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BIOMEDICAL IRB APPLICATION EXPEDITED/FULL COMMITTEE REVIEW

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| --- |
| **Background information to evaluate the study’s preparedness for IRB review:**1. Is this an interventional study?

[ ]  Yes [ ]  No **If you answered “Yes” to the previous question, please proceed to answer the following questions. If you answered “No”, skip questions 2 and 3 and proceed with filling out this application.** 1. Did this project meet funding requirements from internal sources (e.g., MPP or seed funds)?

[ ]  Yes [ ]  No 1. Did this project meet funding requirements from external sources?

[ ]  Yes [ ]  No **If the answer is “No” to both questions, your study will undergo a scientific assessment in addition to an ethical review. Please complete the** [**SPIRIT Checklist**](https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx)**and submit it with this application.** |

**INSTRUCTIONS**

This form can be used to apply for *Full Committee Review* or *Expedited Review*. **This form is not for applying to *exempt* studies or retrospective chart review projects.** (To know more about full committee and expedited reviews, see APPENDIX I). If your study fulfills categories for exempt review or is categorized under retrospective chart review, please refer to the link following to access the relevant application forms: <https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx>

**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.
3. Fill out and attach appropriate documents required by responses in this application.
4. Attach protocol. Guidance for writing a protocol and a checklist relevant to clinical trials can be accessed below:

[Guidelines for writing research proposals](https://www.aub.edu.lb/irb/Documents/8-5.pdf)

[SPIRIT Checklist](https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx)

1. Complete the checklist that accompanies this form to assure **all requirements** for submission are completed so that the review process is not delayed. The checklist can be accessed on <https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx>

1. 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 US 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. If the activity does not fulfill any of the below categories, a full board review will be required.**

|  |  |
| --- | --- |
| Category 1  | [ ]  |
| Category 2  | [ ]  |
| Category 3  | [ ]  |
| Category 4  | [ ]  |
| Category 5  | [ ]  |
| Category 6  | [ ]  |
| Category 7  | [ ]  |

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**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 INSTITUTIONAL REVIEW BOARD:**

 **EXPECTED STARTING DATE OF STUDY:**

# **PROJECT IDENTIFICATION**

**1.1 Project Title**

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

Click or tap here to enter text.

* 1. **Is this a student or FRRP project?**

[ ]  Yes [ ]  No

|  |
| --- |
| 1.3 Principal investigator: |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:** ☐ Yes ☐ No ☐ Pending  | **CITI course module:**  | **CITI Expiry date:** |
| **Position:** | [ ]  Professor [ ]  Associate professor [ ]  Assistant professor [ ]  Instructor [ ]  Other If other, please indicate the position:Click or tap here to enter text. |

|  |
| --- |
| 1.4 Co-investigator/staff: (copy and paste table if necessary) |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:**☐ Yes ☐ No ☐ Pending | **CITI course module:**  | **CITI 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 [ ]  Blood withdrawal [ ]  Data collection [ ]  OtherIf other, please indicate the role:Click or tap here to enter text. |
| **Use of AUB/AUBMC resources** | Is the co-investigator or involved staff a full-time employee with no dedicated research time in their appointment?[ ]  Yes [ ]  NoIf the answer is “Yes”, this may require clearance from the appropriate channels by filling and submitting the “Request to Use Hospital Equipment &and Resources for Research Projects” form. The form can be accessed on the following link: <https://www.aub.edu.lb/irb/Pages/biomedicalforms.aspx> |

|  |
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| 1.5 Study Coordinator: (copy and paste table if necessary) |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:**☐ Yes ☐ No ☐ Pending | **CITI course module:**  | **CITI 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 [ ]  Consent [ ]  Blood withdrawal [ ]  Data collection [ ]  OtherIf other, please indicate the role:Click or tap here to enter text. |
| **Use of AUB/AUBMC resources** | Is the involved coordinator a full-time employee with no dedicated research time in their appointment?[ ]  Yes [ ]  NoIf the answer is “Yes”, this may require clearance from the appropriate channels by filling and submitting the “Request to Use Hospital Equipment and Resources for Research Projects” form. The form can be accessed on the following link: <https://www.aub.edu.lb/irb/Pages/biomedicalforms.aspx> |

|  |
| --- |
| 1.6 Collaborators: Collaborators at other institutions outside AUB/AUBMC: |
| **Name:** | **Signature:** | **Department or affiliation:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:** ☐ Yes ☐ No ☐ Pending  | **CITI course module:**  | **CITI 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 [ ]  Blood withdrawal [ ]  Data collection [ ]  OtherIf other, please indicate the role:Click or tap here to enter text. |

# **FUNDING**

**2.1 Is this research funded or has an application for funding been submitted?**

 ☐Yes. Please fill the below table and copy the same table for more than one source of funding, if applicable

|  |  |
| --- | --- |
| Source of funding/Sponsor name | [ ] AUB-University Review Board (AUB-URB)[ ] Faculty of Medicine-MPP Research Committee (FM-RC)[ ] Other AUB internal funding source, specify Click or tap here to enter text.[ ] External funding source, specify Click or tap here to enter text. |
| Status  | [ ]  Funded [ ]  Pending [ ]  Not funded |
| Proposed annual budget |  |
| Role of funding agency |  |
| Federal money (e.g., NIH) | [ ]  Yes [ ]  No |

 [ ] No. Please explain how any costs of research will be covered:

 Click or tap here to enter text.

*If funding was requested from AUB-URB, FM-RC or other internal AUB funding entity, the IRB will request the original proposal, the comments provided by the reviewers, as well as the any submitted modified proposal based on these comments. Your submission of this application indicates your permission to request these documents. The IRB review will be conducted independently of the review process of the FM-RC/AUB-URB/other internal AUB entity.*

# **SUMMARY OF ACTIVITIES**

The following questions must be answered **in lay language or language understood by a person unfamiliar with your area of research**. Area-specific jargon should be avoided or explicitly explained. **Do not respond with “see protocol” or “protocol attached” or “refer to section X”.**

1. **Briefly describe the background leading to the present study, summarizing existing knowledge and identifying the gaps the project is intended to fill.**

Click or tap here to enter text.

* 1. **State your research question/hypothesis.**

Click or tap here to enter text.

* 1. **State what the subjects will be asked to do if they accept to participate in the study.**

Click or tap here to enter text.

* 1. **Indicate the number of months you anticipate this research will last from the time final approval is granted.**

Click or tap here to enter text.

* 1. **Select the category that applies to your study:**

|  |  |
| --- | --- |
| [ ]  Randomized controlled trial  | [ ]  Quasi experimental study  |
| [ ]  Observational or correlational study  | [ ] Descriptive/Exploratory |
| [ ] OtherIf other, please indicate the category: Click or tap here to enter text. |

* 1. **If the study involves the administration of an approved/unapproved drug, describe the process that will be followed to dispense and store the drug.**

Click or tap here to enter text.

# **OVERSIGHT AND MONITORING**

1. **Will this research utilize AUB/AUBMC resources?**

[ ]  Yes

[ ]  No

**If yes,** select the resources to be utilized:

[ ] Medical/pathology records [ ] Hospital equipment [ ] Nurse time

[ ]  Phlebotomist time [ ] Other Click or tap here to enter text.

Use of equipment and/or nursing/phlebotomist time requires clearance from the appropriate channels by filling and submitting the “Request to Use Hospital Equipment and Resources for Research Projects” form. The form can be accessed on the following link: [**https://www.aub.edu.lb/irb/Pages/biomedicalforms.aspx**](https://www.aub.edu.lb/irb/Pages/biomedicalforms.aspx)

* 1. **Is the research being conducted at additional sites/institutions other than AUB/AUBMC?**

[ ] Yes

[ ] No

**If yes**, please refer to the following:

* Specify the sites involved: Click or tap here to enter text.
* Will the other site lead this study?

[ ] Yes

 [ ] No

* Will you share data with outside sites?

[ ] Yes

 [ ] No

* Has approval been sought from another institution/IRB committee?

[ ] Yes, provide documentation of approval.

[ ] No, justify.

Click or tap here to enter text.

**If data sharing applies, please refer to the Office of Grants and Contracts for assistance in preparing the appropriate agreement.**

# **SUBJECT PROFILE**

1. **Number of subjects:**
* How many subjects do you plan to enroll at AUB/AUBMC site?

Click or tap here to enter text.

* If this is a multi-centered study, what is the total number of subjects to be enrolled from all centers?

Click or tap here to enter text.

* 1. **Age range:**

Check all that apply**:**

[ ] 0-6 (Provide parental consent forms)

[ ] 7-12 (Provide child assent and parental consent forms)

[ ] 13-17 (Provide adolescent assent and parental consent forms)

[ ] 18-65

[ ] 65 and older

**Exact ages to be included:** Click or tap here to enter text.

* 1. **Inclusion/exclusion of children in this research:**

If this research proposes to ***include*** children, this inclusion must meet one of the following criteria for the risk/benefit assessment according to the US federal regulations *(45CFR46, Subpart D*).

Check ***one*** appropriate box:

[ ]  Minimal risk\*

[ ]  Greater than minimal risk\*\* but holds prospect of direct benefit to subjects.

[ ]  Greater than minimal risk\*\*, no prospect of direct benefit to subjects, but likely to yield generalizable knowledge about the subjects’ disorder or condition.

Explain how the selected criterion is met for this study

Click or tap here to enter text.

*\*Minimal risk: The probability and magnitude of harm and discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examination or tests.*

*\*\*For studies that fall under greater than minimal risk, obtaining the signature of both parents on the consent is required.*

* 1. **Other protected populations to be targeted or included in this research:**

[ ] Pregnant women

[ ] Fetuses

[ ] Prisoners

[ ] Comatose

[ ] Mentally/emotionally/developmentally disabled persons

[ ] Elderly Subjects-65+

[ ] Terminally ill participants

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

**Describe why it is necessary to include these groups in the study:**

Click or tap here to enter text.

* 1. **Inclusion and exclusion of subjects in this research study:**

Describe the criteria for inclusion and exclusion of subjects in this study:

Inclusion criteria:

 Click or tap here to enter text.

Exclusion criteria:

Click or tap here to enter text.

* 1. **Location of subjects during research activities or location of records to be accessed for research.**

Check all that apply:

[ ] AUBMC OPD/private clinics records

[ ] AUBMC ED

[ ] AUBMC inpatient settings

[ ] AUB campus (non-clinical)

[ ] Non-AUB/non-AUBMC sites specify Click or tap here to enter text.

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

[ ] International location, specify Click or tap here to enter text.

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

# **SUBJECTS RECRUITMENT**

* 1. **Specify the strategies you will use to identify subjects.**

|  |
| --- |
| [ ]  Face-to-face [ ] Email [ ] Flyers [ ] Phone call[ ] Social medial platform, specify: Click or tap here to enter text. |
| [ ] Other, specify Click or tap here to enter text. |

* 1. **Describe how participants will be contacted and approached.**

Attach a copy of any recruitment material to be used (i.e., advertisements, email invitations, scripts, URLS of websites used to augment recruitment, etc.)

Click or tap here to enter text.

*NOTE: Indicate in your response how the contact information will be secured. Consider that the Initial contact of subjects identified through record search must be made by the official holder of the records; i.e., treating physician, clinical fellow, nurse, school officials, etc.*

*In case you will use the snowballing technique, please consider that the investigator should give contact details of the research team to already recruited participants, and these can pass them on to others who may be interested in the study. Interested individuals can then contact the research team OR the contact information of potential subjects can be shared with the investigators, only if approval has been sought from the seed participant to share this information.*

# **INFORMED CONSENT PROCESS**

* 1. **How will you assess the subjects’ understanding of the consent and what measures will be implemented to ensure their comprehension? (e.g., depending on participants’ age and condition, will clinical judgment be employed to assess their capacity to comprehend the consent document, or will alternative methods be utilized?)**

 Click or tap here to enter text.

* 1. **Specify all languages that will be used for the informed consent documents:**

[ ] English

[ ] French

[ ] Arabic

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

*In case other languages will be used, all consent forms must represent an accurate translation of the original consent form.*

* 1. **When and where will the consent be discussed and documentation obtained? Be specific.**

*Keep in mind that potential subjects need adequate time to consider participation.*

Click or tap here to enter text.

* 1. **Will the investigator(s) be securing the informed consent?**

 [ ] Yes

 [ ] No

* If not, please make sure to specify the names of individuals who will obtain informed consent in sections 1.4-1.6.
* If the person obtaining consent is the treating physician/clinical care team of the targeted subjects, please indicate ways of protecting against undue influence or coercion:

Click or tap here to enter text.

* 1. **Waiver of documentation of consent forms (oral consent forms):**

Will you request a waiver of documentation of informed consent or alteration of any requirements (e.g., non-disclosure of information to subject)? Please refer to criteria under Appendix II)

 [ ] Yes

 [ ] No

 **If yes,** check all that applies in the table under Appendix II.

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

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

 [ ] No

* 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

* 1. **Will others (such as next-of-kin or legal guardians) be asked to give consent on behalf of adult participant/subject to participate in the research? This is applicable for participants who have cognitive disability, terminally ill, comatose, etc.**

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

 [ ]  No

# **INCENTIVE/COMPENSATION**

**8.1 Will subjects receive any inducements, transportation fees, or rewards as part of this research study?**

[ ] Yes. Note that this information needs to be included in consent documents, under the heading “Compensation”, and not in the “Benefits” section. Also, payment for multiple visits should be prorated. Describe. Click or tap here to enter text.

 [ ] No

**8.2 Will the subjects be charged for research related procedures?**

 [ ] Yes, describe and justify the reason for charging the participant and indicate whether clinic visits are included Click or tap here to enter text.

 [ ] No

# **RISKS**

**9.1 What does the research involve?**

Check all that apply:

|  |
| --- |
| **Sample collection** |
| [ ] Biopsy | [ ] Bone marrow aspirate/biopsy |
| [ ] Blood draw | [ ] Tracheal/nasal swab |
| [ ] Urine[ ] Oropharyngeal/nasal swab | [ ] Saliva sampling[ ] CSF [ ] Stool sample |
| [ ] Other, specify:Click or tap here to enter text. |  |
| **Procedures** |
| [ ] Surgical, specify: Click or tap here to enter text. | [ ] Other procedures (for example: Bronchoscopy, laryngoscopy, colonoscopy, etc.). Specify: Click or tap here to enter text. |
| [ ] Use of radiation, fill in the Research Application Form to Use Radiation on Human Subjects https://www.aub.edu.lb/irb/Pages/biomedicalforms.aspx) |  |
| **Drugs and devices** |
| [ ] Administration of FDA or EMA approved drug(s) | [ ] Administration of unapproved drug(s) |
| [ ] Administration of FDA approved device(s) | [ ] Administration of unapproved device(s)  |
| [ ] Administration of placebo |  |
| **Genetic work** |
| [ ] Genetic testing (whole genome/exome sequencing, targeted genetic testing), specify: Click or tap here to enter text. |  |
| **Data collection** |
| [ ] Use of medical records | [ ] Administration of questionnaires  |
| **Other**, specify: Click or tap here to enter text. |

**9.2 Describe the impact and likelihood of the risk/s or harm/s checked above by filling the below table. Refer to the example below and implement for every risk associated with your study. (Copy and paste table if necessary)**

*The described risks/harms should be documented in consent documents.*

|  |  |  |  |
| --- | --- | --- | --- |
| **STUDY PROCEDURE** | **RISK** | **IMPACT** | **LIKELIHOOD** |
| Ex: Blood withdrawal | Hematoma | [ ] Severe [ ] High [ ] Moderate [ ] Low [ ] Negligible | [ ] Expected [ ] Likely [ ] Possible [ ] Unlikely [ ] Remote |
|  |  | [ ] Severe [ ] High [ ] Moderate [ ] Low [ ] Negligible | [ ] Expected [ ] Likely [ ] Possible [ ] Unlikely [ ] Remote |
|  |  | [ ] Severe [ ] High [ ] Moderate [ ] Low [ ] Negligible | [ ] Expected [ ] Likely [ ] Possible [ ] Unlikely [ ] Remote |
|  |  | [ ] Severe [ ] High [ ] Moderate [ ] Low [ ] Negligible | [ ] Severe [ ] High [ ] Moderate [ ] Low [ ] Negligible |

**9.3 Describe the precautions that will be taken to minimize risks to subjects**

Click or tap here to enter text.

**9.4 Justify the risks in terms of potential scientific yield and in relation to the anticipated benefits to the subjects.**

Click or tap here to enter text.

**9.5 Please describe your plan for data safety monitoring and reporting adverse effects to the IRB. Include in your response whether an agency board or designee other than the investigator will be responsible for monitoring this research.**

Click or tap here to enter text.

#  **BENEFITS**

1. **List any anticipated *direct* and/or *social* benefits to participation in this research project. If none, state that fact here and in consent documents.**

***Note:*** *Compensation paid to subjects is not considered a “benefit” but should be described in question 7.5. The benefit of receiving the treatment is not necessarily a benefit of participation in the research project. That distinction is central to the consent process.*

Click or tap here to enter text.

1. **Assess the relative weights of the study’s risks and benefits. Where appropriate, discuss provisions for ensuring medical or professional intervention in the event of adverse effects to the subject (e.g., an unblinded co-investigator in a high-risk phase I study).**

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that is expected to be gained.

Click or tap here to enter text.

#  **BIOLOGICAL SAMPLES**

**11.1 Will this research include blood drawing, bone marrow aspirate, cerebrospinal fluid collection, or biopsy of other tissue?**

[ ] Yes

[ ] No

**If yes**, state the amount (volume measured) and frequency in which the samples are taken. The consent must include lay term equivalents for the amounts; e.g., teaspoons.

Click or tap here to enter text.

  **If yes**, please clarify whether the samples will be obtained as extra or left over.

Click or tap here to enter text.

Please distinguish procedures that are diagnostic from procedures that are performed solely for research purposes.

Click or tap here to enter text.

**11.2. Are you going to store (“bank”) any samples (including DNA/RNA)?**

[ ] Yes

[ ] No

**If yes,** specify where the storage will take place and who will be accessing the samples.

Click or tap here to enter text.

**11.3. Are you going to share samples from AUB/AUBMC to external sites?**

[ ] Yes

[ ] No

**If yes, please indicate the entity that will receive the samples and refer to the Office of Grants and Contracts for assistance in preparing the appropriate agreement.**

Click or tap here to enter text.

1. **CARE OF SUBJECTS IN CASE OF ACCIDENT**

**12.1 If this research involves a potential for injury, injury compensation must be referred to in the consent form.**

If there is an insurance policy to cover research-related injuries, attach such documentation with your IRB package submission.

[ ] Sponsor funded compensation

[ ] No compensation available

#  **CONFIDENTIALITY OF DATA**

**13.1 Describe how you will ensure that privacy will be respected and that confidentiality of the information will be maintained.**

Elaborate on the tools that will be utilized in collection and storage of data/samples. Who will have access to them? How long will they be stored? Will any codes or locks be applied? When the study is concluded, how will unstored documents/files/samples be disposed of?

Click or tap here to enter text.

#  **CONFLICT OF INTEREST**

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

Fill the column on the right if you answer yes to any of the below questions.

|  |  |
| --- | --- |
| Do you currently work or are you employed as part time or full time in an institution or business that is sponsoring this research?[ ] Yes [ ] No | [ ] Has been disclosed to AUB[ ]  Has not been disclosed to AUB |
| [ ] Do you or any of your family members have a financial or personal interest that could benefit from the outcome of this research?[ ] Yes [ ] No | [ ] Has been disclosed to AUB[ ]  Has not been disclosed to AUB |
| [ ]  Are you or any of your family members participating as participants/ subjects in this research?[ ] Yes [ ] No | [ ]  Has been disclosed to AUB[ ]  Has not been disclosed to AUB |
| [ ]  Do you or any of your family members serve as members of the Board of directors/trustees/owners of a business from which sponsored research support has been received for this study through a gift/grant/contract administered to AUB?[ ] Yes [ ] No | [ ]  Has been disclosed to AUB[ ]  Has not been disclosed to AUB |
| [ ]  Do you or any of your family members receive material benefits from the sponsor/business that is funding this research?[ ] Yes [ ] No | [ ]  Has been disclosed to AUB[ ]  Has not been disclosed to AUB |
| [ ]  Does the research involve the use, study, or validation of any intellectual property (e.g., patents or patent applications, inventions, discoveries, devices, licenses, copyrights of software, or educational materials)? [ ] Yes [ ] No | [ ]  Has been disclosed to AUB[ ]  Has not been disclosed to AUB |
| [ ]  Do you or any of your family members have any other interests that could give rise to conflicts of interest?[ ] Yes [ ] No**If yes**, please specify: Click or tap here to enter text. | [ ]  Has been disclosed to AUB[ ]  Has not been disclosed to AUB |
| [ ]  No conflict of interest |

**14.2 If a conflict of interest is present, please attach a conflict-of-interest management plan.**

**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’s responsibility to provide the personnel with effective training. |[ ]
| Ensuring that the study will be conducted by qualified personnel who are knowledgeable about AUB regulations and policies governing this research, and who were acknowledged officially by the IRB.  |[ ]
| 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 providing documentation 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 ascertain 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’s 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 be terminated and all activities must cease, including analysis of previously collected data, until IRB approval is re-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 other 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. | [ ]  |
| Documenting the enrollment of patients in clinical/interventional research and their research encounters on the research module in EPIC. |[ ]
| Ensuring that if PI is unavailable due to reasons such as sabbatical or other type of leave, the PI will submit arrangements for conducting the study to the IRB, including the appointment of a temporary PI at AUB during the PI’s absence. |[ ]
| Ensuring that all personnel and investigators are aware of this research and have 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 Department / Dean of the Faculty or representative , I acknowledge that this research is in keeping with the standards of my department and I assure 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**

**Full committee and Expedited Reviews**

* **Full committee review:**
	+ Research involving more than minimal risk to the participant requires review by a full committee. Full review covers all research that is not specifically suited for “expedited review” or is “exempt”. For example:
* Randomized clinical trials
* Studies that involve the use of radiation for research purposes
* Studies that involve the use of investigational drug or device
* Studies that involve genetic testing
* **Expedited review:**
* Expedited review covers research that involves only minimal risk procedures. For example:
* The study of individuals or group behavior in which the behavior is not manipulated, and the subjects are not exposed to any stressful situation
* The drawing of small amounts of blood
* Moderate exercise by healthy volunteers
* **Timeline for review**:

Provided that the IRB submission package is complete, expedited applications are typically reviewed within 4-6 weeks. Full board applications are included on the agenda of the meeting that follows the submission within a 1-month period. For a listing of the biomedical IRB meeting dates, please refer to the following link:

<https://www.aub.edu.lb/irb/Pages/fullboardmeetingsdates.aspx>

For this application to be considered for expedited review, please revise the categories below and identify which one applies to your study and tick the applicable category on the first page of the application.

|  |
| --- |
| **Check the box corresponding to the eligibility of research for expedited review category** 45 CFR 46.110 **which best describes the proposed research: 󠆶** |
| [ ] Category 1 | Clinical studies of drugs and medical devices only when condition (a) or (b) is met.(a) 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.)(b)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. |
| [ ] Category 2 | Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture. For adults, normally not more than 550 ml during an 8-week period, and not more than twice a week. For children and those under 50 kg, not more than 50 ml or 3 ml/kg, whichever is less during an 8-week period. Also, collection may not occur more frequently than 2 times per week. |
| [ ] Category 3 | Prospective collection of biological specimens for research purposes by noninvasive means; e.g., 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, deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction, permanent teeth if routine patient care indicates a need for extraction, uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue, and sputum collected after saline mist nebulization. |
| [ ] Category 4 | Collection of data through noninvasive means (not involving general anesthesia or sedation) routinely employed in clinical practice **excluding X-rays and microwaves**. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of a medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Example: Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy, weighing or testing sensory acuity, 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. |
| [ ] Category 5 | Research involving materials already collected (such as data documents, records, and pathological or diagnostic specimens) or will be collected solely for non-research purposes (such as medical treatment or diagnosis). |
| [ ] Category 6 | Collection of data from voice, video, digital or image recordings made for research purposes. |
| [ ] Category 7  | 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**

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

**Waiver of written consent (Oral consent)**

If you are requesting a **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 information that is provided orally and information that is provided in writing, including 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 they would like documentation linking the subject with the research, and the subject’s wishes will govern. |
| [ ] The written script of information that is provided orally and information that is provided in writing, including 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)**, please complete the table below:

|  |
| --- |
| **A justification is required for waiver or alteration of the consent 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 practicably 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, i.e. research that involves deception, please provide the IRB with a copy.) *Explain:*  |