SBS IRB APPLICATION

EXPEDITED/FULL COMMITTEE REVIEW

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**INSTRUCTIONS**

This form can be used to apply for *Full Committee Review* or *Expedited Review*. **This form is not for applying to *exempt* studies.** (To know more about Full Committee and Expedited Reviews, see APPENDIX I)

**How to complete your application and begin the IRB review process:**

1. This form must not be handwritten.
2. Fill out **all the sections** on this form completely. Fill out and attach the appropriate appendices as by this application.
3. Attach the study proposal. Guidance on writing a research study proposal can be accessed at <https://www.aub.edu.lb/irb/Pages/resources.aspx>
4. Complete the IRB submission Guide/Checklist found at [**https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx**](https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx) to ensure that **all requirements** for submission are completed so that the review process is not delayed.
5. Select the type of submission requested:

 ☐ Initial

☐ Rebuttal (response to IRB initial comments)

1. To request that this application be considered for expedited review, please select below the category for which this research should be considered. The IRB will make the final determination if this research meets federal requirements for expedited review. Tick the category that applies to your research. For a clear **description of each category, please refer to Appendix I.**

|  |  |
| --- | --- |
| Category 1  | [ ]  |
| Category 2  | [ ]  |
| Category 3  | [ ]  |
| Category 4  | [ ]  |
| Category 5  | [ ]  |
| Category 6  | [ ]  |
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|  |
| --- |
| **FUNDED**  [ ]  Yes [ ]  No  If **yes,** indicate the source: Click or tap here to enter text. |

**Review Category:** [ ]  Expedited review 󠆶 [ ]  Full Board review 󠆶

Any study that does not fit any of the expedited or exempt review categories must be submitted for Full Board IRB review.

**Date of submission to the Institutional Review Board:** Click or tap here to enter text. **Expected starting date of study:** Click or tap here to enter text.

1. **PROJECT IDENTIFICATION**
	1. **Title of proposal:**

(Project title on the application must match title added to **all** corresponding documents):

Click or tap here to enter text.

* 1. **Student project:** [ ]  Yes [ ]  No

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| --- |
| * 1. Principal investigator:
 |
| **Name:**  | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:** [ ]  Yes [ ]  No [ ]  Pending  | **Course module:**  | **Expiry date:** |

|  |
| --- |
| * 1. Co-investigator/Staff: (Attach Extra Sheet If Necessary)
 |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:**[ ]  Yes [ ]  No [ ]  Pending | **Course module:**  | **Expiry Date:** |
| **Position:** | [ ] Professor [ ] Associate Professor [ ] Assistant Professor[ ] Instructor [ ] Research Assistant [ ] Research fellow [ ] Other If other, please indicate the position:Click or tap here to enter text. |
| **Role in study:** | [ ] Recruitment [ ] Consenting [ ] Data collection [ ] Study Coordinator [ ] OtherIf other, please indicate the role:Click or tap here to enter text. |

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| * 1. Student–investigator: (Attach extra sheet if necessary)
 |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification/Equivalent:**[ ]  Yes [ ]  No [ ]  Pending | **Course module:** [ ]  Student minimal risk module | **Expiry Date:** |

|  |
| --- |
| * 1. Data collection company: 󠆶 [ ]  Yes 󠆶 [ ]  No, skip this section 󠆶
 |
| **Name of company:** | **Non-Disclosure Agreement:** [ ]  Yes (attached) [ ]  No [ ]  Pending |
| **Name of data collector(s):****(Attach extra sheet if necessary)** | **CITI Certification, if any:**[ ]  Social and Behavioral Basic Refresher Course Expiry Date: Click or tap here to enter text.[ ]  Biomedical Basic Refresher Course Expiry Date: Click or tap here to enter text.[ ]  If other ethical training course, please provide the IRB with the training material for review and approval |

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| * 1. Collaborators: (Attach extra sheet if necessary)
 |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification/equivalent:**[ ]  Yes [ ]  No [ ]  Pending | **Course module:**  | **Expiry date:** |

**IF YOU HAVE COLLABORATORS, PROVIDE INFORMATION ON THE FOLLOWING**

1. **Briefly describe the role and contribution of each collaborator to the project.**

Click or tap here to enter text.

1. **Will you send participants’ /subjects’ research data information to any of the collaborator(s)?**

[ ]  Yes [ ]  No

*If yes, kindly submit a Non-Disclosure Agreement (NDA) signed off by AUB and each collaborating individual or institution with whom or with which data will be shared.**(Please contact the Office of Grants and Contracts (OGC) for setting the agreement)*

Click or tap here to enter text.

1. **Kindly submit copies of IRB approvals from all collaborating institutions, if available. If not, please specify the timeline for obtaining and submitting this information*.***

Click or tap here to enter text.

1. **SUMMARY OF ACTIVITIES**
	1. **Research/study question or hypothesis:**

Click or tap here to enter text.

* 1. **Brief overview of the research activities (Abstract)**

*If your study ONLY involves secondary use of data / biospecimens and Information* ***that does not include any identifiers*** *whether directly or indirectly and there is no plan by the investigator to contact the subjects or re-identify them, then there is no need to fill the rest of the application; please fill the “****Request to create a de-identified dataset from research data, clinical data or other identified data source****” and fill an* ***Exempt application*** *(Otherwise, please continue).*

Click or tap here to enter text.

* 1. **Research method/procedure and provide the sample size**

Click or tap here to enter text.

* 1. **Check which of the following design(s) apply to the study:**

[ ]  Randomized Controlled Trial [ ]  Discourse Analysis

[ ]  Quasi Experimental Study [ ]  Grounded Theory

[ ]  Observational or Correlational Study [ ]  Ethnography

[ ]  Survey [ ]  Phenomenology

[ ]  Other: specify Click or tap here to enter text. [ ]  Descriptive/Exploratory

* 1. **Data collection site:**

[ ]  AUB campus [ ]  Banks

[ ]  AUBMC [ ]  Company/s

[ ]  Public School/s [ ]  Camps

[ ]  Private School/s [ ]  Households

[ ]  NGO [ ]  Universities

☐ Hospitals

☐ Healthcare center

[ ]  Others: specify Click or tap here to enter text.

If there are plans to conduct the research outside AUB for example private school, company, universities, etc.

[ ]  Yes, provide the IRB with a copy of the permission letter that indicates that permission has been sought.

Click or tap here to enter text.

[ ]  No, please skip.

1. **STUDY PARTICIPANTS AND RECRUITMENT**
	1. **Expected number of recruited participants/subjects:**

**First Year:** Total: Click or tap here to enter text.

Number and Location: Click or tap here to enter text.

**Whole study (complete only if the study will continue more than one year):**

Total:Click or tap here to enter text.

Number and Location:Click or tap here to enter text.

* 1. **Age range of recruited participants/subjects:**

 Click or tap here to enter text.

* 1. **Describe the participant/subject population:**

Click or tap here to enter text.

* 1. **Indicate the time involvement for participants in the research (and each research**  **activity if applicable).**

Click or tap here to enter text.

* 1. **Target populations include:**

[ ]  Children/minors [ ]  Pregnant/lactating women

 [ ]  0-less than 8 years [ ]  Neonates

 [ ]  8-less than 18 years [ ]  Inpatients

[ ]  Institutionalized people [ ]  Outpatients

[ ]  Adults with legal guardians [ ]  Terminally ill participants/subjects

[ ]  Cognitively impaired [ ]  Military members

[ ]  Prisoners [ ]  Comatose/traumatized

[ ]  Employees [ ]  Students

[ ]  including subordinates [ ]  Student participant/subject pool

[ ]  Elderly

 [ ]  more than or equal to 65-less than 74 years

 [ ]  more than or equal 75 years

[ ]  Specific ethnic group, specify: Click or tap here to enter text.

[ ]  Low income/disadvantaged group

[ ]  Other, specify: ­­­­­­­­ Click or tap here to enter text.

[ ]  None of the above populations will be targeted (jump to 6D)

1. **Are AUB students targeted? 󠆶 󠆶 󠆶**

[ ]  Yes, indicate which group of students is targeted.

*If invited by email©, please indicate the lists needed for this research and fill the* ***Form for Release of Students E-mail Addresses for Research Projects*** found on

[*https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx*](https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx) *to secure the email lists*. Click or tap here to enter text.

[ ]  No, skip this item.

1. **AUB students from psychology pool:**

[ ]  Yes, please follow the guideline for Access on the Psychology available at then following link: <https://www.aub.edu.lb/irb/Pages/resources.aspx> and provide a clear description how they will be recruited and through whom. In addition, provide the IRB with the advertisement for review and approval.

Click or tap here to enter text.

[ ]  No, skip this item.

1. **AUB/AUBMC faculty or staff:**

[ ]  Yes, indicate which group is targeted.

If invited by email©, please indicate the lists needed for this research for the IRB to secure. Click or tap here to enter text.

[ ]  No, skip this item.

1. **List the specific criteria for inclusion and exclusion criteria of participants/subjects:**

Click or tap here to enter text.

1. **Justify the exclusion of any group based on age, sex, ethnicity, and social or economic factors.**

Click or tap here to enter text.

1. **Explain why the targeted population is necessary and specify the measures put in place to avoid any undue influence or coercion to participate in the study and clarify who will be directly recruiting the participants.**

Click or tap here to enter text.

* 1. **Provide a thorough description of your recruitment strategy, participants’ identification and invitation to the research. Indicate how would potential participants be contacted (example: face-to-face, email, flyers, advertisements, phone call etc.), and how would their contact information be secured.**

(For Snowballing, *the investigator can give the contact details of the research team to already recruited participants who can pass them on to others who may be interested in the study. Those interested can then contact the research team.* ***OR*** *contact information of potential subjects can be shared with the investigators, only if approval was sought by the seed participant to share this information).*

Click or tap here to enter text.

* 1. **Explain who will be approaching the human participants/subjects to participate in the study, and what measures have been taken to protect individual’s privacy.**

Click or tap here to enter text.

* 1. **Provide the IRB with a copy of the recruitment material. This may include but is not limited to:**

[ ]  Recruitment script

[ ]  Email invitation

[ ]  Flyer

[ ]  Advertisement

[ ]  Cover letter

[ ]  Others, specify.

For templates, please refer to IRB website: <http://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx>

*Please note that no advertisements can be used prior to IRB approval of the specific recruitment tool.*

1. **COMPENSATION OR COST TO PARTICIPANTS**
	1. **Will compensation/incentive be offered to the participants’ before/during/after participation?**

[ ]  Yes, provide justification for the incentive/compensation and what it entails ie., money payment, credit, chance to enter a draw, etc. Provide the IRB with the following information: amount, method, and timing of disbursement. Click or tap here to enter text.

 [ ]  No, please skip.

*In case of providing an extra credit to students, this is only applicable to psychology 101/201 students.*

*(Follow psychology pool guideline) and students should be provided an alternate option to gain the extra credit.*

* 1. **Describe how and when compensation is provided to participants, if any.**

Click or tap here to enter text.

* 1. **If applicable, describe whether any compensation is available to the participant/subject if he/she is upset/offended/unhappy because of participating in the study.**

Click or tap here to enter text.

* 1. **Reimbursement:**

*There are very limited circumstances under which study participants/subjects may need reimbursement for unavoidable costs associated with taking part in a study****.***

[ ]  Yes, indicate how this will be implemented. Click or tap here to enter text.

[ ]  No, please skip.

1. **RISKS AND** **BENEFITS**
	1. **Does the research involve any of the following possible risks / harm (check all that applies):**

[ ]  Use of private records (medical/ employment/ educational)

[ ]  Use of deceptive technique

[ ]  Social isolation (stigmatization, psychological stress)

[ ]  Legal/ criminal risk (example: research on illicit behavior)

[ ]  Possible invasion of participant’s (subject’s)/ family privacy

[ ]  Social or economic risk

[ ]  Any sort of probing for personal or sensitive information from surveys

☐ Identification of potential malpractice

[ ]  Other risks, specify: Click or tap here to enter text.

* 1. **Describe the frequency and magnitude (minimal risk°, greater than minimal risk) of the risks. In addition, describe and explain the steps that are taken to minimize the anticipated risks and harms of the human participants/subjects.**

Click or tap here to enter text.**.**

*°Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*



* 1. **Describe the anticipated benefits to the participant/subject. If no direct benefits are expected – state so and include in the consent form. (Monetary compensation is not considered a benefit)** Click or tap here to enter text.
	2. **Describe any anticipated benefits to the group or class to which the participants/subjects belong.** Click or tap here to enter text.
	3. **Describe the benefits to society or to the relevant body of knowledge as a whole.**

Click or tap here to enter text.

* 1. **Discuss why the risks to participants/subjects are reasonable in relation to the anticipated benefits to participants/subjects and in relation to the importance of the knowledge that may reasonably be expected to be gained.**

Discuss provisions for ensuring appropriate professional intervention in the event of adverse effects to the participant/subject, (example: referral to appropriate mental health resource/clinic, etc.).

Evaluate and compare the potential advantages and disadvantages of the study. In other words, determine how significant and impactful the risks are compared to the benefits.

Click or tap here to enter text.

1. **INFORMED CONSENT**
	1. **Provide the IRB with all applicable informed consent form(s) for your study:**

[ ]  Written informed consent form

[ ]  Online consent form

[ ]  Oral consent form

[ ]  Parental /Guardian consent form

[ ]  Assent form age 7-12 years

[ ]  Assent form age 13-17 years

[ ]  Debriefing form

* 1. **Specify all languages to be used in seeking and maintaining informed consent.**

*Every application must have an English consent form in addition to an Arabic consent form if the latter is to be used. All consent forms must represent an accurate translation of the original consent form.*

[ ]  English (required at all times)

[ ]  Arabic (required at all times, unless only English speakers are targeted)

[ ]  French

[ ]  Other, specify: Click or tap here to enter text.

* 1. **Written informed consent will be secured from research participants.**

[ ]  Yes

[ ]  No, if requesting a waiver or alteration to any of the informed consent requirements, including documentation of informed consent, please provide the justification. (Use Appendix III for assistance)

 Click or tap here to enter text.

*In addition, the informed consent process should be described even if**it will be an oral consent (a script of the consent information is required upon submission of the proposal). You can use verbal scripts, online scripts, emails, etc.* [**https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx**](https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx)The script should explain that participation in the study is completely voluntary and that the subject has the right to discontinue his/her participation, skip certain sensitive questions, etc.

* 1. **Describe the consent process.**

Specify how, when, and where the informed consent will take place and indicate who will obtain informed consent.

Click or tap here to enter text.

* 1. **Will there be any waiting period between informing the prospective participant/subject about the study and obtaining his/her consent form?**

[ ]  Yes, explain. Click or tap here to enter text.

[ ]  No, please skip this item.

* 1. **Are there illiterate participants/or visually impaired participants? (In this case a witness independent of the research team should be present while securing consent)**

[ ]  Yes, explain how informed consent will be secured. Click or tap here to enter text.

 [ ]  No, please skip this item.

* 1. **If participants are minors, clarify how parental consent and child assent will be secured.**

[ ]  Yes, explain. Click or tap here to enter text.

[ ]  No, please skip this item.

* 1. **Will others (such as next-of-kin or legal guardians) be asked to act on behalf of adult participant/subject for giving consent to participate in the research?**

[ ]  Yes, justify. Click or tap here to enter text.

 [ ]  No, please skip this item.

* 1. **In case of deception, describe the participant debriefing procedure that will be used to explain why deception was necessary in the research. Provide a full description of debriefing procedure, including when debriefing occurs, who will do the debriefing, etc.**

A script of debriefing explanation should be attached.

Click or tap here to enter text.

1. **DATA COLLECTION**
	1. **Attach copies of all data collection tools and methods to be used.**

[ ]  Questionnaire /survey

[ ]  Interviews questions

[ ]  Observation (indicate what will be observed)

[ ]  Focus group discussion (attach the questions/themes/topic guide)

 [ ]  Audiotapes/digital voice

[ ]  Videotapes

[ ]  Still photos

[ ]  Deception

[ ]  Anthropometric evaluations

☐ Blood pressure measurements

[ ]  Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (such studies may be reviewed by the biomedical IRB)

[ ]  Collection of biological samples, such as urine, hair, etc. through noninvasive means, specify (such studies may be reviewed by the biomedical IRB)

[ ]  Other imaging, specify: Click or tap here to enter text.

[ ]  Others, specify: Click or tap here to enter text.

**Are you using secondary data only?**

Research on secondary data involves analyzing data that have been already collected from participants/subjects and no new data collection will take place during this study.

[ ]  Yes

[ ] No, please skip.

If **de-identified data**, there is no need to fill sections below but please make sure to fill the form “Request to create a de-identified dataset from research data, clinical data or other identified data source”.

If identified data, please justify the request for the IRB to assess.

Click or tap here to enter text.

* 1. **Explain what will be collected from the participants. A detailed description is needed, including how much time is required from the participant in each phase and for how long the participant will be involved in the study.**

Click or tap here to enter text.

* 1. **Indicate where and how data collection will take place; ie., explain where any survey, interview, focus group discussion, etc. will take place (example: online, face to face, using tablet or hard copy, etc.)**

Click or tap here to enter text.

* 1. **Describe the instances (if any) that might result in the PI’s termination of participant’s/subject’s participation.**

Click or tap here to enter text.

1. **CONFIDENTIALITY OF DATA AND RECORDS**
	1. **Clarify whether any direct identifiers, names, addresses, telephone number, etc. will be recorded:**

[ ]  Yes, please explain why it is necessary and specify what coding system will be used to protect the privacy of the participants/subjects. Click or tap here to enter text.

 [ ]  No, please skip.

* 1. **Audio/visual: Will the participant be audiotaped or videotaped (select all that apply).**

 [ ]  Audiotape

 [ ]  Videotape

If videotape, please justify. Click or tap here to enter text.

If audio/video-taped, please explain whether the recording will be shared, who will transcribe them, and where. Who will have access to these recordings? When and by whom will the recording be destroyed? Click or tap here to enter text.

[ ]  No, please skip.

* 1. **Will any link between identifiers and study code numbers after data collection be retained?**

 [ ]  Yes, please explain why it is necessary and state how long will the link be kept.

 Click or tap here to enter text.

 [ ]  No, please skip.

* 1. **Indicate how, where, and how long will the data be stored? Will any passwords, codes, or locks be used? Please note, data should be stored with the principal investigator.**

Click or tap here to enter text.

* 1. **How will the data be analyzed?**

Click or tap here to enter text.

* 1. **How will the data be destroyed?**

Click or tap here to enter text.

* 1. **In what form will the research results be disseminated (project report, thesis, conference presentation, journal article, feedback to community members, research population, etc.).**

Click or tap here to enter text.

* 1. **Describe the plan for reporting adverse events to the IRB.**

Click or tap here to enter text.

* 1. **Describe the data safety monitoring plan, if applicable.**

Click or tap here to enter text.

Bibliography and references:

List up to five relevant publications that, in your opinion, would be helpful to the IRB in reviewing this study.

Conflict of interest (COI):

Indicate below if any investigator, any member of the research study, and/ or any member of their immediate families, has any kind of personal/ financial interest in the design, conduct, or reporting of research project. (You may check more than one if applicable).

Please check what is applicable. You may check more than one.

|  |  |
| --- | --- |
| [ ]  The researcher and/or family member is participating in a research topic sponsored by a business which the researcher and/or family member has a financial interest in or is related to an investigator/family business which could benefit from the outcome of the study. | [ ]  Has been disclosed to AUB.[ ]  Has not been disclosed to AUB. |
| [ ]  The researcher and/or family member is participating as a participant/subject in a research topic developed by that researcher. | [ ]  Has been disclosed to AUB.[ ]  Has not been disclosed to AUB. |
| [ ]  The researcher and/or family member serves on the Board of Directors of a business from which the member receives sponsored research support through a gift/grant/contract administered by AUB. | [ ]  Has been disclosed to AUB.[ ]  Has not been disclosed to AUB. |
| [ ]  The researcher and/or family member receives material benefits from the business that funds his/her research. | [ ]  Has been disclosed to AUB.[ ]  Has not been disclosed to AUB. |
| [ ]  The researcher and/or family member has intellectual property such as patent, copyrights, licensing, etc. | [ ]  Has been disclosed to AUB.[ ]  Has not been disclosed to AUB. |
| [ ]  Other conflict of interest, please specify:-------------------------------------------------------------------------------- | [ ]  Has been disclosed to AUB.[ ]  Has not been disclosed to AUB. |
| [ ]  No conflict of interest |

PLEASE FILL IN THE AUB COI FORM (APPENDIX II) AND IF CONFLICT OF INTEREST IS PRESENT, PLEASE ATTACH A CONFLICT MANAGEMENT PLAN. FOR FURTHER INFORMATION, CHECK OUT [**AUB’S POLICY ON CONFLICT OF INTEREST**](http://www.aub.edu.lb/hr/policies/Documents/Conflict_of_Interest.pdf).

Principal investigator’s assurance statement

I agree to abide by the policies and procedures of the AUB IRB regarding the protection of human subjects, including, but not limited to, the following:

|  |  |
| --- | --- |
| I certify that the information provided in this application is complete and accurate | [ ]  |
| I understand that as principal investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights, safety, and welfare of the human participants/subjects, and strict adherence to the study protocol and any conditions or modifications stipulated by the AUB Institutional Review Board.  | [ ]  |
| I will submit modifications of the protocol and/or the informed consent form and/or any other documents to the IRB for approval prior to applying those changes in the study.  | [ ]  |
| Ensuring that all personnel involved in the study have completed the human subjects training online course offered by CITI. If the first language of personnel is other than what is available for training on CITI website, it is the PI responsibility to provide the personnel with efficient training. | [ ]  |
| Ensuring that the study will be conducted by qualified personnel who are knowledgeable about AUB regulations and policies governing this research. | [ ]  |
| Obtaining informed consent from participants/subjects or their legally appointed representatives or guardians, written in a language that is understandable to them and approved by the IRB, unless the IRB has specifically approved a waiver of consent form. All subjects are provided with a copy of the signed form/oral script unless the IRB has specifically approved a waiver of providing this information to the subject. | [ ]  |
| Meeting recognized standards for safety when utilizing certain equipment, facilities, and procedures related to this research and documentation is provided to the IRB. | [ ]  |
| Not initiating any change or modification in the approved research and/or consent documents without prior IRB approval, except when it is necessary to eliminate apparent immediate hazards to the participating subjects. In this case, I will be reporting to the IRB this modification within **two** business days to enable the IRB to decide that the modification is done to preserve the participants’/ subjects’ welfare and safety. | [ ]  |
| Reporting adverse events or other unexpected problems and risks involving human subjects to the IRB promptly. | [ ]  |
| Promptly complying with IRB decision to stop or discontinue the research, including the analysis of data already collected unless specifically approved by the IRB.  | [ ]  |
| Complying with the continuing review requirements of the IRB. Specifically, obtaining approval for continuing with the study before the initial approved period of the study expires. I understand that if I fail to apply for continuing IRB review and approval within the approval period, IRB-approval of the study will automatically terminate and all activity must cease, including analysis of previously collected data, until IRB approval is granted. | [ ]  |
| Maintaining accurate and complete research records including all informed consent documents, for at least 3 years from the completion of the research project. | [ ]  |
| Fully informing the IRB of all locations in which participants/subjects will be recruited for this study and being responsible for obtaining and maintaining IRB approvals and letters of cooperation from non-AUB sites. | [ ]  |
| Facilitating site visits and audits for evaluating and monitoring the research activities by certain authorized bodies. | [ ]  |
| If I am unavailable, on sabbatical, or on another type of leave, I will submit for IRB approval the arrangements for conducting the study, including the appointment of a temporary PI at AUB in my absence. | [ ]  |
| Ensuring that all personnel and investigators are aware of this research and approved this submission. | [ ]  |

|  |
| --- |
| I certify that the above information is correct |
| Printed name of Principal Investigator: Date:Click or tap to enter a date.Signature:  |  |

|  |
| --- |
| As Chairperson of the Department / Dean of the Faculty or Representative, I acknowledge that this research is in keeping with my department's standards and that the principal investigator has met all departmental requirements for review and approval of this research.Printed Name of Chairperson of Department / Dean of the Faculty or RepresentativeDate: Click or tap to enter a date.Signature: |

Appendix I

If a study is submitted for expedited review; then, it should fall under at least one of the categories below.

|  |  |
| --- | --- |
| [ ]  | 1. **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
2. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
3. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
 |
| [ ]  | 1. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.**
2. For adults, normally not more than 450 ml during an eight-week period, and not more than twice a week.
3. For children and those less than 50 kg, not more than 50 ml or 3 ml/kg, whichever is less, during an eight-week period and collection may not occur more frequently than twice a week
 |
| [ ]  | 1. **Prospective collection of biological specimens for research purposes by noninvasive means,**

Example: Non-disfiguring hair and nail clipping, excreta and external secretion, placenta at delivery, amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, mucosal and skin cells collected by buccal scraping or swab, skin swab or mouth washings, etc. |
| [ ]  | 1. **Collection of data through noninvasive means (not involving general anesthesia or sedation) routinely employed in clinical practice *excluding X-rays and microwaves*.**

Example: ECG, EEG, MRI, ultrasound, echocardiography, electrocardiography, electroencephalography, ultrasound, Doppler blood flow, thermography, body composition assessment, moderate exercise by healthy volunteers, muscular strength testing, weighing testing, and sensory acuity. |
| [ ]  | 1. **Research involving material already collected (data documents, records, and pathological or diagnostic specimens) or will be collected solely for non-research purposes (such as medical treatment or diagnosis).**
 |
| [ ]  | 1. **Collection of data from voice, video, digital or image recordings made for research purposes.**
 |
| [ ]  | 1. **Research on individual or groups characteristics or behavior such as perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior, test development where the investigator does not manipulate that subject’s behavior and no stress to the subject may occur, or research using survey, interview, oral history, or quality assurance methodologies.** (Some research in this category can be exempt)
 |

Appendix II.

**FORM FOR DISCLOSURE OF ACTIVITIES WHICH MAY INVOLVE CONFLICT OF INTEREST**

 I, ­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, have read and understood the “University Policy on Duality of Interest” of November 19, 1993, as revised on March 19, 2004, and in accordance with this policy I state the following:

1. I attach a list of all my affiliations with any person (including any officer or employee of the University), firm, organization, or corporation with which I have reason to believe the University does business.

[ ]  Not applicable

[ ]  List attached

1. I attach a list of my consulting arrangements, whether or not I believe that they may involve potential conflict of interest.

[ ]  Not applicable

[ ]  List attached

1. I shall amend these two lists promptly (items 1 and 2) whenever my affiliations or duties change.
2. If I become aware that any member of my family (parents, brothers, sisters, children, spouse, and/or in-laws) is engaged in business with the University, I shall disclose my relationship with the person(s) concerned and nature of his business.
3. I understand that I am not to participate in any decision or vote on an issue in which I may have conflicts of interest because of affiliations listed in items 1, 2, and 4.

I submit this information to the President of the University

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Position:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Faculty/Department:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A new declaration shall be submitted not less frequently than as follows:

1. Management and academic staff Annually in January
2. Non-academic staff in Grades 1-12 At any change of status

In addition, individuals are expected to amend their declarations from time to time as their affiliations or duties change.

Failure to declare a conflict of interest may result in disciplinary action up to and including termination of employment.

**Appendix III**

**Eligibility for oral consent or waiver of the consent process**

**Waiver of written consent (oral consent)**

If you are requesting **waiver of participants’ signature** (waiver of written consent), complete the table below based on the review type **that applies to your study (Expedited or Full Board):**

|  |  |
| --- | --- |
| **Expedited (all should apply)** | **Full Board (all should apply)** |
| [ ] The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context. | [ ] The research is not USFDA-regulated. |
| [ ] The written script of the information to be provided orally and all written information to be provided include all the required and appropriate additional elements of consent disclosure. | [ ] The only record linking the subject and the research would be the consent document. |
| [ ] The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality. |
| [ ] Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. |
| [ ] The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure.  |

**Waiver or alteration of the informed consent process:**

If are you requesting to waive or alter the **informed consent process (example: waiving the consent process for retrospective chart reviews)**, complete the table below:

|  |
| --- |
| **A justification is required for waiver or alteration of the consenting process. Provide supporting information to all the criteria below, taking into consideration that the research is not USFDA-regulated and does not involve non-viable neonates.** |
| [ ] The research involves no more than minimal risk to the subjects. *Justification:*  |
| [ ] The waiver or alteration will not adversely affect the rights and welfare of the subjects.*Justification:* |
| [ ] The research could not practically be carried out without the waiver or alteration. *Justification:* |
| [ ] Whenever appropriate, the subjects will be provided with additional pertinent information after participation. (if a debriefing letter will be provided, ie. research that involves deception, please provide the IRB with a copy.) *Explain:*  |