# TABLE OF CONTENTS

## INTRODUCTION

1. Background
2. Responsibilities and Authorities
3. Mission
4. Vision
5. Membership

## PART A GUIDELINES FOR HUMANS

### I. ETHICAL GUIDELINES

1. International Instruments and Guidelines
2. General Ethical Principles

### II. TYPES OF REVIEW

1. Exempt Research
2. Expedited Review
3. Full Review
4. Continuing Review
5. Others
   - Revisions
   - Suspension or Termination of Research
   - Unintentional

### III. CRITERIA FOR IRB APPROVAL OF RESEARCH

1. Risks to Subjects
2. Risk/Benefit Ratio
3. Selection of Subjects

### IV. INFORMED CONSENT

1. General Requirements
2. Documentation

### V. IRB SUBMISSION AND REVIEW PROCESS

1. Submission Material
2. Estimated Review Schedule

## PART B INSTITUTIONAL ANIMAL CARE AND USE GUIDELINES (IACUG)

### I. ROLE OF IACUG

1. Communication with IACUG

### II. APPROVAL CONDITIONS AND DECISION MAKING

1. Positive Decision
2. Conditional Decision
3. Negative Decision
IV. ETHICS REVIEW AND GUIDELINES FOR RESEARCH USING ANIMALS .................16

V. FOLLOW UP ........................................................................................................18
   A. Submission of Progress Reports
   B. Publication of Results

PART C REFERENCES AND FORMS

I. REFERENCES .......................................................................................................18

II. FORMS ................................................................................................................19
   A. 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)

   B. 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)
INTRODUCTION

A. BACKGROUND
Beirut Arab University has established its Institutional Review Board 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 or student investigates on 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 with the institutional responsibility for assurance of protection of humans and animals involved in research or related activities.

B. RESPONSIBILITIES AND AUTHORITIES
Beirut Arab University’s Institutional Review Board (IRB) is a formally designated committee to review, approve, and monitor biomedical and behavioral research involving humans and animals conducted by academic staff and students at BAU and/or its affiliates. BAU’s IRB have the right to approve, require modifications in planned research prior to approval, or disapprove research. The IRB has the right to regularly monitor the compliance to the ethical guidelines of the approved protocols, at intervals of at least once per year, till the research is completed.

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

IRB provides independent and timed decision, based on the adherence to the guidelines in compliance with international declarations including Nuremberg, Helsinki and Belmont declarations1.

C. MISSION
The IRB aims to safeguard the protection of the dignity, rights, safety, and welfare of all actual or potential research subjects.

D. VISION
IRB is looking towards a modern approaches and concepts, practical and ethical scientific research, to ensure the strengthening of the movement of scientific research in accordance with international standards and to the service of society and the requirements of the labour market.
E. MEMBERSHIP
The Institutional Review Board (IRB) chairperson, coordinator and members are appointed by BAU administration. It has the freedom to work independently and decide on the merits of proposals without interference within the institutional framework.

The BAU/IRB is composed of at least eight members, based on these criteria:

- The members must have enough collective experience, expertise, and diversity to make an informed decision 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
  - A dentist
  - A pharmacist
  - A health sciences field member
  - A scientist
  - A law expert
  - An expertise in Social Behavioral Sciences
  - 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.

All regarding preclinical and animal experiments are included in (part VII). Refer to (IACUG).

PART A GUIDELINES FOR HUMANS

I. ETHICAL GUIDELINES

A. 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 “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 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 and 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\textsuperscript{4} (CIOMS) 1993, has issued many ethical guidelines on clinical trials which have been published by several international organizations. This has included, from the World Health Organization\textsuperscript{5}, in 1995, Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products; and from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), in 1996, 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 programme on HIV/AIDS published in 2000 the UNAIDS Guidance Document Ethical Considerations in HIV Preventive Vaccine Research\textsuperscript{6}. on the other hand, UNESCO adopted in 19 October 2005 the Universal Declaration on Bioethics and Human Rights\textsuperscript{7}.

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 science 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) are some examples of these instruments.

**B. 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 the abstract 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 for self-determination in treating those who are capable of deliberation about their personal choices.
- Persons with impaired or diminished autonomy should be afforded security against harm or abuse.
“Beneficence” refers to the ethical obligation to maximize benefit and to 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 to safeguard the welfare of the 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 (do no harm).

“Justice” refers to the ethical obligation to treat each person in accordance with what is morally right and proper, 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 the 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.

II. TYPES OF REVIEW

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

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - i) Research on regular and special education instructional strategies.
  - ii) 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:
  - i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.
  - ii) Any disclosure of the human subjects 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 subject to the approval of Department or Agency heads and which are designed to study, evaluate, or otherwise examine:
  
  i) Public benefit or service programs.
  
  ii) Procedures for obtaining benefits or services under those programs.
  
  iii) Possible changes in or alternatives to those programs or procedures.
  
  iv) Possible changes in methods or levels of payment for benefits or services under those programs.

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

It should be noted that only IRB members may determine that a study is exempt from Expedited or Full Review.

B. EXPEDITED REVIEW

In some circumstances, if there is no more than minimal risk, expedited review can be conducted even on studies involving minors. The 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 potentially 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 small.

• Collection of blood samples by finger stick, heel stick, ear stick or veni-puncture not to exceed 50 ml or 3 ml per kg (whichever is less) in an 8 week period, and collection may not occur more frequently than 2 times per week.
• Collection of hair and nail clippings in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

• Collection of excreta and 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 in accordance 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 marketing. 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, magnetic resonance imaging, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic infrared imaging, Doppler blood flow, and electroretinography. Subjects can participate in moderate exercise, muscular strength testing, 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 factors evaluation, or quality assurance methodologies.

C. 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 that involves 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 been 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, patients with medical disorders) at more than minimal risk.

D. 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 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 review will be conducted by the full IRB.

E. OTHERS
1. 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, the type of review Expedited or Full and notify the IRB members.

2. 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, 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.
3. UNINTENTIONAL
In the event research is conducted without the intention of involving human subjects, and subsequently the researcher wishes to involve human subjects in the research, the research must be reviewed by the IRB in accordance with the policies and procedures outlined in this manual.

III. CRITERIA FOR IRB APPROVAL OF RESEARCH

A. RISKS TO SUBJECTS
Risks to subjects are minimized:
   i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

   ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

1. Have the rationale and basis 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?

B. RISK/BENEFIT RATIO
Risks to subjects are reasonable in relation to anticipated benefits, to subjects and the importance of the knowledge that may reasonably be 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 or 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?

C. 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?

IV. INFORMED CONSENT

A. 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, in seeking informed consent the following information shall be provided to each subject:

   a. A statement that the study involves research, an explanation of the purpose(s) 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.

   b. A description of any reasonably foreseeable risks or discomforts to the subject.

   c. A description of any benefits to the subject or to others which may reasonably be expected from the research.

   d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

   e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

   f. For research involving more than minimal risk, an explanation as to whether any compensation 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.

   g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact the event of a research-related injury to the subject.

   h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled to receive 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. 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 unforeseeable.

   b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subjects' consent.

   c. Any additional costs to the subject that may result from participation in the research.

   d. The consequences of the subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject.
e. A statement that significant new findings developed during the course of the research which may relate to the subjects' willingness to continue participation will be provided to the subject.

f. 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:

   a. The research involves no more than minimal risk to the subjects.

   b. The research could not practicably be carried out without the waiver or alteration.

   c. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

   d. The researcher demonstration project is to be conducted by or subject to the approval of government officials and is designed to study, evaluate, or otherwise examine:

      i) Programs under the public benefit or service programs.

      ii) Procedures for obtaining benefits or services under those programs.

      iii) Possible changes in or alternatives to those programs or procedures.

      iv) Possible changes in methods or levels of payment for benefits or services under those programs.

B. DOCUMENTATION

1. Except as provided in part (3) 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.

2. Except as provided in part (3) of this section, the consent form may be either 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".

3. 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.

V. IRB SUBMISSION AND REVIEW PROCESS

1. If you are sure that your project qualifies as human subjects’ research, complete the Human Subjects 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 all supplements and required signatures and mail them to the committee. Alternately, you may e-mail pdf files with signature pages scanned to e-site. Be sure to provide certification that you have completed the required training to conduct human subject's 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 the IRB 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. The IRB will meet at least once a month and review applications. Approved applications will be valid for up to three years.

7. 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.

8. 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.

9. 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.

A. SUBMISSION MATERIAL

- Complete Application Form signed by both the Primary Investigator (PI) and the Department Chair.

- When appropriate, any and all necessary appendices required by the Application Form.

- English and 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/questionnaires 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, if sponsored clinical trial (if applicable).

- Insurance certificate from sponsor or Clinical Trial Agreement which documents subject injury medical expenses, is covered by sponsor (if applicable).

B. ESTIMATED REVIEW SCHEDULE

The review schedule dates are calculated from the date 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 the reviewer concerns.

- Exempt Research Studies: within 3-4 weeks for review and approval.

- Expedited Review requires approximately 6-8 weeks for review and approval.

- Full Committee Review should be submitted at least 4 weeks prior to the IRB meeting date; review and approval by the IRB may require from one to three months after initial IRB review at a convened meeting.
PART B INSTITUTIONAL ANIMAL CARE AND USE GUIDELINES (IACUG)

BAU Institutional Animal Care and Use Guidelines (IACUG) are intended to facilitate the IRB review to the 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 the compliance to the ethical guidelines of the approved protocols, till 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.”

I. ROLE OF IACUG

IACUG is established to prove safety and welfare of experimental animals used for research and ensures 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 reviewing are performed free of bias and influence.

The IRB provides independent and timed decision, based on the adherence to the guidelines detailed hereafter. These guidelines are based on the Animal Welfare Act¹² and the Canadian Council on Animal Care’s (CCAC) Guide to the Care and Use of Experimental Animals¹³. IACUG is to be also involved in the on-going monitoring of the approved research. IACUG is taking into account the interests and needs of the researchers, and having due regard for the requirements of the relevant regulatory and applicable laws.

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; and it may include the format sheets for applications (Form A-I, A-III).

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

1. Cooperating, advising, supporting with other relevant committees in matters of common interest such as Faculty Research Committee.

2. Promoting community awareness and consulting with individuals, communities and government on ethics 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.
II. COMMUNICATION WITH IACUG

All communications and submitted applications is performed directly, mailed or e-mailed to the committee. Online applications are accepted for reviewing, but final decision is withheld until a hard copy is submitted with 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).

III. 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, IRB needs to consider the scientific value and validity justification, methodology, proposed analytical methods, etc., as well as ethical issues as stated hereafter. Communications and decisions are given in a written form under the signature of the IRB chairperson or coordinator in the relevant (Form A-II).

A. POSITIVE DECISION

The approval decision is subjected 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.

B. CONDITIONAL POSITIVE DECISION

A conditional approval may be granted animal to 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).

C. 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 IRB.
IV. ETHICS REVIEW AND GUIDELINES FOR RESEARCH USING ANIMALS

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\textsuperscript{11} and Canadian Council on Animal Care’s (CCAC) Guide to the Care and Use of Experimental Animals\textsuperscript{12}:

1. If animals must be used, animals 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:

   a. Experiments involving withholding pre and post-operative pain-relieving medication.

   b. Paralyzing and immobilizing experiments where there is no reduction in the sensation of pain.

   c. Electric shock as negative reinforcement.

   d. Extreme environmental conditions such as low or high temperatures, high humidity, modified atmospheres, or sudden changes therein.

   e. Experiments studying stress and pain.

   f. 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.
g. 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:
   a. Utilization of muscle relaxants or paralytics (curare and curare-like) alone, without anaesthetics, during surgical procedures.
   b. Traumatizing procedures involving crushing, burning, striking or beating in un-anaesthetized animals.

7. 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.

8. 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.

9. Painful experiments or multiple invasive procedures on animals should be done without pain using adequate anaesthesia.

10. Waste disposal should be in compliance with BAU waste handling procedures that meet local environmental requirements which is essential to ensure the safe transport and disposal of waste, especially, the 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 sharps containers are stored securely before periodically collected by licensed waste contractors for final disposal using approved technologies by licensed/accredited contractors (for detailed procedure, please contact +961 1300110 Ext: 2554).
V. FOLLOW UP
IACUG consider the advisability of monitoring progress of research approved by them.

A. SUBMISSION OF PROGRESS REPORTS
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”.

B. PUBLICATION OF RESULTS
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.

PART C REFERENCES AND FORMS

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

A. 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)

B. 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)

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 on this sheet.

Please indicate whether this submission is for an expedited or full review and check all documents that are being submitted. 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>Are the inclusion/exclusion criteria clearly stated and reasonable?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is the selection of subjects appropriate and equitable?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Are minorities, women, children or other vulnerable populations included?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Is the inclusion or exclusion of minorities, women, children and other vulnerable populations justified?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Are additional safeguards in place to protect subjects who may be vulnerable to coercion or undue influence?</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
</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>
<tr>
<td>If yes, are materials non-coercive and easily understandable?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>Are there acceptable methods for screening subjects prior to enrolment?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Notes:**

### Section III: Research Plan

**Purpose:**

**Introduction:**

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

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

**Inclusion/Exclusion Criteria:**

**Risks and Inconveniences:**

**Specific Aims, Background and Significance**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the study aims/objectives clearly specified?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>Adequate preliminary data to justify research?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>Are adequate references provided?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>Is there appropriate justification for this research protocol?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
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</tbody>
</table>

**Scientific Design**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the rational for proposed number of subjects reasonable?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>Is the scientific design adequate to answer the study’s questions(s)?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>Is the scientific design adequately described and justified?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>Are the study aims/objectives likely to be achieved within the given time period?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>Are there adequate plans for data safety and monitoring?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>Are the plans for data and statistical analysis defined and justified?</td>
<td>☐</td>
<td>☑</td>
<td>☐</td>
</tr>
</tbody>
</table>
### Research Procedures

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the rationale and details of research procedures adequately described?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>For treatment studies, is there a clear differentiation between research procedures and standard of care and evaluation?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are there adequate plans to inform subjects about research results?</td>
<td>☐</td>
<td>☐</td>
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</tbody>
</table>

### Resources

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there appropriate resources to conduct this research (e.g., equipment, space, lab, staff)?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Is appropriate monitoring of subjects during and after the research assured?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Will counseling or support services be provided, if applicable?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are there adequate plans to inform subjects about research results?</td>
<td>☐</td>
<td>☐</td>
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</tbody>
</table>

### Economic Considerations

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is compensation to subjects reasonable, not coercive?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If subject does not complete study, will compensation be pro-rated?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>For student participants, is experimental credit offered and clearly defined?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

### Risks and Benefits

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the risks and benefits adequately identified, evaluated and described?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are the risks reasonable in relation to the benefits?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are the risks reasonable in relation to importance of knowledge to be gained?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Are the risks minimized to the extent possible?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tbody>
</table>

### Subject Privacy and Confidentiality

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there adequate provisions to protect the privacy of subjects?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are there adequate provisions to protect the confidentiality of data during and after research?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Are there adequate provisions for storage, coding and use of identifiers?</td>
<td>☐</td>
<td>☐</td>
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</tr>
</tbody>
</table>

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>
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</thead>
<tbody>
<tr>
<td>Is the process well defined?</td>
<td></td>
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<tr>
<td>Does this process provide sufficient time, privacy and adequate setting for the subject to consider?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Is the individual(s) obtaining consent/assent appropriate?</td>
<td></td>
<td></td>
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<tr>
<td>Are the issues of subject’s comprehension and autonomy considered?</td>
<td></td>
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</tbody>
</table>

Notes (if any):

### Signature

PI:

Department Chair:

### 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 protocol be reviewed more often than once per year?</td>
<td></td>
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<tr>
<td>Are there any notable conflicts of interest?</td>
<td></td>
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<tr>
<td>For studies that involve collaborating institutions or investigators, has the correct paperwork been submitted?</td>
<td></td>
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</tbody>
</table>
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 the informed consent document, protocol or other study materials.
- ☐ Minor clarification(s) concerning specific aspect of study or additional information requested from PI.

**Deferral**
- ☐ There is an unacceptable risk/benefit ratio.
- ☐ Protocol is poorly written, lacking significant amounts of information regarding scientific justification, study procedures, risk reduction, etc.
- ☐ It is possible that a response for 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 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 IRB Approval for this study.

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

IMPORTANT

This form is for renewal of 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, 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, no further contact with participants.

2. Describe any adverse events or participant complaints related to study procedures and describe 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

- # of participants actively enrolled or records/samples being reviewed (at present).
- # of participants enrolled, or records/samples reviewed since most recent approval.
- # of participants enrolled, or records/samples reviewed since original approval (Total).
- # 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 researches)**

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 ONLY ONE YEAR

Other (Specify):

IRB Signature:

Date:
Protocol Application Checklist (Form H-IV)

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>For each proposed amendment, does the PI address whether the proposed amendment does or does not increase the level of risk to participants?</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**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...

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the study procedures described in the protocol the same as those</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>described in the new grant?</td>
<td></td>
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<tr>
<td>If applicable, is there adequate funding in the budget to compensate</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>subjects as described in the protocol?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If new funding, review the source and consider whether an IRB Authorization Agreement, Individual Investigator Agreement, or other IRB review is needed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are any investigators on this protocol required to submit the supplemental significant Financial Interest Review Form?</td>
<td></td>
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</tr>
<tr>
<td>If applicable, identify the individual(s):</td>
<td></td>
<td></td>
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<tr>
<td>Notes (if any):</td>
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</tbody>
</table>

**Section IV: Human Subjects**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the number of participants being changed?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>If so, is this reflected properly here and in the Justification of Sample Size/Data Analysis Section?</td>
<td></td>
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<tr>
<td>Is there adequate justification for the increase?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does participant selection remain equitable?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Are recruitment procedures being amended?</td>
<td></td>
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<tr>
<td>If so, does recruitment material meet current standards?</td>
<td></td>
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<tr>
<td>Is permission from off-campus site required?</td>
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<tr>
<td>Are there concerns about coercion because of the changes?</td>
<td></td>
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<tr>
<td>Are special/vulnerable populations now being recruited?</td>
<td></td>
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<tr>
<td>If so, are consent procedures still adequate?</td>
<td></td>
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<tr>
<td>Are safeguards still adequate?</td>
<td></td>
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<tr>
<td>Do study documents need to be translated?</td>
<td></td>
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<tr>
<td>Does the recruitment material/process meet current standards?</td>
<td></td>
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<tr>
<td>Notes (if any):</td>
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</tbody>
</table>
### Section V: Drugs/Devices, Genetic Testing, Radiation and Biological Samples

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are biological samples now being collected?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>If so, was approval from the biosafety office submitted?</td>
<td></td>
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<tr>
<td>If changes were made to the amount of samples collected, is this reflected in the study procedures and consent form?</td>
<td></td>
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<tr>
<td>Are procedures involving use of radiation now being used?</td>
<td></td>
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<tr>
<td>If so, was approval from the radiation safety office submitted?</td>
<td></td>
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<tr>
<td>Are the new procedures adequately documented in the procedures section, risks identified in the risk section and reflected in the consent form?</td>
<td></td>
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</tbody>
</table>

Notes (if any):

### Section VI: Research Plan

**Design, Procedures, Materials and Methods**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were changes made to the research design and procedures?</td>
<td></td>
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<tr>
<td>If so, does the change impact the scientific integrity of the study?</td>
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<tr>
<td>Does the amendment increase the amount of time for the participants?</td>
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<tr>
<td>If so, was the consent form revised?</td>
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</tbody>
</table>

Notes (if any):

**Justification of Sample Size/Data Analysis**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the amendment require a change in sample size?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Do data analysis procedures need to be changed as a result of the amendment?</td>
<td></td>
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<tr>
<td>Is the sample size still adequate to achieve meaningful results?</td>
<td></td>
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<tr>
<td>Is there an increased likelihood of attrition?</td>
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</tbody>
</table>

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

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

**Notes (if any):**

### Risks and Inconveniences

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the level of risk change?</td>
<td></td>
<td></td>
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<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 it 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>
<td></td>
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<tr>
<td>If so, was the consent form appropriately revised?</td>
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</tbody>
</table>

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

**Notes (if any):**

### Privacy/Confidentiality

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are procedures to protect privacy and confidentiality still adequate?</td>
<td></td>
<td></td>
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<tr>
<td>If not, are changes required?</td>
<td></td>
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<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>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are appropriate changes as a result of the amendment reflected in the</td>
<td></td>
<td></td>
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<tr>
<td>revised consent form?</td>
<td></td>
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<tr>
<td>Is there an increased need to assess capacity to consent?</td>
<td></td>
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<tr>
<td>Should currently enrolled participants be re-consented?</td>
<td></td>
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<td></td>
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<tr>
<td>Should previously enrolled participants be re-consented?</td>
<td></td>
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<tr>
<td>Is the consent process still appropriate for all populations?</td>
<td></td>
<td></td>
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<tr>
<td>Does the consent form/process meet current standards?</td>
<td></td>
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<tr>
<td>Should participants be afforded an increased level of privacy during</td>
<td></td>
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<tr>
<td>consent?</td>
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<tr>
<td>Are previously granted waivers of consent/signed consent still</td>
<td></td>
<td></td>
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<tr>
<td>appropriate?</td>
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<tr>
<td>Can a waiver of consent/signed consent be granted now?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Notes (if any):</td>
<td></td>
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</tbody>
</table>

#### 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

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the risks still reasonable in relation to anticipated benefits?</td>
<td></td>
<td></td>
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<tr>
<td>Are the risks minimized through sound research design?</td>
<td></td>
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</tbody>
</table>

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

- [ ] Approve as submitted
- [ ] Require 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?

☐ ☐ ☐

If so, what time frame is appropriate?
Protocol Application Checklist (Form H-V)

PI Last Name: 
Protocol Number: 

1: General Information

Nature of Study: Other Investigators:
Study Title: Other IRB Reviews:
Study Objective: Collaborating Institutions:
Principal Investigator: Study Location:

2. 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.

3. 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).

4. 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

5. 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 can reasonably be 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.

6. Confidentiality. Describe what identifiers will be collected on the participants. If participants will be identified, describe the procedures in place to protect their confidentiality.
7. 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).

8. 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 the 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, include 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 stop 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 stop 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, 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 IRB 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:**

**Date:**
 silly text
إن المخاطر المقترنة بالمشاركة في هذه الدراسة لا تتجاوز تلك التي نواجهها في الحياة اليومية (أو خلال الأداء الروتيني للفحوصات أو الاختبارات الجسدية أو النفسية).

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 إخراج تقدم في المعالفة حول موضوع البحث يمكن إضافتة عبارة مثل ما يلي:

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

المشاركة التطوعية وحق الانسحاب

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

- إذا ما تطلب الانسحاب المشارك الامن من الدراسة اية إجراءات خاصة (صف هذه الإجراءات).

- أضف العبارة التالية إذا تناسب الأمر:

  إذا ما توصلنا إلى أي معلومات جديدة خلال الدراسة والتي قد تثير في قراركم بالاستمرار في المشاركة فإننا سوف نناقش هذه المعلومات معكم.
الظروف التي قد تؤدي إلى إنهاء مشاركتكم

أضاف هذا الجزء إذا ما كانت هناك ظروف محددة قد تؤدي إلى إيقاف المشاركات عن الدراسة.

- ابدأ بهذه العبارة: في ظل ظروف معينة، قد نقرر إنهاء مشاركة طفلكم قبل أن يستكمل الدراسة وتحديداً فإننا قد نضع حداً لمشاركة طفلكم إذا ما [صف الأسباب المحتملة لإنهاء مشاركة الشخص] فورنا إلغاء مشاركتكم قبل نهاية الدراسة وذلك بسبب [أذكر الأسباب]

إذا كانت قائمة الأسباب غير واضحة:

قد تطرأ ظروف أخرى قد تؤدي إلى إنهاء مشاركة طفلكم.

إذا اقتضى الأمر، أضيف الجملة التالية في نهاية هذا الجزء:

في حال أنهينا مشاركة طفلكم قبل نهاية الدراسة، ستوفر نوفر التعويض عن مشاركتهما/مشاركتهما حتى تاريخه.

بدائل للمشاركة

أذكر هذا الجزء في حالة: (أ) استفادة المشارك من المشاركة في هذه الدراسة، و (ب) امكانية الحصول على فوائد مماثلة أو مشابهة بطريقة أخرى. على سبيل المثال، في حالة عمل دراسة تزود تدريسًا خاصة لمشاركين، اضف هذا الجزء، إذا كان هناك امكانية وجود سبل مشابهة أو مماثلة للطلاب الغير مشاركين في الدراسة.

اشرح البدائل للمشارك التي قد تمنح منافع شبيهة أو مماثلة.

السرية

أضاف إلى أي مدى ستتم الحفاظ على سرية المسجلات الخاصة بالمشارك. تطبيق العبارة التالية في أغلب الدراسات:

سيتم الحفاظ على أي سجلات خاصة بالدراسة والتي تعزف بك، وقد يقوم ببروفيسور المسجلات مشاركتكم أشخاص مسؤولون عن ضمان سلامة الإجراءات البحثية بما في ذلك أعضاء مجلس أخلاقية البحث العلمي. وبالطبع فإن السجلات الخاصة بك لن تفتح سوى للأشخاص القائمين على الدراسة ما لم تقدموا إذناً للمشاركين بالإطلاع على الدراسة.

بعض الدراسات تطلب الكشف عن المعلومات لأطراف أخرى ويتطلب ذلك من المشاركين إشارة مالية للمعلومات التي سوف يتم أو قد يتم الكشف عنها، وفقاً لذلك، ستتم الكشف عن هذه المعلومات.
صف كيف سيتم تحميل وتخزين والحفاظ على سجلات الدراسة لحماية سرية المعلومات (على سبيل المثال: استخدام أرقام كودية بدلاً من أسماء المشاركين على استمارات جمع البيانات والحفاظ على السجلات في خزانة محكمة الإغلاق).

بعض الدراسات تطلب الكشف عن المعلومات لأطراف أخرى وفى مثل هذه الدراسة اشرح ماهية المعلومات التي سوف يتم أو قد يتم الكشف عنها ومن.

التعويض

حدد كافة المكافآت وغيرها من التعويضات.

في حال عدم وجود أية تعويضات، أذكر العبارة التالية:

لن تتلقى أي مكافأة أو تعويض عن المشاركة في هذه الدراسة.

إذا كانت لديك أية أسئلة أو استفسارات:

يمكن لكم طرح الأسئلة حول هذه الدراسة الآن أو في أي وقت أثناء أجراء الدراسة، وذلك من خلال التحدث إلى الباحث / الباحثين الذين يعملون معكم من خلال الاتصال بالبحث العلمي في جامعة بيروت العربية على الرقم 1000011111. وضح تعويضات / العلاج للمشاركين المتضررين، وفي هذه الحالة صف التعويض / العلاج، أو حدد المكان الذي يمكن الحصول منه على المزيد من المعلومات، ووضح ما إذا العلاج سيقدم مجانية للمشارك أو إذا ما سيطلب من المشارك تحمل تكاليفه.
* في حال عدم توافر تعويض أو علاج، أضف العبارة التالية:

لا تتضمن هذه الدراسة أي برامج للتعويض أو علاج طفلكم عن الضرر الذي قد يلحق به نتيجة لمشاركته.

ما يترتب عليه توقيعكم:

إن توقيعكم أسفله يعني أنكم قد فهمتم المعلومات المدرجة في استمارة الموافقة. كما يعني أيضاً موافقتكم على المشاركة في الدراسة.

توقيع المشارك:
التاريخ:

توقيع الشخص الحاصل على الموافقة:
التاريخ:
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 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, include 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 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 stop 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 stop 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.

- 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, 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.

Child’s Name:

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:
(Investigator or IRB-Approved Designee)

Date:

Witness to Consent Procedures (if required by IRB):

Date:
المجلس أخلاقيات البحث العلمي

استمارة موافقة الأهل

العنوان: عنوان الدراسة البحثية كما هو مكتوب في الطلب المقدم إلى مجلس أخلاقيات البحث العلمي (IRB) . في حال استخدام استمارات مختلفة، أضيف عناوين فرعية لتوضيح الفئة المستهدفة.

الباحث الرئيسي: الاسم/ العلاقة بجامعة بيروت العربية

التاريخ: تاريخ إعداد الاستمارة

الهدف البحثي:

• إبدأ بما يلي:

    هدف الدراسة: إن الهدف من هذه الدراسة هو (وصف للغرض أو الهدف بما يوضح القيمة العلمية للدراسة).

    على أن يتضمن الهدف العبارة التالية:

من المتوقع أن يشارك في هذه الدراسة ما يقارب (عدد) من الأطفال

الإجراءات

1. صف باختصار ما سيطلب من المشارك القيام به ومع تحديد الإجراءات ذات الطبيعة التجريبية إن وجدت (مثال: طرق غير تقليدية).

2. حدد المدة المتوقعة لمشاركة الطفل مع تحديد المدة المتوقعة لكل جلسة وعددها.

المخاطر/ العوائق

• صف المخاطر أو العوائق التي قد تواجه المشارك.

• إذا اقتضى الأمر، أذكر العبارة التالية:

قد تطور المشاركة في هذه الدراسة على مخاطر لا يمكن التنبؤ بها الآن.

• في حال وجود الحد الأدنى من المخاطر، أذكر العبارة التالية - مع أو بدون ذكر العبارة بين الفوسيين حسب نوعية البحث:

إن المخاطر المقدمة بالمشاركة في هذه الدراسة لا تتجاوز تلك التي نواجهها في الحياة اليومية (أو خلال الأداء الروتيني للمحوسنات أو الاختبارات الحسية أو النفسية).
الفوائد:

- صَف الفوائد المتوقعة من البحث والتي تعود على المشاركين وصفاً وضعاً.

- في حالة عدم وجود أيَّة فائدة، أذكر العبارة التالية:

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

- صَف 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 إجراز تقدم في موضوع البحث يمكن إضافة عبارة مثل ما يلي:

هذه الدراسة يمكن أن تفيد المجتمع إذا ما أدت نتائجها إلى فهم أفضل لم (تحديدو الموضوع).

المشاركة التطوعية وحق الانسحاب

إبدأ بالعبارة التالية مع إدراج ما بين القوسين عندما يتاسب ذلك مع سن المشارك وحالته العقلية:

إن مشاركة طفلكم في الدراسة هي مشاركة طوعية بالكامل. أي أنه من حقكم السماح لطفلكم بالمشاركة (كما أننا أيضاً سوف نسأل طفلكم عما إذا كان موافقاً على المشارك في الدراسة). في حالة قررم عدم السماح لطفلكم بالمشاركة (أو قرر طفلكم عدم المشاركـة) فإن يكون هناك أي عواقب كما أنكم وطفلكم لن تخسروا أي من الامتيازات المستحقة، وفي حال اختيار المشارك في الدراسة، يمكن التوقف عن المشاركة في أي وقت بدون أي عواقب. برجاء (شرح ما يتوجب على الأهل أو الطفل القيام به لإكمال الانسحاب).

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

إذا ما تطلبت الانسحاب الآمن من الدراسة أي إجراءات خاصة صَف هذه الإجراءات.

أضاف العبارة التالية إذا تناسب الأمر:

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 (و مع طفلكم).

ظروف الوضع التي قد تؤدي إلى إنهاء مشاركتكم

أضاف هذا الجزء إذا ما كانت هناك ظروفًا ابتعدها قد تؤدي إلى إقلاع المشارك عن الدراسة.

ابدا بهذه العبارات: في ظل ظروف معينة، قد تقرر إنهاء مشاركة طفلكم قبل أن يستكمل الدراسة وتحديداً فإننا قد نضع حداً لمشاركة طفلكم إذا ما [صف الأسباب الممثلة لإنهاء مشاركة الطفل قررنا إنهاء مشاركة ولذَّكم قبل نهاية الدراسة وذلك بسبب (أذكر الأسباب)]
• If you are not clear about the causes, additional conditions that may lead to the end of your child’s participation.

• If necessary, add the following sentence at the end of this section:

  "If we end your child’s participation before the end of the study, we will provide compensation for their participation until the end of the study."

Alternative Participation

• Remember this section in cases: (a) benefit of the participant from participating in this study, and (b) the possibility of obtaining similar or equivalent benefits in another way. For example, in the case of a study that provides insurance benefits to participants, add this section, if there is a possibility of similar or equivalent benefits for the non-participating students.

• Explain the alternatives that may benefit the participants.

The Code of Ethics

• Describe the methods of securing confidentiality in the study’s files, and how the researchers will handle them. In the majority of studies:

  Confidentiality is maintained on the study files, which are the participant or your child, and the files are reviewed by the researchers. We have a list of committees that oversee the research procedures, including the Ethics Committee of the Arab University Beirut (and all those who participate in maintaining the confidentiality of your child’s identity). In cases where we exceed this, the files will be made available to the researchers only if they request it.

• Some studies may require the disclosure of information to other parties. In such cases, disclose the nature of the information that will be disclosed and to whom.

• Describe how the data will be stored and protected (for example: using codes instead of names on data collection forms, and keep the files in a locked cabinet).

Exceptions to the study

• Some studies may require the disclosure of information to other parties. In such cases, disclose the nature of the information that will be disclosed and to whom.

• Describe the code of practice and confidentiality of the data collected, and how the researchers will handle them. In the majority of studies:

  Confidentiality is maintained on the study files, which are the participant or your child, and the files are reviewed by the researchers. We have a list of committees that oversee the research procedures, including the Ethics Committee of the Arab University Beirut (and all those who participate in maintaining the confidentiality of your child’s identity). In cases where we exceed this, the files will be made available to the researchers only if they request it.

• Some studies may require the disclosure of information to other parties. In such cases, disclose the nature of the information that will be disclosed and to whom.

• Describe how the data will be stored and protected (for example: using codes instead of names on data collection forms, and keep the files in a locked cabinet).
التعويض

حدد كافة المكافآت وغيرها من التعويضات (على سبيل المثال: درجات إضافية في مقرر ما، أو بدل انتقال) يحصل عليها المشارك أو ولي الأمر. اضف تفاصيل كافية عن أساليب الدفع أو الحوافز.

• 

في حال عدم وجود أية تعويضات، أذكر العبارة التالية:

لن يتلقى طفلكم أي مكافأة أو تعويض عن المشاركة في هذه الدراسة.

إذا كانت لديك أية أسئلة أو استفسارات

يمكن لكم (وطفلكم) طرح الأسئلة حول هذه الدراسة الآن أو في أي وقت أثناء إجراء الدراسة، وذلك من خلال التحدث إلى الباحث / الباحثين الذين يعملون معكم (ومع طفلكم) أو من خلال الاتصال ب (إضف اسم الباحث / الباحثين ورقم الهاتف) أو على البريد الإلكتروني (إضف البريد الإلكتروني).

إذا كان لديكم (أو لدى طفلكم) أية أسئلة تخص حقوق الطفل باعتباره مشارك في البحث أو في حال شعرتم أن طفلكم لم يعامل بإنصاف، الرجاء الاتصال بجامعة بيروت العربية في جمعة أخلاقيات البحث العلمي في جامعة بيروت العربية على الرقم 300110 100961 2743.

في حالة تعرض لضرر جراء المشاركة في الدراسة

إضف هذا الجزء إذا ما كان هناك احتمال أن يمثل هذا البحث قدراً أكبر من الخدمة الإضافية أو الضرر المرتبط على البحث (جسدياً أو نفسياً أو اجتماعياً أو مالياً أو غيرها) على المشاركون. إذا ما شعرتم أن طفلكم تعرض لضرر ما أو حق به ضرر ما نتيجة المشاركة في هذه الدراسة، الرجاء الاتصال بجامعة أخلاقيات البحث العلمي في جامعة بيروت العربية على الرقم (إضف رقم الهاتف)، وأيضاً برجاء إخطار مسؤولي البحث العلمي بموقع البحث العلمي.

إذا ما شعرتم أن طفلكم تعرض لضرر ما أو حق به ضرر ما نتيجة المشاركة في هذه الدراسة، الرجاء الاتصال بجامعة أخلاقيات البحث العلمي في جامعة بيروت العربية على الرقم (إضف رقم الهاتف).

إذا كانت لديك أي ملاحظة أو استفسار، الرجاء الاتصال بجامعة بيروت العربية.

في حالة عدم توفر تعويض أو علاج، أضع العبارة التالية:

لا تضمن هذه الدراسة أي برامج للتعويض أو علاج طفلكم عن الضرر الذي قد يلحق به نتيجة مشاركته.
ما يترتب عليه توقيعكم:

إن توقيعكم أدناه يعني أنكم قد فهمتم المعلومات المدرجة في استمارة الموافقة. كما يعني موافقتكم على السماح بالمشاركة في الدراسة.

إن توقيعكم على استمارة الموافقة، لا يعد تنازلًا عن أي حقوق قانونية قد تحصل عليها طفلكم من جراء مشاركته في هذه الدراسة البحثية.

اسم الطفل:

توقيع الطفل (إذا انطبق):

التاريخ:

توقيع ولي الأمر:

التاريخ:

توقيع ولي الأمر الآخر (إذا لزم الأمر):

التاريخ:

توقيع الوصي القانوني (إذا انطبق):

التاريخ:

توقيع الشخص الحاصل على الموافقة (الباحث/الممثل المعتمد من مجلس أخلاقيات البحث العلمي):

التاريخ:

الشاهد على إجراءات الموافقة:

التاريخ:

(إذا طلب من قبل مجلس أخلاقيات البحث العلمي)
Assent Form (English version) (Form H-X)

(under 18 year age 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 subtitles 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:**
 المجلس إخلاقيات البحث العلمي (Form H-XI)

استمارة موافقة (من هم دون 18 عاماً والمشاركين في الدراسات الاجتماعية/السلوكية)

العنوان: [عنوان الدراسة كما هو مبين على طلب مجلس إخلاقيات البحث العلمي IRB في حال استخدام استمارات مختلفة، أضف العناوين الفرعية لتوضيح الفئة المستهدفة]

الباحث الرئيسي: [الاسم، والعلاقة بجامعة بيروت العربية]

التاريخ: [تاريخ إعداد الاستمارة]

نود أن نفيدكم عن الدراسة البحثية الذي نقوم بها. فالدراسة البحثية هي سبيل للتعرف الأمثل عن المواضيع المختلفة. ونود أن نكتشف المزيد عن [أضف عنوان الدراسة، وصف أهدافها بلغة بسيطة]. ندعوكم للانضمام إلى الدراسة لأجل [أضاف أسباب اختيار الطفل للبحث]

وإذا ما وافقتم على الانضمام أو المشاركة في هذه الدراسة فسوف يطلب منكم أن [صف الإجراءات، مثل ذلك: استبيانات، أنشطة) بكلمات بسيطة يعرفها الطفل ويفهمها. أضاف أيضاً عدد الزيارات والإطار الزمني في كلمات يسهل للطفل أن يفهمها]

صف المخاطر المحتملة (على سبيل المثال العوائق) بلغة بسيطة.

لاستخدام أي من العبارات التالية إن كانت ملائمة: ليس مؤكداً ما إذا كانت مشاركتكم في هذه الدراسة مفيدة لكم إلا إذا توقع أن الدراسة سوف تفيدكم من خلال [صف كيف].

فإذا تعرف على أمور تساعد أطفالاً آخرين يعانون من [أضاف اسم الحالة أو الموضوع قيد البحث] يوماً ما، وسوف نستفيدنا هذه الدراسة على التعرف على المزيد عن [الموضوع قيد البحث].

ليس لزاماً عليكم المشاركة في هذه الدراسة في حال أنتم الرجوع على قراراً لاحقاً. وكذل ما يطلب منكم هو إخبارنا برغبتكم في التوقف، ولن يسبب ذلك غضب أي أحد منكم إن لم ترغبوا في المشاركة في الدراسة أو إذا ما شاركتم في الدراسة ثم تراجعتم عن قراركم وانسحبتم.

وفي حال مشاركتكم أو رفضكم للمشاركة في هذه الدراسة سوف يجيب عن كافة الأسئلة التي لدينا. كما أنه يمكنكم طرح الأسئلة في أي وقت إذا ما شاركتم في الدراسة. كأنا عليكم سأوى إخبار الباحث إن كان لديكم أي استفسار أو سؤال.

إذا أردتم المشاركة في هذه الدراسة، برجاء توقيع اسمكم وسوف تحصلون على نسخة من هذه الاستمارة للاحتفاظ بها.

الاسم:
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 performed 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:
Project Information Form – Research Involving Animals (Form A-I)

Application No.:                          Date Received:                        
Reviewed By: 
IRB-IACUG Meeting Date: 
Form type      Original   Amendment

1. Title of Project/Course

2. 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:
Expected date of the experiment

Start:

End:

Has ethics review for this study been requested earlier from IRB or another committee?

☐ Yes* ☐ No

*Where:

*When:

*Result:

Objectives of the research/course:

If collaborative project, please list cooperation partner(s) and affiliation:

Animal species used:

Species

No. of Females

No. of Males

Animal source:

Place of performing the experimental part:

Briefly describe the experiments procedures:
Please report any expected problems:

- Any change of 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 and understood the general guidelines and accept to abid by.

**Correspondant Name:**

**Correspondant Signature:**

**Date:**
### Project Information Form – Final Decision (Form A-II)

**FOR OFFICIAL USE ONLY**

#### The final decision is based on

<table>
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<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
</table>

#### A. Are all documents provided:

- [ ]
- [ ]
- [ ]

Comments

#### B. Scientific Validity:

<table>
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<th></th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
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</table>

1. Will the study lead to improvements in human wellbeing or increase knowledge?  
   - [ ]
2. Can the intervention 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?  
   - [ ]

#### C. Assessment of Benefits/Risks:

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<th>Yes</th>
<th>No</th>
<th>NA</th>
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1. Are the researcher 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?  
   - [ ]
D. Project compliance with the IACUC requirements:

1. Does the experiment design comply with the Animal Welfare Act and the Canadian Council on Animal Care requirements and related laws and international standards?  
   Yes ☐ No ☐ NA ☐

2. Is the designated method of animal killing appropriate?  
   Yes ☐ No ☐ NA ☐

3. Are the procedures of sample storage and disposal adequate?  
   Yes ☐ No ☐ NA ☐

E. Responsibilities of the researcher

1. Are there any conflicts of interest, including payments and other rewards?  
   Yes ☐ No ☐ NA ☐

2. Are there any other ethical / legal / social / financial issues in the study?  
   Yes ☐ No ☐ NA ☐

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 No.:  
Date Received:  
Reviewed By:  
IRB Meeting Date:  

1. **Title of project and place of implementation**

2. **Investigator(s)**  
   
   [The correspondent investigator/supervisor]  

   - [ ] Principal Investigator  
   - [ ] Co-investigator  
   - [ ] Supervisor  

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

   **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, equipment**  
   - [ ] Yes  
   - [ ] No
If yes, please summarise the problems encountered.

Please provide a one-page summary of the project outcomes:

- Any change of 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 and understood the general guidelines and accept to abid by.

**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: