الدراسة البحثية التي نشأ بها. الدراسة البحثية هي سبيل التعرف الأفضل عن المواضيع المختلطة. نود أن نستكشف المنظم منها (صف العنوان، وصف مقدمتها بعبارات بسيطة)

نحثكم لأهمية الدراسةً لأنك (صف إعداد اثناء الاطفال للبحث)، وإذا ما أطلقنا على الدراسة أو المشاركة في هذه الدراسة فسوف يطلب منكم أن تدعي إصداراً، (صف البريد) وعندما تدعي إصداراً، (صف البريد) في حين تدعي إصداراً، (صف البريد)

ومع ذلك، فإننا نتوقع أن الدراسة سوف تفيدكم من خلال (صف حرف).

فقد تعرف على أهمية تجد على أطرافاً. إذا استلموا (صف اسم المتالعة أو الموضوع قبل البحث، وما سيستلهمها هذه الدراسة في التعرف على الموضوع في الدراسة، وما سيستلهمها هذه الدراسة في التعرف على الموضوع في الدراسة)

ليس أن نعدها على الدراسة الدراسية أو ما إذا تم الرفع عن فرارك للدقيمة. لا يمكن أن يكون كوراً أو الحاجز في الدراسة، ولكن يجب أن تكون بوريغون في الدراسة. إلا أننا نشجعكم على المشاركة في الدراسة، وإذا ما شاركتم في الدراسة لم تقعكم عن فراركم والسكتكم.

ومع ذلك، فإننا نتوقع أن تكون المشاركة في هذه الدراسة سوف تتيحكم الفرصة للتأكد من كيفية الاستفادة التي تقدم لكي. كما أننا نتمنى أن تكون المشاركة في هذه الدراسة، وإذا ما شاركتم في الدراسة، معلماً لشيء يعزز البحث.

إذا أردتم المشاركة في هذه الدراسة، يرجى توقع السؤال وسوف تحصل على نسبة من هذه الاستمارة للاختتاق بعذار

الاسم:

التوقيع:

التاريخ:

Research Project Final Approval Letter (Form H-XII)

Acceptance Number:

Journal Name:

Date:

Dear

By signing this form, we declare that:

Human subjects in the research titled hereafter were treated in accordance with the regulations and guidelines stipulated by the Institutional Review Board (IRB) at Beirut Arab University, Lebanon.

Research Title:

Main Correspondent Name:

Sincerely,

IRB Chairperson /Coordinator:

Date:
Project Information Form - Research Involving Animals
(Form A-I)

Application Number:                Date Received:
Reviewed By:  IRB-IACUG Meeting Date:
Form Type:  ☐ Original  ☐ Amendment

TITLE OF PROJECT/COURSE

INVESTIGATOR(S) [1st is the correspondent investigator/supervisor]
Title:
Name:
Qualifications:
Designation:
Place of Work:
Address:
Contact Number:
Email Address:
Signature:
☐ Principal Investigator  ☐ Co-investigator  ☐ Supervisor

Title:
Name:
Qualifications:
Designation:
Place of Work:
Address:
Contact No.:
Email Address

Objectives of the research/course:

In the case of a collaborative project, please list cooperation partner(s) and affiliation:

Animal species used:
Species
Number of Females
Number of Males

Animal source:
Place of performing the experimental part:

Briefly describe the experiment procedures:

Please report any expected problems:

- Any change of the above information and an amendment form must be attached and approved by the committee within 30 working days.
- By signing this form, we declare that we have carefully read, understood, and accept to abide by the general guidelines.

Correspondant Name:
Correspondant Signature:
Date:

Has ethical review for this study been requested earlier from IRB or another committee?
☐ Yes*  ☐ No
*Where:
*When:
*Result:
Project Information Form – Final Decision (Form A-II)

FOR OFFICIAL USE ONLY

The final decision is based on

Are all documents provided:  Yes No N/A

Comments:

Scientific Validity

1- Will the study lead to improvements in human wellbeing or increase knowledge?  ☐  ☐  ☐
2- Can the intervention method studied be practically implemented?  ☐  ☐  ☐
3- Has the research protocol been approved by a competent body?  ☐  ☐  ☐
4- Are the objectives stated clearly?  ☐  ☐  ☐
5- Is the study design appropriate in relation to the objectives?  ☐  ☐  ☐
6- Is the study designed using accepted principles, methods and practices?  ☐  ☐  ☐
7- Is there a plausible data analysis plan?  ☐  ☐  ☐
8- Are the investigators’ qualifications, competence and experience appropriate to conduct the study?  ☐  ☐  ☐
9- Are the facilities at the site adequate to support the study?  ☐  ☐  ☐

Assessment of Benefits/Risks

1- Are the researcher’s qualifications, competence, and experience suitable to ensure safe conduct of the study?  ☐  ☐  ☐
2- Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?  ☐  ☐  ☐
3- Is the site, including support staff, facilities and emergency procedures, adequate?  ☐  ☐  ☐
4- Have adequate provisions been made for safety monitoring and termination of the research project?  ☐  ☐  ☐

Project Compliance with the IACUC Requirements

1- Does the experiment design comply with the Animal Welfare Act, the Canadian Council on Animal Care requirements, and related laws and international standards?  ☐  ☐  ☐
2- Is the designated method of animal killing appropriate?  ☐  ☐  ☐
3- Are the procedures of sample storage and disposal adequate?  ☐  ☐  ☐

Responsibilities of the Researcher

1- Are there any conflicts of interest, including payments and other rewards?  ☐  ☐  ☐
2- Are there any other ethical / legal/social/financial issues in the study?  ☐  ☐  ☐

Additional Comments:

Recommendation:
☐ Approve  ☐ Reject  ☐ Conditional Approval (please state the conditions)

Name of Reviewer:

Signature:

Chairperson:

Signature:

Date:
Project Information Form – Completion of Research (Form A-III)

Application Number: [ ]
Date Received: [ ]
Reviewed By: [ ]
IRB Meeting Date: [ ]

TITLE OF PROJECT AND PLACE OF IMPLEMENTATION

INVESTIGATOR(S) [1st is the correspondent investigator/supervisor]

☐ Principal Investigator ☐ Co-investigator ☐ Supervisor

Title:
Name:
Qualifications:
Designation:
Place of Work:
Address:
Contact Number:
Email Address:
Signature:

Duration of the Experiment
From: [ ]
To: [ ]

Were any problems encountered in the following areas?

Study Design ☐ Yes ☐ No
Ethics ☐ Yes ☐ No
Finance ☐ Yes ☐ No
Facilities and Equipment ☐ Yes ☐ No

If yes, please summarise the problems encountered.

Please provide a one-page summary of the project outcomes

- In case of any change in the above information, an amendment form must be attached and approved by the committee within 30 working days.
- By signing this form, we declare that we have carefully read, understood, and accept to abide by the general guidelines.

Correspondant Name:
Correspondant Signature:
Date : [ ]
Research Project Final Approval Letter (Form A-IV)

Acceptance Number:

Journal Name:

Date:

Dear

By signing this form, we declare that:
Animal care and handling for the research titled hereafter were performed in accordance with the regulations and guidelines stipulated by the Institutional Animal Care and Use Guidelines (IACUG) at Beirut Arab University, Lebanon.

Research Title:

Main Correspondant Name:

Sincerely,

IRB Chairperson /Coordinator:

Date:

REFERENCES
2- The Universal Declaration of Human Rights.
3- The International Covenant on Civil and Political Rights.
4- The Council for International Organizations of Medical Sciences.
5- The World Health Organization.
6- UNAIDS Guidance Document on Ethical Considerations in HIV Preventive Vaccine Research.
7- Universal Declaration on Bioethics and Human Rights (19 October 2005).
14- Bridgewater State University
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INTRODUCTION

BACKGROUND

Beirut Arab University has established its Institutional Review Board (IRB) to review and approve the increasing number of research projects involving humans and animals conducted at/by BAU and the Affiliated University Hospitals.

All projects in which a university academic staff member or student investigates humans or animals for research purposes must be reviewed by the Institutional Review Board (IRB) prior to initiation of the project. It is the responsibility of the investigator to seek review of any study involving humans and animals.

The IRB is in charge of the institutional responsibility for assurance of protection of humans and animals involved in research or related activities.

RESPONSIBILITIES, AUTHORITIES, AND OBJECTIVES

Beirut Arab University’s Institutional Review Board (IRB) is a formally designated committee to review, approve, and monitor biomedical and behavioral research involving human subjects conducted by academic staff and students at BAU and/or its affiliates. BAU Institutional Review Board is also concerned in safeguarding animal rights. BAU’s IRB has the right to approve, require modifications in planned research prior to approval, or disapprove research. The IRB has the right to regularly monitor compliance to the ethical guidelines of the approved protocols at intervals of at least once per year until the research is completed.

The IRB reviews any research performed within the University premises or in collaboration with other institutes or hospitals either within the University or at other locations.

The IRB provides independent and timed decisions based on adherence to the guidelines in compliance with international declarations including Nuremberg, Helsinki, and Belmont declarations.
MISSION
The IRB aims to safeguard the protection of the dignity, rights, safety, and welfare of all actual or potential research subjects.

VISION
The IRB is looking towards modern approaches and concepts and practical and ethical scientific research to ensure the strengthening of the quality of scientific research in accordance with international standards for the service of society and the requirements of the labour market.

MEMBERSHIP
The Institutional Review Board (IRB) chairperson, coordinator and members are appointed by BAU administration at the beginning of each academic year, the duration of appointment lasts one year. The IRB has the freedom to work independently and decide on the merits of proposals without interference within the institutional framework.

The BAU Institutional Review Board is composed of at least eight members based on these criteria:

- The members must have enough collective experience, expertise, and diversity to make informed decisions on whether the research is ethical, informed consent is sufficient, and appropriate safeguards have been put in place.
- If the IRB works with studies that include vulnerable populations, the IRB should have members who are familiar with these groups.
- The IRB includes:
  - A physician, dentist, pharmacist, health sciences field member, and social behavioural science expert
  - A law expert
  - A "Community Member" familiar with social values, who is not affiliated with the institution or in the immediate family of a person affiliated with the institution.

Whenever there is a possibility of conflict of interest, members are asked to declare their association with the proposal and withdraw from the reviewing process. IRB members may not vote on their own projects.
ETHICAL GUIDELINES¹

International Instruments and Guidelines

The first international instrument on the ethics of medical research, the Nuremberg Code, was published in 1947 as a consequence of the trial of physicians (the Doctors Trial) who had conducted atrocious experiments on un-consenting prisoners and detainees during the Second World War. The Code, designed to protect the integrity of the research subject, set out conditions for the ethical conduct of research involving human subjects, emphasizing their voluntary consent to research.


The Covenant in “Article 7” states that “no one shall be subjected without his/her free consent to medical or scientific experimentation”. It is through this statement that society expresses the fundamental human value that is held to govern all research involving human subjects and the protection of the rights and welfare of all human subjects of scientific experimentation. The Declaration of Helsinki, issued by the World Medical Association in 1964, is the fundamental international document in the field of ethics in biomedical research; it has influenced the formulation of international, regional and national legislation and codes of conduct. The Declaration, amended several times, most recently in 2000, is a comprehensive statement of the ethics of research involving human subjects. It sets out ethical guidelines for researchers engaged in both clinical and nonclinical biomedical research.

After the publication of the Council for International Organizations of Medical Sciences³ (CIOMS) in 1993, many ethical guidelines on clinical trials have been published by several international organizations. This has included a publications by the World Health Organization⁴ in 1995 entitled Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products and a publication by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), in 1996 entitled, Guideline on Good Clinical Practice, designed to ensure that data generated from clinical trials are mutually acceptable to regulatory authorities in the European Union, Japan and the United States of America. The Joint United Nations program on HIV/AIDS published the UNAIDS Guidance Document Ethical Considerations in HIV Preventive Vaccine Research⁵ in 2000. On the other hand, UNESCO adopted the Universal Declaration on Bioethics and Human Rights⁶ in 19 October 2005.

When dealing with biomedical research involving human subjects, the international Human Rights instruments should be considered. The Universal Declaration of Human Rights, which, in particular in its scientific provisions, was highly influenced by the Nuremberg Code; the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights. Since the Nuremberg experience, Human Rights Law has expanded to include the protection of women (Convention on the Elimination of all Forms of Discrimination against Women) and Children (Convention on the Rights of the Child).

General Ethical Principles

The three basic ethical principles, namely respect for persons, beneficence, and justice should guide all research involving human subjects. These principles, which in concept have equal moral force, guide the conscientious preparation of proposals for scientific studies. They may be expressed differently in varying circumstances and given different moral weight and their application may lead to different decisions or courses of action.

Two fundamental ethical considerations are assimilated in “Respect” for persons, namely:
- Autonomy, respect for the capacity of self-determination in treating those who are capable of deliberation about their personal choices.
- Persons with impaired or diminished autonomy should be offered security against harm or abuse.

“Beneficence” refers to the ethical obligation to maximize benefit and minimize harm. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and safeguard the welfare of research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, no maleficence (no harm).

“Justice” refers to the ethical obligation to treat each person in accordance with what is morally right and proper and to give each person what is due to him or her. In the ethics of research involving human subjects, the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and benefits of participation in research. Differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons; one such distinction is vulnerability.

“Vulnerability” refers to a substantial incapacity to protect one’s own interests, owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons.

WORKING PROCEDURES

Meeting Procedures

- The IRB will meet four times per academic year and review applications. Approved applications will be valid for up to three years.
- The IRB meeting is called to order when a quorum of more than half of the members is present. Approval of an action requires a majority vote when a quorum is present. IRB members with conflicting interests cannot count towards quorum. The meeting ends when business is finished. The meeting agenda should be arranged and sent electronically one week before to all the members.
Voting System

1- Voting at a convened meeting takes place under the following conditions:
   - A quorum of the members must be present for all reviews/actions voted on at a convened meeting.
   - A passing vote must consist of a majority of members present voting in favour of the motion.
   - External consultant do not hold a voting right in the IRB.
   - External consultants will not participate in the vote.
   - Community members must always be present for a vote.
   - A physician must be present to vote on human subject regulated research.

2- If the outcome of the IRB vote is that modifications and/or additional information is required, the IRB chairperson or the coordinator may review and approve the PI’s response on behalf of the IRB.

Issuing and Reporting the Final Decision

Investigators will be notified electronically and/or by a formal letter of the decision of the IRB and any changes required. If minor specific changes are required, the changes, once returned, may be reviewed and approved by the chairperson or coordinator. The IRB chairperson or the coordinator may approve minor specific changes without return to the full board for review (e.g. address change, addition or deletion of study personnel, change in number of subjects to be recruited, etc.) The IRB shall notify investigators and the institution electronically via email of its decision to disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, the reasons for its decision will be sent electronically to give the investigator an opportunity to respond. Any Suspension or Termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported to the investigator.

Documentation Archival and Duration

The IRB, through its administrative staff, shall prepare and maintain adequate documentation of IRB activities, including the following:

1- Copies of all research proposals reviewed and any associated documentation or materials, including: scientific evaluations, sample consent documents, progress reports, amendments or extensions submitted by investigators, reports of incidents or injuries to subjects, and copies of all correspondences between the IRB and the investigators. FDA has specified record-keeping and record retention requirements; generally, FDA regulated research records must be kept for 2 years. Accordingly, BAU IRB regulations, research records are archived for 3 years after completion of all its activities while digital records are kept for more than 5 years.

2- Minutes of IRB meetings show attendance at the meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against and abstaining, the name of any person with a conflict of interest and reason for conflict, the basis for requiring changes in disapproved research proposals, and a written summary of the discussion of controversial issues and their resolution.

3- Listing of continuing review activities and research proposals that have been approved under the expedited and exempt review procedures.

4- A list of IRB members and working procedures guidelines.

Records required by this policy and those relating to conducted research shall be retained for at least three years after completion of the research. The records of the IRB pertaining to individual research activities will not be accessible outside the IRB and the individual researcher except for purposes of audit or inspection by federal agencies to assure compliance.

Funding Resources

BAU is the main and only source of funding for BAU Institutional Review Board. The IRB does not charge any fees for review of research studies involving human and animal subjects.

TYPES OF REVIEW

Exempt Research

Research that presents no more than minimal risks to non-vulnerable participants is exempt from the IRB’s review and approval process. The IRB chairperson or coordinator determines that a research project proposal qualifies as exempt from Expedited or Full Review. Research that falls into one of the categories below may be exempted from IRB review:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - Research on regular and special education instructional strategies.
  - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), or observation of public behavior, unless:
  - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.
  - Any disclosure of human subject responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

- Research involving watching public behavior of children, where the investigator does not take part in the activities.

- Research involving data, documents, pathological specimens, or diagnostic specimens publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
• Research and demonstration projects which are conducted by or subjected to the approval of department or agency heads with which the investigator is associated with the project.
• Public benefit or service programs.
• Procedures for obtaining benefits or services under those programs.
• Possible changes in or alternatives to those programs or procedures.
• Possible changes in methods or levels of payment for benefits or services under those programs.
• Taste and food quality evaluation and consumer acceptance studies.
• If wholesome foods without additives are consumed.
• If consumed food containing a food ingredient at or below the level of toxicity is found to be safe or if agricultural chemicals or environmental contaminants at or below the level of toxicity are 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 regulatory bodies.

Expedited Review

In some circumstances, if there is no more than minimal risk, expedited review can be conducted even on studies involving minors. Categories for expedited review are:
• Surveys/interviewing of children or observation of public behavior involving children when the researcher participates in the activity being observed.
• Surveys requesting information that expose the informant to criminal or civil liability or are extremely personal in nature in which the likelihood of associating the individual with the responses is very big.
• Collection of blood samples by finger stick, heel stick, ear stick, or veni-puncture not exceeding 50 ml or 3 ml per kg (whichever is less) in an eight week period, and collection may not occur more frequently than two times per week.
• Collection of hair and nail clippings in a non-disfiguring manner or of deciduous teeth and permanent teeth if patient care indicates a need for extraction.
• Collection of excreta, external secretions including sweat or un-cannulated saliva.
• Collection of both supra-and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth, and the process is accomplished with accepted prophylactic techniques.
• Recording of data from subjects using non-invasive procedures routinely employed in clinical practice, excluding X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for the market. Examples include the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or invasion of the subject's body orifices. Data collected includes body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

• Voice, video, digital or image recordings made for research purposes, such as investigations of speech defects. For example, an audio recording on which subjects are asked to speak common words for the purpose of measuring voice timber would qualify for Expedited Review. A recording of a therapy session with a patient would not qualify for Expedited Review; a Full Review would be required due to the sensitive nature of the contents.
• Research on individual or group behavior characteristics of individuals (such as studies of 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 factor evaluation, or quality assurance methodologies.

Full Review

Full review by the entire IRB panel is reserved for studies that have potential risk to human subjects. This may include, but is not limited to:
• Research involving the administration of new drugs or other substances.
• Research that materially affects the pregnancy of a woman or the health/well-being of fetuses in utero.
• Research involving subjects with life-threatening physical conditions.
• Research involving physically intrusive procedures.
• Research which previous experience (by the particular investigator or other investigators) has shown to create a potential of risk to subjects.
• Research that may result in a significant level of psychological or physical stress.
• Research which potentially could put the subject at risk for legal or civil liability or invade a subject's privacy in regard to sensitive aspects of his/her behavior (e.g. illegal conduct, drug use, sexual behavior, alcohol use) when there is a possibility that the subject could be identified.
• Research involving prisoners.
• Research that places protected populations (such as children, mentally retarded individuals, mentally ill individuals, and patients with medical disorders) at more than minimal risk.

Continuing Review

Continuing review of research conducted on human subjects by academic staff and students must be done in accordance with the policies and procedures outlined in this manual at intervals appropriate to the degree of risk but not less than once per year.

The IRB cannot approve a research project for more than 12 months. All reviews for continuation will be conducted by expedited review if no changes have been made to the research protocol and no adverse or unexpected reactions or side effects have occurred or are expected. (However, the full IRB will be given the opportunity to review the continuation/renewal report.) In all other instances, continuing the review will be conducted by the full IRB.
Revisions

If the investigator, during the course of conducting the research, revises the research protocol (e.g., makes changes to the informed consent form, survey instruments used, or number and nature of subjects), the principal investigator will notify the IRB chairperson immediately. The chairperson will determine the need for additional review and the type of review (Expedited or Full) and will notify the IRB members.

Suspension or Termination of Research

The IRB shall have authority to suspend or terminate research that is not being conducted in accordance with the IRB’s requirements and other institutional and governmental requirements or has been associated with any serious harm to subjects. Concerns regarding the conduct of research must be reported immediately to the chairperson of the IRB by any individual having such knowledge. Any Suspension or Termination of research must include a statement of the IRB’s action, and the chairperson must report its decision promptly to the principal investigator, the Dean and the funding agency in the case of a sponsored project.

Unintentional

In the event of research conducted without the intention of involving human subjects, which subsequently involves human subjects (by intention of the researcher), the research must be reviewed by the IRB in accordance with the policies and procedures outlined in this manual.

Criteria for IRB Approval of Research

Risks to Subjects

Risks to subjects are minimized:
- By using procedures that are consistent with a sound research design and which do not unnecessarily expose subjects to risk.
- Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
  1. Have the rationale and base for the study hypothesis been provided in the background information?
  2. Has the research been preceded by adequate laboratory and/or animal studies?
  3. Are the design of the research and the proposed research procedures adequate to answer the research questions?
  4. Can data from procedures or tests being performed for diagnostic or treatment purposes be used in lieu of procedures or tests being performed solely for research purposes?
  5. Could procedures that involve less risk be used to answer the research question?
  6. Is the sample size (number of subjects) adequate?
  7. Is the method proposed for selecting and assigning subjects to treatment groups unbiased?
  8. Are the study endpoints and methods of data analysis appropriate for the study?

Risk/Benefit Ratio

Risks to subjects are reasonable in relation to the anticipated benefits to subjects and importance of knowledge that may be reasonably expected to result:
  1. What are the anticipated physical, psychological, social, legal, or economic risks to individual subjects?
  2. What are the potential benefits, if any, to individual subjects?
  3. What information is likely to result from the research and what impact, if any, will the information have on furthering the understanding of human physiology, diagnosis, or treatment of the disease or condition being studied?
  4. Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research? Are the procedures for identifying such individuals adequate?
  5. Are there adequate plans to exclude subjects who are vulnerable to injury during the period of withdrawal of active and effective therapy, if that is part of the research design?

Selection of Subjects

Selection of subjects is equitable.
  1. Does the nature of the research require or justify using the proposed study population?
  2. Will the solicitation of subjects avoid placing a disproportionate share of the risks and discomfort as well as inconvenience of the research on any single group of individuals?
  3. Are women of childbearing potential eligible for participation or, if not eligible, has their exclusion been justified?
  4. Has the selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?
  5. Are any payments to subjects reasonable based upon the complexities and inconveniences of the study and the particular subject population?

Informed Consent

General Requirements

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive
or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

1- Basic elements of informed consent, except as provided in paragraph (3) of this section, shall be provided for each subject according to the following:

- A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
- A description of any reasonably foreseeable risks or discomforts.
- A description of any benefits to the subject or to others which may be reasonably expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- An explanation for research involving more than minimal risk, as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and subjects’ rights and whom to contact in the event of a research-related injury to the subject.
- 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 the subject is otherwise entitled for participation up to the point of their termination.

2- Additional elements of informed consent, when appropriate, one or more of the following elements of information shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unexpected.
- Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subjects’ consent.
- Any additional costs to the subject that may result from participation in the research.
- The consequences of the subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of the research, which may relate to the subjects’ willingness to continue in participation, will be provided to the subject.
- The approximate number of subjects involved in the study.

3- The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- The subjects will be provided with additional pertinent information after participation, when appropriate.
- The researcher project demonstration is to be conducted by or subject to the approval of government officials and is designed to study, evaluate, or otherwise examine:
  - Programs under public benefit or service.
  - Procedures for obtaining benefits or services under those programs.
  - Possible changes in or alternatives to those programs or procedures.
  - Possible changes in methods or levels of payment for benefits or services under those programs.

Documentation

1- The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
- 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.

In documentation where the signed consent is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

2- Except as provided in item (1) of this section, 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. A copy shall be given to the person signing the form.

3- Except as provided in item (1) of this section, the consent form may be one of the following:

- A written consent document that embodies the elements of informed consent. This form may be read to the subject or the subject’s legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.
- A “short form” written consent document stating that the elements of informed consent have been presented orally to the subject or representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the “short form”.

IRB SUBMISSION AND REVIEW PROCESS

1- If you are sure that your project qualifies as a Human Subject Research, complete the Human Subject Research Determination Form and submit it to the IRB coordinator. If you are instructed to apply for IRB exemption or approval, proceed to step (2).
2. To apply for exemption (review the categories for exemption) from IRB approval, complete a request for exemption form. If your research is not exempt, complete an IRB application and attach evidence and required signatures and mail them to the committee. Alternatively, you may e-mail PDF files with signature pages scanned to the e-site. Be sure to provide certification that you have completed the required training to conduct Human Subject Research.

3. Your application will be reviewed to determine if it is complete. Incomplete applications will be rejected and returned to the investigator. Completed applications will be evaluated to determine if they fall within one or more of the specified categories of exempt research or if they should have either an expedited (review the categories for expedited review) or full board review.

4. Exempt requests will be reviewed by the IRB coordinator and/or the designated IRB member. Once it is determined if an application is exempt, the investigator will be informed of the decision. Denials will be forwarded to the IRB chairperson for expedited review.

5. Expedited requests will be reviewed by the IRB chairperson or the designated IRB member and/or coordinator. Approvals will be valid for up to one year. Denials for expedited review will be forwarded for full board review by the IRB. The investigator will be informed of the decision.

6. Work on a project cannot extend beyond the date approved by the IRB. If it is necessary for work to extend beyond this date, a Continuation/Termination Request must be submitted.

7. Work on a project cannot be modified from the approved protocol. If any changes are to be made, a Modification Request Form must be submitted.

8. No research can be conducted until the investigator has received confirmation from the IRB coordinator that the application is either exempt or approved, or in the case of renewals and modifications, until they are approved.

Meeting Procedure

The IRB will meet four times per academic year to review applications. Approved applications will be valid for up to three years.

Submission Material

- A Complete Application Form signed by both the Primary Investigator (PI) and/or the Scientific Department Chairperson.
- When appropriate, any and all necessary appendices required by the Application Form.
- English or Arabic consent forms, unless a waiver of documentation of informed consent is being requested by the PI.
- Participant/Subject recruitment materials and samples (e.g. advertisements, brochures, flyers, video tapes or letters to potential subjects) that will be used to inform people about the study (if applicable).
- Questionnaires, tests and/or surveys that will be used in the research study. If this is a pilot study and the final survey(s)/questionnaire(s) is/are still under development, provide examples of the types, content and general subject matter to be covered.
- Curriculum vitae of the PI and co-investigators.
- Clinical Investigator Brochure in case of a sponsored clinical trial (if applicable).
- Insurance Certificate from sponsor or Clinical Trial Agreement, which documents that subject injury medical expenses are covered by sponsor (if applicable).

Estimated Review Schedule

The review schedule dates are calculated from the time of submitting a complete application. Some applications may be reviewed and approved before or after the stated timings based on the complexity of the study and reviewer concerns.

- Exempt Research Studies: announced within 3-4 weeks of review and approval.
- Expedited Review requires approximately 6-8 weeks for review and approval.
- Full Committee Review should be submitted at least four weeks prior to the IRB meeting date; review and approval by the IRB may require from 1-3 months after initial IRB review at a convened meeting.
BAU Institutional Animal Care and Use Guidelines (IACUG) are intended to facilitate the IRB review of research concerning animals. This is to ensure that animal care and handling for the research proposed are performed in accordance with the regulations and guidelines stipulated by the BAU Institutional Review Board (IRB).

IRB has the right to regularly monitor compliance to the ethical guidelines of the approved protocols until the research is completed.

In the words of Gandhi:

“The greatness of a nation and its moral progress can be judged by the way its animals are treated.”

ROLE OF IACUG

Institutional Animal Care and Use Guidelines (IACUG) are established to prove safety and welfare of experimental animals used for research and ensure that the experiments will be performed to safeguard the rights, safety and wellbeing of the animals. IACUG should ensure the full review and evaluation of all ethical aspects of the research proposals it receives before they are carried out to make sure they follow ethical guidelines. The tasks of the review are performed free of bias and influence.

The IRB provides independent and timed decisions based on adherence to the guidelines detailed hereafter. These guidelines are based on the Animal Welfare Act and the Canadian Council on Animal Care’s (CCAC) Guide to the Care and Use of Experimental Animals.

The IACUG are to be also involved in the on-going monitoring of the approved research.

The IACUG take into account the interests and needs of researchers and the requirements of relevant regulatory and applicable laws.

The IACUG herein provide applicants with all the terms of references that set out the work expected of the committee in a standard operating procedure (SOP). The nature of the research determines what is required; it may include format sheets for applications (Form A-I, A-III).

The IACUG is willing to extend its role as an authority in ethical issues concerning research conducted on animals by participating in:

1. Cooperating, advising, and supporting other relevant committees, such as the Faculty Research Committee, in matters of common interest.
2. Promoting community awareness and consulting with individuals, communities, and the government on ethical issues related to research on animals.
3. Keeping up-to-date with international developments in relation to animal care and handling issues and communicating with relevant international organisations and individuals.
COMMUNICATION WITH IACUG

All communications and submitted applications are performed directly and sent through e-mail or regular mail to the committee. Online applications are accepted for review, but the final decision is withheld until a hard copy is submitted with the signature of the applicant.

The application file should include:
1. Before starting the project, Project Information–Research Involving Animals Form (Form A-I) should be submitted for approval.
2. After completing the research, a Project Completion Form (Form A-III) should be submitted to get a final approval letter (Form A-IV).

APPROVAL CONDITIONS AND DECISION MAKING

Submitted research proposals would be ideal if they have been previously reviewed by a relevant scientific committee and found to be scientifically valid. However, where there is no such separate review, the IRB needs to consider the scientific value and validity justification, methodology, proposed analytical methods, etc. as well as ethical issues stated hereafter.

Communications and decisions are given in a written form under the signature of the IRB chairperson or coordinator in the relevant form (Form A-II).

Positive Decision
The approval decision is subject to the adherence of the researcher to the qualification criteria. Any non-adherence leads to withdrawal or suspension of the approval.

Final approval and letter to publishing editors (Form A-IV) is granted according to the follow-up and submission of the research completion sheet.

Conditional Positive Decision
A conditional approval may be granted based on the researcher’s compliance with the conditions stipulated by IRB. The applicant may be asked to submit the required amendments in new sheets. A period of validity of the approval may be stated. The decision is stated in the final decision form (Form A-II).

Negative Decision
In case of a negative decision, a clear statement of the reasons for the negative decision is communicated to the researcher in a special standard format (Form A-II). This involves reasons for refusal and includes whether it may be submitted as a new proposal with appropriate changes. The right to appeal should be submitted only to the IRB.

Ethical Review and Guidelines for Research Using Animals
The IRB believes that the use of animals in research is acceptable only if it promises to contribute to understanding of fundamental biological principles or to the development of knowledge that can reasonably be expected to benefit humans or animals. Animals should be used only if the researcher’s best efforts to find an alternative have failed. Individuals using animals should employ the most humane methods on the smallest number of appropriate animals required to obtain valid information.

The following guidelines and principles should be applied in conjunction with the Animal Welfare Act3 and Canadian Council on Animal Care’s (CCAC) Guide to the Care and Use of Experimental Animals12:
1. If animals must be used, it should be maintained in a manner that provides for their physical comfort and psychological well-being, according to CCAC’s policy statement on social and behavioral requirements of experimental animals.
2. Animals must not be subjected to unnecessary pain or distress. The experimental design must offer them every practicable safeguard. Cost and convenience must not take priority over the animal’s physical and mental well-being.
3. Expert opinion must show the potential value of studies with animals. The following procedures, which are restricted, require independent external evaluation to justify their use in burns, freezing injuries, fractures, and other types of trauma investigation in anesthetized animals. All this must be in concomitant to acceptable veterinary practices for the relief of pain, including adequate analgesia during the recovery period.
4. If pain or distress is a necessary concomitant to the study, it must be minimized both in intensity and duration. Investigators, animal care committees, grant review committees and referees must be especially cautious in evaluating the proposed use of the following procedures:
   - Experiments involving withholding pre and post-operative pain-relieving medication.
   - Electric shock as negative reinforcement.
   - Extreme environmental conditions such as low or high temperatures, high humidity, modified atmospheres, or sudden changes therein.
   - Experiments studying stress and pain.
   - Experiments involving withholding of food and water for periods incompatible with the species-specific physiological needs; such experiments should have no detrimental effect on the health of the animal.
   - Injection of Freund’s Complete Adjuvant must be carried out in accordance with CCAC guidelines on acceptable immunological procedures.
5. An animal observed to be experiencing severe un-relievable pain or discomfort should immediately be humanely killed using a method providing initial rapid unconsciousness.
6. While non-recovery procedures involving anaesthetized animals, and studies involving no pain or distress are considered acceptable, the following experimental procedures inflict excessive pain and are thus unacceptable:
- Utilization of muscle relaxants or paralytics (curare and curare-like) alone, without anaesthetics during surgical procedures.
- Traumatizing procedures involving crushing, burning, striking, or beating in un-anaesthetized animals.
- Studies such as toxicological and biological testing, cancer research and infectious disease investigation may, in the past, have required continuation until the death of the animal. However, in the face of distinct signs that such processes are causing irreversible pain or distress, alternative endpoints should be thought to satisfy both the requirements of the study and the needs of the animal.
- Physical restraint should only be used after alternative procedures have been fully considered and found inadequate. Restraint animals must receive exceptional care and attention in compliance with species-specific and general requirements.
- Painful experiments or multiple invasive procedures on animals should be done without pain using adequate anaesthesia.
- Waste disposal should be in compliance with BAU waste handling procedures that meet local environmental requirements. This is essential to ensure the safe transport and disposal of waste, especially animal waste. Bags and containers for medical waste are colour-coded (yellow) and labelled as biohazard or medical waste. Such waste is placed in appropriate leak-resistant bags and then yellow containers bearing the international black biohazard symbol and clearly marked medical waste. Medical waste and sharp containers are stored securely before being periodically collected by licensed waste contractors for final disposal using approved technology by licensed/accredited contractors (for detailed procedures, please contact +961 1300110 Ext: 2554).

FOLLOW-UP

Institutional Animal Care and Use Guidelines (IACUG) consider the advisability of monitoring progress of research approved by them.

Submission of Progress Reports

The IRB may call for reports at predetermined intervals every twelve months. On the conduct of the research during projects and on completion to help the IRB in formulating its guidance, reports should be submitted so that the IRB can be assured that projects continue to conform to the approved ethical standards. A final report should be followed at the end of the project.

“This will not in any way reduce the responsibility of the researcher to ensure such conformity”.

Publication of Results

The IRB will maintain a record of all proposed research projects and may require a formal report on completion of the project in order to review the outcome of the research and its contribution to knowledge.

Publication confirmation of results together with a reprint may be requested.
FORMS

Human Forms

1. IRB Face Page (Form H-I)
2. Protocol Application Checklist (Form H-II)
3. Protocol Application Checklist (Form H-III)
4. Protocol Application Checklist (Form H-IV)
5. Protocol Application Checklist (Form H-V)
6. Informed Consent Form (English Version) (Form H-VI)
7. Informed Consent Form (Arabic Version) (Form H-VII)
8. Parental Permission Form (English Version) (Form H-VIII)
9. Parental Permission Form (Arabic Version) (Form H-IX)
10. Assent Form (English Version) (Form H-X)
11. Assent Form (Arabic Version) (Form H-XI)
12. Research Project Final Approval Letter (Form H-XII)

Animal Forms

1. Project Information - Research Involving Animals (Form A-I)
2. Project Information - Final Decision (Form A-II)
3. Project Information - Completion of Research (Form A-III)
4. Research Project Final Approval Letter (Form A-IV)

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Institutional Review Board Face Page (Form H-I)

PI Name: 
Correspondent Name: 
Faculty: 
Department/Division: 
Protocol Title: 

Instructions: When submitting documents to the Institutional Review Board, please check off all that apply for this submission. Be sure to include the protocol number and all attachments as noted in this sheet.

Please indicate whether this submission is for an expedited or full review and check all submitted documents. Be sure to include the correct number of copies with each submission as indicated and all applicable documentation. If incomplete, the documents will be returned to you.

☐ New Protocol Application - Signed  (H-I)
☐ Expedited Review
☐ Original (required)
☐ One Copy (required)
☐ Consent Form(s)/Information Sheet(s) (required)

☐ Full Review
☐ Original (required)
☐ Eight Copies (required) + Soft
☐ Consent Form(s)/Information Sheet(s) (required)

Please note: Complete documentation must be provided at the time of continuing review or study termination. If your protocol has been modified since your last IRB review, please provide a comprehensive protocol inclusive of all modifications and an Amendment Review Form (H-III).

☐ Re-approval - Signed (H-II)

Protocol Number: 

☐ Protocol Application (H-I) (2) (Current Copies)
☐ Consent Form/Information Sheet / Assent Form (Clean Copy)
☐ Consent Form/Assent Form (Submit (4) signed with last names blacked out)

Please note: Any change to an existing protocol must be approved by the IRB prior to its implementation. Please submit a complete document.
☐ Amendment Review Form - Signed (H-III) Protocol Number:
☐ Protocol Application (H-I) Revised (required: (2) Copies)
☐ Revised Consent Form/Information Sheet/Assent Form (required: (2) Copies)
☐ Survey Instruments
☐ Interview Questions

☐ Request for Exemption - Signed (H-IV) Protocol Number:
☐ Consent Form/Information Sheet
☐ Survey Instruments
☐ Interview Questions

Note: Copies should consist of (1) with track changes and (1) original copy for all documents amended.

FOR BAU-IRB USE ONLY

Notes/Comments

BAU-IRB Receipt

Submitted Material Received by:

Date Received:

New Submission Assigned Protocol Number:

---

Protocol Application Checklist (Form H-II)

PI Last Name:
Protocol Number:
Date of Meeting/Review:

SECTION I
General Information
Nature of Study/Specialty: Other Investigators:
Study Title: Collaborating Institutions:
Study Objectives: Study Location:
PI:
Correspondent:
Notes:

SECTION II
Human Subjects
Anticipated Total Enrollment: Recruitment:
Subject Population: Special Population(s):
BAU Students or Employees:

Inclusion/Exclusion Criteria
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the inclusion/exclusion criteria clearly stated and reasonable?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Is the selection of subjects appropriate and equitable?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are minorities, women, children or other vulnerable populations included?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Is the inclusion or exclusion of minorities, women, children and other vulnerable populations justified?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are additional safeguards in place to protect subjects who may be vulnerable to coercion or undue influence?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Recruitment
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are recruitment methods for all subjects groups well defined?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are the location, setting, and timing of recruitment acceptable?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are all recruitment materials submitted?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
### Forms

<table>
<thead>
<tr>
<th>BAU Institutional Review Board</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

*If yes, are materials non-coercive and easily understandable?*
☐ ☐ ☐

*Are there acceptable methods for screening subjects prior to enrolment?*
☐ ☐ ☐

**Notes:**

### SECTION II

#### Research Plan

**Purpose:**

**Benefits:**

**Introduction:**

**Risk/Benefit Analysis:**

**Design, Procedures, Materials, and Methods:**

**Economic Considerations:**

**Data Analysis/Justification of Sample Size:**

**Data and Safety Monitoring:**

**Inclusion/Exclusion Criteria:**

**Confidentiality:**

**Risks and Inconveniences:**

**Reference List:**

### Specific Aims, Background, and Significance

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

*Are the study aims/objectives clearly specified?*
☐ ☐ ☐

*Adequate preliminary data to justify research?*
☐ ☐ ☐

*Are adequate references provided?*
☐ ☐ ☐

*Is there appropriate justification for this research protocol?*
☐ ☐ ☐

### Scientific Design

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

*Is the rationale for the proposed number of subjects reasonable?*
☐ ☐ ☐

*Is the scientific design adequate to answer the study’s question(s)?*
☐ ☐ ☐

*Is the scientific design adequately described and justified?*
☐ ☐ ☐

*Are the study aims/objectives likely to be achieved within the given time period?*
☐ ☐ ☐

*Are there adequate plans for data safety and monitoring?*
☐ ☐ ☐

*Are the plans for data and statistical analysis defined and justified?*
☐ ☐ ☐

### Research Procedures

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

*Are the rationale and details of research procedures adequately described?*
☐ ☐ ☐

*For treatment studies, is there a clear differentiation between research procedures and standards of care and evaluation?*
☐ ☐ ☐

*Are there adequate plans to inform subjects about research results?*
☐ ☐ ☐

### Resources

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

*Are there appropriate resources to conduct this research (e.g., equipment, space, lab, staff)?*
☐ ☐ ☐

*Is there a clear differentiation between research procedures and standards of care and evaluation?*
☐ ☐ ☐

*Are there adequate plans to inform subjects about research?*
☐ ☐ ☐

### Economic Considerations

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

*Is compensation to subjects reasonable, not coercive?*
☐ ☐ ☐

*If the subject does not complete the study, will compensation be pro-rated?*
☐ ☐ ☐

*For student participants, is experimental credit offered and clearly defined?*
☐ ☐ ☐

### Risks and Benefits

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

*Are there sufficient risks and benefits adequately identified, evaluated and described?*
☐ ☐ ☐

*Are the risks reasonable in relation to the benefits?*
☐ ☐ ☐

*Are the risks reasonable in relation to importance of knowledge to be gained?*
☐ ☐ ☐

*Are the risks minimized to the least extent possible?*
☐ ☐ ☐

### Subject Privacy and Confidentiality

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

*Are there adequate provisions to protect the privacy of subjects?*
☐ ☐ ☐

*Are there adequate provisions to protect the confidentiality of data during and after research?*
☐ ☐ ☐

*Are there adequate provisions for storage, coding, and use of identifiers?*
☐ ☐ ☐

**Notes (if any):**
### SECTION IV

**Informed Consent**

Consent Setting:

Requesting Waiver or Alteration of Consent:

Capacity to Consent:

Requesting Waiver of Signed Consent:

Parental Permission and Assent:

Documentation of Consent:

<table>
<thead>
<tr>
<th>Process of Obtaining Consent/Assent</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the process well defined?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does this process provide sufficient time, privacy and adequate setting for the subject to consider?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Is the individual(s) obtaining consent/assent suitable?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are issues of the subject’s comprehension and autonomy considered?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Notes (if any):

**Signature**

PI:

Department Chairperson:

**Other Study Materials**

<table>
<thead>
<tr>
<th>Are all applicable materials attached to the submission (e.g., recruitment flyers, questionnaires, medical history forms, etc.)?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Should the protocol be reviewed more often than once per year?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are there any notable conflicts of interest?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

| For studies that involve collaborating institutions or investigators, has the correct paperwork been submitted? | ☐   | ☐  | ☐   |

**REVIEWER’S FINAL ASSESSMENT/OPINION**

**Approval**

☐ No changes: there is an acceptable risk/benefit ratio and protocol is acceptable as submitted.

**Conditional Approval**

☐ Minor changes needed for the informed consent document, protocol or other study materials.

☐ Minor clarification(s) concerning specific aspects of study or additional information requested from PI.

**Deferral**

☐ There is an unacceptable risk/benefit ratio.

☐ Protocol is poorly written or lacking significant amounts of information regarding scientific justification, study procedures, risk reduction, etc.

☐ It is possible that a response from the investigator could alter the risk/benefit ratio.

☐ There are ethical concerns which can be addressed by obtaining more information or requiring changes in study design and procedures.

**Disapproval**

☐ Risks significantly outweigh the benefit or value of the knowledge to be gained.

☐ There are significant ethical concerns or questions that deem the study unacceptable.
 Protocol Application Checklist (Form H-III)

PI:  
IRB No:  
Project Title:  

Check current status below and complete the appropriate section for that option.
☐ This research is still active and being conducted according to the currently approved procedures. I wish to renew the IRB Approval for this study.

Complete SECTION A and SECTION C, sign and return this form.
☐ The research has never been initiated, but will be conducted according to the currently approved procedures. I wish to renew the IRB Approval for this study.

Complete SECTION B and SECTION C, sign and return this form.

IMPORTANT
This form is for renewal of the IRB approval of Human Subjects Research without revision. If the research has been revised since its most recent approval, or you intend to revise the research, submit a Request for Amendment Form to the IRB in addition to the Continuing Review.

SECTION A (for researches in progress)
1. Activity Status (choose only one)
☐ The research involves pre-existing records or samples only and no interaction/intervention with participants (skip to point 5).
☐ New participant recruitment is still in progress.
☐ Enrollment is closed, but participants are still undergoing study procedures.
☐ Enrollment is closed; participants have completed study procedures but are still in follow-up.
☐ Remaining study activity is limited to analysis only with no further contact with participants.

2. Describe any adverse events or participant complaints related to study procedures and show how you handled each.

3. Were any of these events unexpected or more serious than expected? 
☐ Yes  ☐ No

4. Describe any additional risks or benefits observed during the course of the study.

5. Participant/Numbers
☐ Number of participants actively enrolled or records/samples being reviewed (at present).
☐ Number of participants enrolled or records/samples reviewed since most recent approval.
☐ Number of participants enrolled or records/samples reviewed since original approval (Total).
☐ Number of additional participants to be recruited or records/samples needed to complete the study.

6. Provide a summary of your progress to date.

7. When do you expect the research to be completed?

SECTION B (For studies that have never been initiated)
1. Provide an explanation of why the research was never initiated.

2. List any additional risks that have been identified since the most recent approval.

SECTION C (for all research)
1. Informed Consent Procedures (choose only one)
☐ The remaining research procedures do not involve interaction or intervention with human participants and/or no participants will be recruited.
☐ I will continue to use the IRB stamped consent/permission/assent form(s) to recruit participants without revision.

Attach an electronic copy of the approved consent/permission/assent form(s) with IRB approval stamp.
(IRB USE ONLY):
Level of review:
Expedited (Category):
Full Board:

THE APPROVAL PERIOD IS FOR ONE YEAR ONLY
Other (Specify):
IRB Signature:
Date:

---

**Protocol Application Checklist (Form H-IV)**

<table>
<thead>
<tr>
<th>PI Last Name:</th>
<th>Protocol Number:</th>
<th>Date of Meeting/Review:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. For each proposed amendment, does the PI provide a rationale for why the amendment is being made?</td>
<td></td>
<td></td>
<td>☐</td>
</tr>
<tr>
<td>2. For each proposed amendment, does the PI address whether the proposed amendment increases the level of risk to participants?</td>
<td></td>
<td></td>
<td>☐</td>
</tr>
</tbody>
</table>

**SECTION I- GENERAL INFORMATION**

<table>
<thead>
<tr>
<th>Key Personnel</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Any changes to Key Personnel?</td>
<td></td>
<td></td>
<td>☐</td>
</tr>
<tr>
<td>2. If so, are changes, including the new researcher’s roles/responsibilities, properly documented?</td>
<td></td>
<td></td>
<td>☐</td>
</tr>
<tr>
<td>3. Do the changes raise any human subjects training issues?</td>
<td></td>
<td></td>
<td>☐</td>
</tr>
<tr>
<td>4. Is the amendment significant enough to require a change to the study title… or to the Study Objective?</td>
<td></td>
<td></td>
<td>☐</td>
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<tr>
<td>Notes (if any):</td>
<td></td>
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</tr>
</tbody>
</table>

**SECTION II- COLLABORATING INSTITUTIONS/FACILITIES AND OTHER IRB REVIEWS**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. If new personnel are added from other institutions, is IRB approval from that institution needed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes (if any):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION III- FUNDING
If the protocol was amended to include a new funding source...

- Are the study procedures described in the protocol the same as those described in the new grant? [Yes] [No] [N/A]
- If applicable, is there adequate funding in the budget to compensate subjects as described in the protocol? [Yes] [No] [N/A]
- In case of new funding, is review of the source and consideration whether an IRB Authorization Agreement, Individual Investigator Agreement, or other IRB review needed? [Yes] [No] [N/A]
- Are any investigators on this protocol required to submit the supplemental significant Financial Interest Review Form? [Yes] [No] [N/A]

Notes (if any):

SECTION IV- HUMAN SUBJECTS

- Will the number of participants change? [Yes] [No] [N/A]
- If so, is this reflected properly here and in the Justification of Sample Size/Data Analysis Section? [Yes] [No] [N/A]
- Is there appropriate justification for the increase? [Yes] [No] [N/A]
- Does participant selection remain equitable? [Yes] [No] [N/A]
- Are recruitment procedures amended? [Yes] [No] [N/A]
- If so, does recruitment material meet current standards? [Yes] [No] [N/A]
- Is permission from off-campus site required? [Yes] [No] [N/A]
- Are there concerns about coercion because of the changes? [Yes] [No] [N/A]
- Are special/vulnerable populations currently being recruited? [Yes] [No] [N/A]
- If so, are consent procedures still adequate? [Yes] [No] [N/A]
- Do study documents need to be translated? [Yes] [No] [N/A]
- Does the recruitment material/process meet current standards? [Yes] [No] [N/A]

Notes (if any):

SECTION V- DRUGS/DEVICES, GENETIC TESTING, RADIATION, AND BIOLOGICAL SAMPLES

- Are biological samples currently being collected? [Yes] [No] [N/A]
- If so, was approval from the biosafety office submitted? [Yes] [No] [N/A]
- If changes were made to the amount of samples collected, is this reflected in the study procedures and consent form? [Yes] [No] [N/A]
- Are procedures involving use of radiation currently being used? [Yes] [No] [N/A]
- If so, was approval from the radiation safety office submitted? [Yes] [No] [N/A]
- Are the new procedures adequately documented in the procedures section and risks identified in the risk section and reflected in the consent form? [Yes] [No] [N/A]

Notes (if any):

SECTION VI- RESEARCH PLAN

Design, Procedures, Materials, and Methods
- Were changes made to the research design and procedures? [Yes] [No] [N/A]
- If so, does the change impact the scientific integrity of the study? [Yes] [No] [N/A]
- Does the amendment increase the amount of time for the participants? [Yes] [No] [N/A]
- If so, was the consent form revised? [Yes] [No] [N/A]

Notes (if any):

Justification of Sample Size/Data Analysis
- Does the amendment require a change in sample size? [Yes] [No] [N/A]
- Do data analysis procedures need to be changed as a result of the amendment? [Yes] [No] [N/A]
- Is the sample size still adequate to achieve meaningful results? [Yes] [No] [N/A]
- Is there an increased likelihood of attrition? [Yes] [No] [N/A]

Notes (if any):
Inclusion/Exclusion Criteria

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
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</tbody>
</table>

Should the criteria be changed as a result of the amendment?
| ☐   | ☐  | ☐   |

If so, were the screening procedures and consent form revised?
| ☐   | ☐  | ☐   |

Is exclusion of certain participants still justified?
| ☐   | ☐  | ☐   |

Notes (if any):

Risks and Inconveniences

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
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<tbody>
<tr>
<td>☐</td>
<td>☐</td>
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</tr>
</tbody>
</table>

Does the level of risk change?
| ☐   | ☐  | ☐   |

If so, are the risks and procedures to minimize risk adequately addressed?
| ☐   | ☐  | ☐   |

If so, is risk greater than minimal requiring review by the full board?
| ☐   | ☐  | ☐   |

If so, does the risk/benefit ratio change?
| ☐   | ☐  | ☐   |

If so, was the consent form appropriately revised?
| ☐   | ☐  | ☐   |

Are the risks still reasonable in relation to the benefits?
| ☐   | ☐  | ☐   |

Are the risks still reasonable in relation to importance of knowledge to be gained?
| ☐   | ☐  | ☐   |

Notes (if any):

Data Safety Monitoring

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Does the Data Safety Monitoring plan need to be changed because of the amendment?
| ☐   | ☐  | ☐   |

Notes (if any):

Privacy/Confidentiality

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Are procedures to protect privacy and confidentiality still adequate?
| ☐   | ☐  | ☐   |

If not, are changes required?
| ☐   | ☐  | ☐   |

Were appropriate changes made to the consent form?
| ☐   | ☐  | ☐   |

Notes (if any):

SECTION VII- INFORMED CONSENT

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Are appropriate changes as a result of the amendment reflected in the revised consent form?
| ☐   | ☐  | ☐   |

Is there an increased need to assess capacity to consent?
| ☐   | ☐  | ☐   |

Should currently enrolled participants be re-consented?
| ☐   | ☐  | ☐   |

Should previously enrolled participants be re-consented?
| ☐   | ☐  | ☐   |

Is the consent process still appropriate for all populations?
| ☐   | ☐  | ☐   |

Does the consent form/process meet current standards?
| ☐   | ☐  | ☐   |

Should participants be afforded an increased level of privacy during consent?
| ☐   | ☐  | ☐   |

Are previously granted waivers of consent/signed consent still appropriate?
| ☐   | ☐  | ☐   |

Can a waiver of consent/signed consent be granted now?
| ☐   | ☐  | ☐   |

Notes (if any):

REVIEWER RECOMMENDATIONS SUMMARY

Level of Risk

☐ Remains ... or ☐ Has changed to...

☐ Minimal risk (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)

☐ Greater than minimal risk

Are the risks still reasonable in relation to anticipated benefits?
| ☐   | ☐  | ☐   |

Are the risks minimized through sound research design?
| ☐   | ☐  | ☐   |

Recommended IRB Determination (check one):

☐ Approve as submitted

☐ Requires Modifications to Secure Approval (summarize below)

☐ Defer (summarize below)

☐ Disapprove (summarize below)
LENGTH OF APPROVAL PERIOD
Continuing review of research should be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year.

If applicable, does the amendment increase risks such that the protocol should be reviewed more frequently?

☐  ☐  ☐

Are there concerns that warrant continuing review at 6 months or other time frame?

☐  ☐  ☐

If so, what time frame is appropriate?

Protocol Application Checklist (Form H-V)

PI Last Name:
Protocol Number:

SECTION I- GENERAL INFORMATION
Nature of Study: Other Investigators:
Study Title: Other IRB Reviews:
Study Objectives: Collaborating Institutions:
Principal Investigator: Study Location:

SECTION II- ABSTRACT
Provide an abstract of the proposed research. The abstract should summarize the objectives of this project and the procedures to be used with an emphasis on what will happen to the participants.

SECTION III- RISK CLASSIFICATION
What is the overall risk classification of the research?
Minimal: If the classification is minimal risk, please justify why that category is appropriate.
Greater than minimal: If the research involves greater than minimal risk, then it is not eligible for exemption.

SECTION IV- PARTICIPANTS
Describe the participants who will be included in this research. Identify the location(s) in which participants will be recruited.

- Indicate if any of the following will be included in this research:
  - Children
  - Cognitively Impaired
  - Institutionalized Persons
  - Prisoners
  - Students
  - Employees
  - Pregnant Women/Fetuses/Neonates
  - Handicapped
SECTION V- INSTRUMENTS
Describe the instruments, if any, to be used to collect data in this study:
Attach copies of all questionnaires, surveys, interview questions, etc. If the research involves
interviews that could evolve as the research progresses, include a list of discussion topics and any
“starter” questions for each topic that are reasonably expected to be covered. If a draft of a written
questionnaire or survey is attached, it should be clearly labeled as such, and a final version must
be submitted before data collection begins.

SECTION VI- CONFIDENTIALITY
Describe what identifiers will be collected for the participants. If participants will be identified,
describe the procedures in place to protect their confidentiality.

SECTION VII- PRIVACY
Explain provisions to protect privacy interests of participants. This refers to how investigators
will contact participants and/or access private information from or about participants during
and after their involvement in the research (e.g. time, place, etc. of research procedures).

SECTION VIII- CONSENT
a- Will consent be obtained from participants?
   Yes. If yes, describe how consent will be obtained and documented.
   No. If no, explain why this is justified.

b- If consent will be obtained, will consent be documented?
   Yes. If yes, describe how consent will be documented.
   No. If no, explain why this is justified.

Note: All of the data or materials must exist prior to proposing the research.
Please submit a signed application along with initialled supplements to the IRB office.

PRINCIPAL INVESTIGATOR: I will conduct
the study identified above in the manner described.
If I decide to make any changes in the procedure, or if a participant is injured, or if any problems
occur which involve risk or the possibility of risk to participants or others, I will immediately
report such occurrences or contemplated changes to BAU Institutional Review Board.
Please print your name:
Date:

THIS SECTION IS FOR IRB OFFICE USE ONLY

IRB Protocol Number: Reviewed by:

Informed Consent Form (English Version) (Form H-VI)

Title: [Title of the research study as it appears on the IRB application. If multiple consent forms
will be used, add subtitles to clarify the target population].
PI: [Name and BAU affiliation].
Date: [Date the form was prepared].

Purpose of Research Study
- Begin as follows:
  The purpose of this research study is [describe the purpose in a way that makes the potential
  value of the study clear].
  Include the following statement or an appropriate paraphrase:
  We anticipate that approximately [insert number] people will participate in this study.

Procedures
- Briefly describe what the participant will be asked to do and identify any procedures that are
experimental (e.g. non-standard instructional methods).
- Give the expected duration of the participant’s participation, indicating the expected number
and duration of each session.

Risks/Discomforts
- Describe any reasonably foreseeable risks and discomforts to the participant.
  If appropriate, include the following statement:
  Participation in this study may involve risks that cannot be foreseen at this time.
  For studies involving minimal risk, use the following statement, including or excluding the
  material in brackets as appropriate:
  The risks associated with participation in this study are no greater than those encountered in
daily life [or during the performance of routine physical or psychological examinations or tests].

Benefits
- Describe any benefits to the participant that may be reasonably expected from the research.
  The description should be clear and not overstated.
  If there are no benefits to the participant, include the following statement:
  There are no direct benefits to you from participating in this study.
- Describe benefits to others that may be reasonably expected from the research, such as benefits to other people suffering from a disorder being studied or benefits to the general public or society. For example, in the case of general benefits accruing from advances in knowledge about the topic under investigation, a statement such as the following might be included: This study may benefit society if the results lead to a better understanding of [insert topic].

Voluntary Participation and Right to Withdraw

Begin with the following statements:
Your participation in this study is entirely voluntary: You choose whether to participate. If you decide not to participate, there are no penalties and you will not lose any benefits to which you would otherwise be entitled.

If you choose to participate in the study, you can discontinue your participation at any time without any penalty or loss of benefits. If you want to withdraw from the study, please [explain what the participant should do to withdraw].

- If a decision to withdraw from the study would have any significant consequences for the participant, explain these consequences.
- If any special procedures are required for the participant’s safe withdrawal from the study, describe these procedures.
- Include this statement, if appropriate:
  If we learn any new information during the study that could affect whether you want to continue participating, we will discuss this information with you.

Circumstances that Could Lead Us to End Your Participation

Include this section if there are specific circumstances that could lead to the participant being taken out of the study.

Begin with these statements:
Under certain circumstances, we may decide to end your participation before you have completed the study. Specifically, we may discontinue your participation, if [describe possible reasons for terminating the participant’s participation (e.g. we determine that it would be unsafe for you to continue in the study)].

- If the list of reasons is not exhaustive, add this sentence:
  There may also be other circumstances that would lead us to end your participation.
- If appropriate, include this sentence at the end:
  If we end your participation before you have completed the study, we will provide compensation for your participation up to that time.

Alternatives to Participation

Include this section when (a) the participant may benefit from participating in the study and (b) the same or similar benefits may be obtained in some other way. For example, in the case of an educational study that provides special tutoring to participants, include this section if the same or similar tutoring is also available to students not taking part in the study.

Describe the alternatives to participation that may confer the same or similar benefits.

Confidentiality

- Describe to what extent the confidentiality of records identifying the participant will be maintained. For most studies, the following statement will be appropriate: Any study records that identify you will be kept confidential. The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the BAU Institutional Review Board. (All of these people are required to keep your identity confidential). Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

- Describe how the study records will be created, stored, and maintained to protect confidential information (e.g. use of code numbers rather than participants’ names on data sheets, or keeping records in a locked file cabinet). Some studies may require disclosure of information to other parties. For such studies, explain what information will (or may) be disclosed and to whom.

Compensation

Describe all payments or other compensation.

If no compensation is provided, include the following statement:

You will not receive any payment or other compensation for participating in this study.

If You Have Questions or Concerns

You can ask questions about this research study now or at any time during the study, by talking to the researcher(s) working with you or by calling [insert name and role] at [insert phone number].

If you have questions about your rights as a research participant or feel that you have not been treated fairly, please call the BAU Institutional Review Board at 00961 1 300110 Ext. 2743.

If You are Harmed by Participating in the Study

Include this section if the research is of greater than minimal risk and research-related harm (physical, psychological, social, financial, or other) to the participant is possible.
If you feel that you have been harmed in any way by participating in this study, please call [insert name and role] at [insert phone number]. Please also notify the BAU Institutional Review Board at 00961 1 300110 Ext. 2743.

Then state whether any compensation and/or treatment is available to participants who have been harmed and, if so, describe the compensation/treatment or indicate where further information may be obtained. Make clear whether treatment will be provided without cost to the participant or, instead, the participant will be required to pay.

If no compensation or treatment is available, include the following statement:
This study does not have any program for compensating or treating you for harm you may suffer as a result of your participation.

What Your Signature Means:
Your signature below means that you understand the information in this consent form. Your signature also means that you agree to participate in the study.

Participant's Signature:
Date:
Signature of Person Obtaining Consent:
الفوائد
- صف الفوائد المتوقعة من البحث والتي تعود على المشاركين وصفاً واضحاً.
- لا توجد فوائد مباشرة تعود عليكم من خلال المشاركة في هذه الدراسة.
- صف الفوائد المتوقعة من البحث والتي تعود على الآخرين. ومنها الفوائد التي قد تعود على من يعانون من اضطرابات تتعلق بموضوع البحث أو فوائد تعود على العامة أو المجتمع، على سبيل المثال: في حالة الفوائد العامة الناتجة عن إحراز تقدم في المعرفة حول موضوع البحث يمكن إضافة عبارة مثل ما يلي: هذه الدراسة يمكن أن تفيد المجتمع إذا ما أدت نتائجها إلى فهم أفضل لـ (تحديد الموضوع).

المشاركة التطوعية وحق الانسحاب
- بدأ بالعبارة التالية.
إن مشاركتكم في هذه الدراسة هي مشاركة طوعية بالكامل. إن قرار المشاركة قراركم. وفي حال قررت عدم المشاركة فلن يكون هناك أية عواقب كما أنكم لن تخسروا أياً من الامتيازات التي تحق لكم.
- وفي حال اختيار المشاركة في الدراسة، يمكنكم التوقف عن المشاركة في أي وقت بدون أية عواقب أو فقد لأية امتيازات مستحقة. برجاء (اشرح ما يتوجب على المشارك القيام به لإتمام الانسحاب).
- إذا كان قرار الانسحاب من الدراسة سيكون له أية عواقب للمشارك، اشرح تلك العواقب.
- إذا اقتضى الأمر، أضف الجملة التالية في نهاية هذا الجزء:
إذا ما توصلنا إلى أية معلومات جديدة خلال الدراسة والتي قد تؤثر في قراركم بالاستمرار في المشاركة، فإننا سوف نناقش هذه المعلومات معكم.

الظروف التي قد تؤدي إلى إنهاء مشاركتكم
- ابدأ بهذه العبارات: في ظل ظروف معينة، قد نقرر إنهاء مشاركتكم قبل أن يستكمل الدراسة.
- صف الأسباب المحتملة لإنهاء مشاركة الشخص.
- وتحديداً فإننا قد نضع حداً لمشاركة طفلكم إذا ما قررنا إنهاء مشاركتكم قبل نهاية الدراسة، وذلك بسبب (أذكر الأسباب).
- إذا كانت قائمة الأسباب غير واضحة:
قد تطرأ ظروف أخرى قد تؤدي إلى إنهاء مشاركتكم.
- إذا اقتضى الأمر، أضف الجملة التالية في نهاية هذا الجزء:
في حال أنهينا مشاركة طفلكم قبل نهاية الدراسة، سوف نوفر التعويض عن مشاركته/مشاركتها حتى تاريخه.

بدائل المشاركة
- إذا كنت ترغب في بدائل المشاركة، أبابيل أي مدى ستيم الحفاظ على سيرية السجلات الخاصة بالمشارك.
- إذا استفادت طفلكم من المشاركة في هذه الدراسة، و(ب) امكانية الحصول على فوائد مماثلة أو مشابهة بطريقة أخرى.
- على سبيل المثال، في حالة عمل دراسة تربوية تقدم دروس خاصة لطلاب غير المشاركين، يمكن القول:
إذا كان لدى طفلكم أية أسئلة أو استفسارات يمكن طرح أسئلتهما على الباحث/الباحثين الذين يعملون معكم.

السّرية
- صف إلى أي مدى سيتم الحفاظ على سرية السجلات الخاصة بالمشارك.
- سيتم الحفاظ على أي سجلات خاصة بالدراسة والتي تعرّف بكم، وقد تقوم بمراجعة سجلات المشاركة كأشخاص مسؤولون عن ضمان سلامة الاجراءات البحثية بما في ذلك أخذ موافقات مسبقًا.
- في حالة الدراسة، يمكن إضافة عبارة مثل ما يلي: إن مشاركتكم في هذه الدراسة، يمكن أن تكون مفيدة في تحسين معرفة الجمهور، وقد تقوم بمراجعة سجلات المشاركة كأشخاص مسؤولون عن ضمان سلامة الاجراءات البحثية بما في ذلك أخذ موافقات مسبقًا.

التعويض
- صف كافة المكافآت وغيرها من التعويضات، وفي حال عدم وجود أي تعويضات أذكر العبارات التالية.
- لن تلقى أي إكراهات أو تعويضات من المشاركة في هذه الدراسة.
- إذا كانت لديك أي أسئلة أو استفسارات يمكن طرح أسئلتهما على الباحث/الباحثين الذين يعملون معكم.
- يمكنكم تحضير وتخزين والحفاظ على سجلات الدراسة حتى تاريخه.
- إذا كنت ترغب في بدائل المشاركة، أبابيل أي مدى ستيم الحفاظ على سرية السجلات الخاصة بالمشارك.
- في حالة عمل دراسة تربوية تقدم دروس خاصة لطلاب غير المشاركين، يمكن القول:
إذا كان لدى طفلكم أية أسئلة أو استفسارات يمكن طرح أسئلتهما على الباحث/الباحثين الذين يعملون معكم.

السّرية
- صف إلى أي مدى سيتم الحفاظ على سرية السجلات الخاصة بالمشارك.
- سيتم الحفاظ على أي سجلات خاصة بالدراسة والتي تعرّف بكم، وقد تقوم بمراجعة سجلات المشاركة كأشخاص مسؤولون عن ضمان سلامة الاجراءات البحثية بما في ذلك أخذ موافقات مسبقًا.
- في حالة الدراسة، يمكن إضافة عبارة مثل ما يلي: إن مشاركتكم في هذه الدراسة، يمكن أن تكون مفيدة في تحسين معرفة الجمهور، وقد تقوم بمراجعة سجلات المشاركة كأشخاص مسؤولون عن ضمان سلامة الاجراءات البحثية بما في ذلك أخذ موافقات مسبقًا.

التعويض
- صف كافة المكافآت وغيرها من التعويضات، وفي حال عدم وجود أي تعويضات أذكر العبارات التالية.
- لن تلقى أي إكراهات أو تعويضات من المشاركة في هذه الدراسة.
- إذا كانت لديك أي أسئلة أو استفسارات يمكن طرح أسئلتهما على الباحث/الباحثين الذين يعملون معكم.
- يمكنكم تحضير وتخزين والحفاظ على سجلات الدراسة حتى تاريخه.
- إذا كنت ترغب في بدائل المشاركة، أبابيل أي مدى ستيم الحفاظ على سرية السجلات الخاصة بالمشارك.
- في حالة عمل دراسة تربوية تقدم دروس خاصة لطلاب غير المشاركين، يمكن القول:
إذا كان لدى طفلكم أية أسئلة أو استفسارات يمكن طرح أسئلتهما على الباحث/الباحثين الذين يعملون معكم.

السّرية
- صف إلى أي مدى سيتم الحفاظ على سرية السجلات الخاصة بالمشارك.
- سيتم الحفاظ على أي سجلات خاصة بالدراسة والتي تعرّف بكم، وقد تقوم بمراجعة سجلات المشاركة كأشخاص مسؤولون عن ضمان سلامة الاجراءات البحثية بما في ذلك أخذ موافقات مسبقًا.
- في حالة الدراسة، يمكن إضافة عبارة مثل ما يلي: إن مشاركتكم في هذه الدراسة، يمكن أن تكون مفيدة في تحسين معرفة الجمهور، وقد تقوم بمراجعة سجلات المشاركة كأشخاص مسؤولون عن ضمان سلامة الاجراءات البحثية بما في ذلك أخذ موافقات مسبقًا.

التعويض
- صف كافة المكافآت وغيرها من التعويضات، وفي حال عدم وجود أي تعويضات أذكر العبارات التالية.
- لن تلقى أي إكراهات أو تعويضات من المشاركة في هذه الدراسة.
- إذا كانت لديك أي أسئلة أو استفسارات يمكن طرح أسئلتهما على الباحث/الباحثين الذين يعملون معكم.
- يمكنكم تحضير وتخزين والحفاظ على سجلات الدراسة حتى تاريخه.
- إذا كنت ترغب في بدائل المشاركة، أبابيل أي مدى ستيم الحفاظ على سرية السجلات الخاصة بالمشارك.
- في حالة عمل دراسة تربوية تقدم دروس خاصة لطلاب غير المشاركين، يمكن القول:
إذا كان لدى طفلكم أية أسئلة أو استفسارات يمكن طرح أسئلتهما على الباحث/الباحثين الذين يعملون معكم.
Parental Permission Form (English Version) (Form H-VIII)

Title: [Title of the research study as it appears on the IRB application. If multiple consent forms will be used, add subtitles to clarify the target population].

PI: [Name and BAU affiliation].

Date: [Date the form was prepared].

Purpose of Research Study
- Begin as follows:
  The purpose of this research study is [describe the purpose in a way that makes the potential value of the study clear].
- Include the following statement or an appropriate paraphrase:
  We anticipate that approximately [insert number] children will participate in this study.

Procedures
- Briefly describe what the participant will be asked to do, and identify any procedures that are experimental (e.g. non-standard instructional methods).
- Give the expected duration of the participant’s involvement in the research, indicating the expected number and duration of each session.

Risks/Discomforts
- Describe any reasonably foreseeable risks and discomforts to the participant.
- If appropriate, include the following statement: Participation in this study may involve risks that cannot be foreseen at this time.
- For studies involving minimal risk, use the following statement, including or excluding the material in brackets as appropriate:
  The risks associated with participation in this study are not greater than those encountered in daily life [or during the performance of routine physical or psychological examinations or tests].

Benefits
- Describe any benefits to the participant that may be reasonably expected from the research. The description should be clear and not overstated.
- If there are no benefits to the participant, include the following statement: There are no direct benefits to your child from participating in this study.
- Describe benefits to others that may be reasonably expected from the research, such as benefits to other people suffering from a disorder being studied or benefits to the general public or society.
For example, in the case of general benefits accruing from advances in knowledge about the topic under investigation, a statement such as the following might be included:
This study may benefit society if the results lead to a better understanding of [insert topic].

Voluntary Participation and Right to Withdraw
- Begin with the statements below. Include the material in brackets when appropriate given the participants’ age and mental status.

Your child’s participation in this study is entirely voluntary: You choose whether to allow your child to participate, [and we will also ask your child whether he or she agrees to take part in the study]. If you decide not to allow your child to participate, [or your child chooses not to participate], there are no penalties, and neither you nor your child will lose any benefits to which you would otherwise be entitled.

If you [and your child] choose to participate in the study, you [or your child] can discontinue participation at any time without any penalty or loss of benefits. If you want to withdraw your child from the study [or your child wants to discontinue participating], please [explain what the parent or child should do to withdraw].

- If a decision to withdraw from the study would have any significant consequences for the participant, explain these consequences.
- If any special procedures are required for the participant’s safe withdrawal from the study, describe these procedures.
- Include this statement if appropriate:

If we learn any new information during the study that could affect whether you [or your child] want to continue participating, we will discuss this information with you [and your child].

Circumstances that Could Lead Us to End Your Participation
Include this section if there are specific circumstances that could lead to the participant being taken out of the study.

- Begin with these statements:

Under certain circumstances, we may decide to end your child’s participation before he or she has completed the study. Specifically, we may stop your child’s participation if [describe possible reasons for terminating the participant’s participation (e.g., we determine that it would be unsafe for your child to continue in the study)].

- If the list of reasons is not exhaustive, add this sentence:

There may also be other circumstances that would lead us to end your child’s participation.

- If appropriate, include this sentence at the end:

If we end your child’s participation before he or she has completed the study, we will provide compensation for his or her participation up to that time.

Alternatives to Participation
Include this section when (a) the participant may benefit from participating in the study and (b) the same or similar benefits may be obtained in some other way. For example, in the case of an educational study that provides special tutoring to participants, include this section if the same or similar tutoring is also available to students not taking part in the study.

Describe the alternatives to participation that may confer the same or similar benefits.

Confidentiality
- Describe to what extent the confidentiality of records identifying the participant will be maintained. For most studies, the following statement will be appropriate:

Any study records that identify you or your child will be kept confidential. The records from your child’s participation may be reviewed by people responsible for making sure that research is done properly, including members of the BAU Institutional Review Board. (All of these people are required to keep your identity and the identity of your child confidential). Otherwise, records that identify you or your child will be available only to people working on the study, unless you give permission for other people to see the records.

- If some studies may require disclosure of information to other parties. For such studies, explain what information will (or may) be disclosed and to whom.

- Describe how the study records will be created, stored, and maintained to protect confidential information (e.g. use of code numbers rather than participants’ names on data sheets, or keeping records in a locked file cabinet).

Compensation
- Describe all payments or other compensation (e.g., extra credit in a course, transportation reimbursement) the participant or parent will receive. Include details of payment methods or bonuses. For example:

- If no compensation is provided, include the following statement:

Your child will not receive any payment or other compensation for participating in this study.

If You have Questions or Concerns
You [and your child] can ask questions about this research study now or at any time during the study by talking to the researcher(s) working with you [and your child] or by calling [insert name and role] at [insert phone number].
If you [or your child] have questions about your child's rights as a research participant or feel that your child has not been treated fairly, please call the BAU Institutional Review Board at 00961 1 300110 Ext. 2743.

If You are Harmed by Participating in the Study
Include this section if the research is of greater than minimal risk and research-related harm (physical, psychological, social, financial, or other) to the participant is possible. If you feel that your child has been harmed in any way by participating in this study, please call [insert name and role] at [insert phone number]. Please also notify the BAU Institutional Review Board at 00961 1 300110 Ext. 2743.

Then state whether any compensation and/or treatment is available to participants who have been harmed and, if so, describe the compensation/treatment or indicate where further information may be obtained. Make clear whether treatment will be provided without cost to the participant or, instead, the participant will be required to pay.

If no compensation or treatment is available, include the following statement:
This study does not have any program for compensating or treating your child for harm he or she may suffer as a result of his or her participation.

What Your Signature Means
Your signature below means that you understand the information in this consent form. Your signature also means that you agree to allow your child to participate in the study. [Your child's signature indicates that he or she agrees to participate in the study].

By signing this consent form, you [and your child] have not waived any legal rights your child otherwise would have as a participant in a research study.

<table>
<thead>
<tr>
<th>Child's Name:</th>
<th>Date:</th>
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<tbody>
<tr>
<td>Child's Signature (if applicable):</td>
<td>Date:</td>
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<tr>
<td>Signature of Parent:</td>
<td>Date:</td>
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<tr>
<td>Signature of Second Parent (if required):</td>
<td>Date:</td>
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<tr>
<td>Signature of Legal Guardian (if applicable):</td>
<td>Date:</td>
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<tr>
<td>Signature of Person Obtaining Consent: (Investigator or IRB-Approved Designee)</td>
<td>Date:</td>
</tr>
<tr>
<td>Witness to Consent Procedures (if required by IRB):</td>
<td>Date:</td>
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</tbody>
</table>
الفوائد
- صف الفوائد المتوقعة من البحث والتي تعود على المشاركين ووضحاً.
- في حال عدم وجود أي فكرة، اذكر العبارة التالية:
لا توجد فوائد مباشرة تعود على طفلكم من خلال المشاركة في هذه الدراسة.
- صف الفوائد المتوقعة من البحث والتي تعود على الآخرين، ومنها الفوائد التي قد تعود على من يعانون من أضطرابات موضوع البحث أو فوائد تعود على العامة أو المجتمع، على سبيل المثال: في حالة الفوائد العامة الناتجة عن إدراج نتائج البحث يمكن إضافة عبارة مثل ما يلي:
هذه الدراسة يمكن أن تفيد المجتمع إذا ما أدت نتائجها إلى فهم أفضل لـ (تحديد الموضوع).

المشاركة التطوعية وحق الانسحاب
- إبدأ بالعبارة التالية مع إدراج ما بين القوسين عندما يتناسب ذلك مع سن المشارك وحالته العقلية.
إن مشاركة طفلكم في الدراسة هي مشاركة طوعية بالكامل. أي إنه من حقكم السماح لطفلكم بالمشاركة (كما أننا أيضاً سوف نطلب من طفلكم أن يوافق على المشاركة بالدراسة). في حال قررت عدم السماح لطفلكم بالمشاركة أو قررت طفلكم عدم المشاركة، فلن يكون هناك أية عواقب كما أنتم وطفلكم لن تخسرون أي من الامتيازات المستحقة، وفي حال اختيار المشاركة في الدراسة، يمكن التوقف عن المشاركة في أي وقت بدون أية عواقب.
- إذا كانت قائمة الأسباب غير واضحة:
قد تطرأ ظروف أخرى قد تؤدي إلى إنهاء مشاركة طفلكم.
- إذا اقتضى الأمر، أضف الجملة التالية في نهاية هذا الجزء:
في حال أنهينا مشاركة طفلكم قبل نهاية الدراسة، سوف نوفر التعويض عن مشاركته/مشاركتها حتى تاريخه.

البدائل للمشاركة
- أذكر هذا الجزء في حالة: (أ) استفادة المشارك من المشاركة في هذه الدراسة، و (ب) إمكانية الحصول على فوائد مماثلة أو مشابهة بطريقة أخرى. على سبيل المثال، إذا كان هناك إمكانية وجود بدائل مشابهة أو مماثلة للطفل.
- إذا لم تكن هناك بدائل مماثلة أو مشابهة، أما إذا كان هناك إمكانية وجود بدائل مشابهة أو مماثلة للطفل.

الشروط
- صف إلى أي مدى سيتم الحفاظ على سرية السجلات الخاصة بالمشارك.
- الإداريين:
 سيتم الحفاظ على أي سجلات خاصة بالدراسة التي تعرف كغير أو طفلكم. وفقاً لمراجعة سجلات بطلتكم، قد نقوم بمراجعة مقارنة أخلاقية البحث العلمي لجامعة بيروت العربية (وليتم كل من الأشخاص المعنيين بذلك، أصحاء صحة البحث، والجسم العلمي، وجميع الأشخاص المعنيين بذلك). وفيما عدا ذلك، فإن السجلات الخاصة بك (أو طفلكم) لن تجد سوى للأشخاص القائمين على الدراسة.

التحريض
- حدد كافٍ من التعويضات (على سبيل المثال: درجات إضافية في مقرر ما، أو نقل).
- في حال عدم وجود كافٍ من التعويضات، أذكر العبارة التالية:
لا يوجد تعويضات أخرى.

الملاحظات النهائية
- إذا كنت تملك أي أسئلة بخصوص حق الطفل باعتباره مشارك في البحوث أو في حال شعرتم أن طفلكم لم يتم معاملته بإنصاف، الرجاء الاتصال بالجنة أخلاقية البحوث العلمية في جامعة بيروت العربية.
- إذا لم تكن لديك أي أسئلة، الرجاء الاتصال بالباحثين.
- إذا لم تكن لديك أي أسئلة، الرجاء الاتصال بالباحثين.

النوع الذي قد توفره المشتركون
- أضف هذه الجملة إذا ما كان هناك طفولك الذي تم علاجه.
- إذا تم علاجه، فأنت إذا ما تم علاجه.
- إذا تم علاجه، فأنت إذا ما تم علاجه.
- إذا تم علاجه، فأنت إذا ما تم علاجه.

المشاركة العضوية وحق الانتظار
- إذا كانت هناك المشاركات العضوية، فأنت إذا ما تم علاجه.
- إذا تم علاجه، فأنت إذا ما تم علاجه.
- إذا تم علاجه، فأنت إذا ما تم علاجه.
- إذا تم علاجه، فأنت إذا ما تم علاجه.

الظروف التي قد تؤدي إلى إنهاء المشاركة
- أضف هذه الجملة إذا ما كان هناك طفولك الذي تم علاجه.
- إذا تم علاجه، فأنت إذا ما تم علاجه.
- إذا تم علاجه، فأنت إذا ما تم علاجه.
- إذا تم علاجه، فأنت إذا ما تم علاجه.
We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about [insert topic and describe goals in simple language]. You are being asked to join the study because [insert name of condition or other reason(s) for inclusion].

If you agree to join this study, you will be asked to [describe procedures, (e.g. questionnaires, activities) in words a child would know and understand. Also, include number of visits and time frame in words easily understood by a child].

Describe possible risks (e.g., discomforts) in simple language. Use any of the following statements that are appropriate: We do not know if being in this study will help you. We expect that the study will help you by [describe how]. We may learn something that will help other children with [insert name of condition or topic under investigation] someday. This study will help us learn more about [topic under investigation].

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop.

Before you say yes or no to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you want to be in this study, please sign your name. You will get a copy of this form to keep.

Date:

Sign your name here:
Research Project Final Approval Letter (Form H-XII)

Acceptance Number:

Journal Name:

Date:

Dear

By signing this form, we declare that:

Human subjects in the research titled hereafter were treated in accordance with the regulations and guidelines stipulated by the Institutional Review Board (IRB) at Beirut Arab University, Lebanon.

Research Title:

Main Correspondant Name:

Sincerely,

IRB Chairperson /Coordinator:

Date:

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Forms

BAU Institutional Review Board

Form H-XI

Council of Social Sciences Research (For minors of 18 years or the participants in social/behavioral research)

For research projects as a form of research in Social Sciences and Behavioral Sciences (IRB), in case of research activities

Institutional Review Board at Beirut Arab University. Lebanon.

Research Title:

Main Correspondent Name:

Sincerely,

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Research Title:

Main Correspondent Name:

Sincerely,

IRB Chairperson /Coordinator:

Date:
Project Information Form - Research Involving Animals
(Form A-I)

Application Number:                 Date Received:  
Reviewed By: IRB-IACUG Meeting Date:  
Form Type: ☐ Original ☐ Amendment  

TITLE OF PROJECT/COURSE

INVESTIGATOR(S) [1st is the correspondent investigator/supervisor]

Title:  
Name:  
Qualifications:  
Designation:  
Place of Work:  
Address:  
Contact Number:  
Email Address:  
Signature:  
☐ Principal Investigator ☐ Co-investigator ☐ Supervisor  

Objectives of the research/course:

In the case of a collaborative project, please list cooperation partner(s) and affiliation:

Animal species used:
Species  
Number of Females  
Number of Males  
Animal source:

Place of performing the experimental part:

Briefly describe the experiment procedures:

Please report any expected problems:

- Any change of the above information and an amendment form must be attached and approved by the committee within 30 working days.  
- By signing this form, we declare that we have carefully read, understood, and accept to abide by the general guidelines.  

Correspondant Name:  
Correspondant Signature:  
Date:  

Has ethical review for this study been requested earlier from IRB or another committee?
☐ Yes* ☐ No  
*Where:  
*When:  
*Result:
Project Information Form – Final Decision (Form A-II)
FOR OFFICIAL USE ONLY

The final decision is based on

Are all documents provided:  Yes ☐ No ☐ N/A ☐

Comments:

Scientific Validity

1- Will the study lead to improvements in human wellbeing or increase knowledge?  Yes ☐ No ☐ N/A ☐
2- Can the intervention method studied be practically implemented?  Yes ☐ No ☐ N/A ☐
3- Has the research protocol been approved by a competent body?  Yes ☐ No ☐ N/A ☐
4- Are the objectives stated clearly?  Yes ☐ No ☐ N/A ☐
5- Is the study design appropriate in relation to the objectives?  Yes ☐ No ☐ N/A ☐
6- Is the study designed using accepted principles, methods and practices?  Yes ☐ No ☐ N/A ☐
7- Is there a plausible data analysis plan?  Yes ☐ No ☐ N/A ☐
8- Are the investigators’ qualifications, competence and experience appropriate to conduct the study?  Yes ☐ No ☐ N/A ☐
9- Are the facilities at the site adequate to support the study?  Yes ☐ No ☐ N/A ☐

Assessment of/Benefits/Risks

1- Are the researcher’s qualifications, competence, and experience suitable to ensure safe conduct of the study?  Yes ☐ No ☐ N/A ☐
2- Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?  Yes ☐ No ☐ N/A ☐
3- Is the site, including support staff, facilities and emergency procedures, adequate?  Yes ☐ No ☐ N/A ☐
4- Have adequate provisions been made for safety monitoring and termination of the research project?  Yes ☐ No ☐ N/A ☐

Project Compliance with the IACUC Requirements

1- Does the experiment design comply with the Animal Welfare Act, the Canadian Council on Animal Care requirements, and related laws and international standards?  Yes ☐ No ☐ N/A ☐
2- Is the designated method of animal killing appropriate?  Yes ☐ No ☐ N/A ☐
3- Are the procedures of sample storage and disposal adequate?  Yes ☐ No ☐ N/A ☐

Responsibilities of the Researcher

1- Are there any conflicts of interest, including payments and other rewards?  Yes ☐ No ☐ N/A ☐
2- Are there any other ethical / legal / social / financial issues in the study?  Yes ☐ No ☐ N/A ☐

Additional Comments:

Recommendation:
☐ Approve  ☐ Reject  ☐ Conditional Approval (please state the conditions)

Name of Reviewer:

Signature:

Chairperson:

Signature:

Date:
Project Information Form – Completion of Research (Form A-III)

Application Number:
Date Received:
Reviewed By:
IRB Meeting Date:

TITLE OF PROJECT AND PLACE OF IMPLEMENTATION

INVESTIGATOR(S) [1st is the correspondent investigator/supervisor]

☐ Principal Investigator ☐ Co-investigator ☐ Supervisor

Title:
Name:
Qualifications:
Designation:
Place of Work:
Address:
Contact Number:
Email Address:
Signature:

Duration of the Experiment
From: To:

Were any problems encountered in the following areas?

Study Design ☐ Yes ☐ No
Ethics ☐ Yes ☐ No
Finance ☐ Yes ☐ No
Facilities and Equipment ☐ Yes ☐ No

If yes, please summarise the problems encountered.

Please provide a one-page summary of the project outcomes

- In case of any change in the above information, an amendment form must be attached and approved by the committee within 30 working days.
- By signing this form, we declare that we have carefully read, understood, and accept to abide by the general guidelines.

Correspondent Name:
Correspondent Signature:
Date:
Research Project Final Approval Letter (Form A-IV)

Acceptance Number:

Journal Name:

Date:

Dear

By signing this form, we declare that:
Animal care and handling for the research titled hereafter were performed in accordance with the regulations and guidelines stipulated by the Institutional Animal Care and Use Guidelines (IACUG) at Beirut Arab University, Lebanon.

Research Title:

Main Correspondant Name:

Sincerely,

IRB Chairperson /Coordinator:

Date:

REFERENCES

2. The Universal Declaration of Human Rights.
3. The International Covenant on Civil and Political Rights.
4. The Council for International Organizations of Medical Sciences.
5. The World Health Organization.
6. UNAIDS Guidance Document on Ethical Considerations in HIV Preventive Vaccine Research.
14. Bridgewater State University