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CONTINUING REVIEW FORM

This form is used to apply for *continuing review for active research projects*. **Do not submit this form to the IRB if one of the following applies to your study:**

* Terminated by the PI
* Canceled / aborted
* Completed (including data analysis)

If one of the above applies, the PI should fill the Project Closure Form which can be accessed on this link: <https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx>

**HOW TO COMPLETE THE FORM**

1. This form must not be handwritten.
2. For retrospective chart reviews, questions 2 to 11 under **study progress,** can be skipped to directly go to question 12.
3. For studies that are ongoing and involve interaction or intervention with participants:
4. Fill out all the sections on this form completely
5. Attach, if applicable, copies of the latest consent documents in use by the research team to recruit participants
6. Attach **Biomedical Research- Basic/Refresher CITI certificates** of all current research members. Social and behavioral CITI certificates are accepted only for studies classified as retrospective chart reviews.
7. During the preparation of this continuing review, if you identify the need to request a modification (amendment) that must be reviewed in parallel with this continuing review, please submit the below documents:

* A separate cover letter explaining the amendment
* Any modified study documents as applicable:
* Study proposal
* Informed consent / assent forms
* Recruitment / advertisement material
* Data collection material (case report forms, data collection sheet, questionnaires, etc.)
* Other relevant documents

**TITLE OF PROPOSAL:** Click or tap here to enter text.

**NAME OF THE PRINCIPAL INVESTIGATOR:** Click or tap here to enter text.

**PROTOCOL IRB ID:** Click or tap here to enter text.

**STUDY TEAM IDENTIFICATION**:

**List the names of all research personnel currently working on the study and attach their most recent CITI certificate *(biomedical or social and behavioral basic refresher course)*.**

**Note: Ensure that any personnel with expired or invalid CITI certification renew their certificates before submitting this form for processing.**

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| **Name** | **Department** | **Role in the study** | **CITI expiry date** |
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| STUDY STATUS |
| Select the status of your study from the options listed below. |
| Ongoing (still open to additional enrollment) |
| Ongoing (permanently closed to additional enrollment; subjects continue to undergo research-related intervention(s)) |
| Ongoing (permanently closed to additional enrollment; all subjects have completed protocol- related treatment(s) / intervention(s); the research remains active for long-term follow-up of subjects). The IRB considers long-term follow-up **to be limited to review of medical records** and checking for survival status, either through contact with the subject or through a review of the medical record) |
| Ongoing (the remaining research activities are limited to data analysis) |
| Did not commence |

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| **STUDY PROGRESS** |
| 1. **Is your study limited to the review of medical records without any interaction with human subjects?** |
| Yes  No |
| If you answered **“Yes”,** **please proceed to answer the following two questions, and skip sections 2-11**. You can then continue filling out the questions from section 12 onward. |
| During the current IRB approval interval, how many patients’ medical charts were reviewed?  Click or tap here to enter text. |
| Since the study began, how many patients’ medical charts were reviewed?  Click or tap here to enter text. |
| 1. **During the current IRB approval interval (from the last date of approval/renewal until the present date)** How many subjects were enrolled into this research study at all sites under the authority of the American University of Beirut (AUB) IRB? Please exclude subjects who did not meet the inclusion criteria during screening (if applicable). |
| Click or tap here to enter text. |
| 1. **Since the study began, how many subjects have been entered into this research study at all sites under the authority of the AUB IRB *(total number of subjects recruited until present date*)? Please exclude subjects who did not meet the inclusion criteria during screening (if applicable).**   Click or tap here to enter text. |
| 1. **If signed consent is required from subjects, have ALL subjects enrolled during the current IRB approval period signed the consent form?** |
| Yes  No |
| If the answer is **“No”,** please explain why signed/written informed consent has not been obtained.  Not applicable: The IRB previously granted a waiver of the requirement to obtain informed consent.  Not applicable: The IRB previously granted a waiver of the requirement to obtain a signed, written informed consent document but all subjects provided verbal consent.    Other (Please specify). Click or tap here to enter text. |
| 1. **During the current IRB approval period, have any subjects withdrawn from the study or been withdrawn from the study by the investigator?** |
| Yes  No |
| If the answer is **“Yes**”, provide a summary describing the number of withdrawals and their reasons.  Click or tap here to enter text. |
| 1. **Since the last IRB review, have there been any subject complaints that were not reported previously to the IRB?**   Yes  No |
| If the answer is **“Yes”,** please provide a summary describing the number and nature of complaints and explain whether the complaint (s) has been resolved.  Click or tap here to enter text. |
| 1. **During the current IRB approval period, has the profile of adverse events (in terms of frequency, severity, or specificity) changed from previous experience or from protocol expectations?** |
| Yes  No |
| If the answer is **“Yes”,** please describe the changes.  Click or tap here to enter text.   1. **Since the last IRB review, have there been any deviations from the IRB-approved research study that were not reported previously to the IRB (i.e. minor deviations that did not require prompt reporting may be summarized at continuing review. Major deviations must be reported on the Unanticipated Problems report form.)**   Yes  No  If the answer is **“Yes”**, attach a summary describing minor protocol deviations.  Attached   1. **Has there been any subject death since the study initiation?**   Yes  No  If the answer is “Yes”, please indicate the total number of subject deaths that have occurred since the study was first approved. |
| At sites under AUB purview Click or tap here to enter text.  Total for all study sites (if known): Click or tap here to enter text.    **AND**    **Please** indicate the number of subject deaths at sites under AUB purview since the last IRB approval was granted: Click or tap here to enter text.  Please choose one of the below options.    Related  Possibly related  Unclear as to relation  No relation  If related, please describe the possible relationship for each subject death.  Click or tap here to enter text. |
| 1. **Select the type of Data Safety Monitoring Plan (DSMP) as applicable to your study:** |
| The principal investigator has sole responsibility for monitoring based on an IRB-approved DSMP at original submission.  A group of designated AUB faculty/staff has responsibility for monitoring.  An independent individual or group of non-AUB individuals will have responsibility for monitoring (e.g., coordinating center) and oversight of problem/events for this research.  A designated medical monitor, or group of monitors, for commercially funded or for not-for-profit sponsored studies has responsibility for monitoring.  A formal Data and Safety Monitoring Board (DSMB) has responsibility for monitoring.  A mixed group including AUB and non-AUB individuals has responsibility for monitoring and oversight of problems, events, and data arising from this study.  There is no DSMP. |
| 1. **During the current approval period, have any changes been made in the data safety monitoring plan, if applicable.** |
| Yes  No  Not applicable |
| If the answer is **“Yes”,** please describe the changes, reasons for changes, and whether the changes are likely to affect the assessment of risk/benefits, Please provide a dated current report from the monitoring entity, such as but not limited to a data safety monitoring board report.  Click or tap here to enter text. |
| 1. **Is this a multicenter study?** |
| Yes  No |
| If the answer is **“Yes”,** please specify the total number of participants from all sites, if known to AUB PI:  Since last approval: N= Click or tap here to enter text.  Since original approval: N= Click or tap here to enter text. |
| 1. **During the current IRB approval interval, has there been any change in the original protocol enrolment targets, including AUB and other authorized sites?** |
| Yes  No |
| If the answer is **“Yes”,** please explain: Click or tap here to enter text. |
| 1. **Based on the current rate of subject accrual, will the subject enrollment plan be met?** |
| Yes  No |
| If the answer is **“No”,** please provide (1) a justification for continuing this research study and (2) the steps that will be taken to increase subject enrollment.  Click or tap here to enter text. |
| 1. **During the current IRB approval interval, have there been any unanticipated problems involving risks to subjects and others, including breach of subject confidentiality, that met the prompt timeframe for reporting as per the guidance document on unanticipated problem involving risks to subjects or others (UPIRSOs).** |
| Yes  No |
| If the answer is **“Yes”,** have they already been reported to IRB?  Yes  No |
| If the answer is **“No”,** please justify the reason for **untimely** reporting and immediately submit an Unanticipated Problem Report <https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx> which must be available for the IRB's consideration during this continuing review.  Click or tap here to enter text.  Attached |
| 1. **During the current IRB approval interval, have there been any unanticipated problems, adverse events, minor deviations, etc. that were not previously reported but are required to be reported at the time of Continuing Review?**   <https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx> |
| Yes  No |
| If the answer is “**Yes”**, please submit along with this form a report listing the events that meet the requirements as per the guidance above for the IRB’s consideration during this continuing review.  Attached |
| 1. **Please provide a narrative summary of the study progress to date**   Click or tap here to enter text. |
| 1. **Have any preliminary results of the research become available since the initial IRB review or the last continuing review?** |
| Yes  No |
| If the answer is “**Yes”**, please explain Click or tap here to enter text. |
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| 1. **Since the last IRB review, has any new information emerged either from the research itself or from other sources that could alter the IRB’s previous determinations, particularly with respect to risk to subject or that may affect the willingness of current or future research subjects to participate in this study?** |
| Yes  No Not applicable |
| If the answer is **“Yes”**, please summarize and include a current risk-benefit assessment based on study results to date the new information:  Click or tap here to enter text. |
| 1. **Have there been any changes in the financial/ nonfinancial interests of any current or proposed additional study personnel, since the most recent IRB review, that require disclosure of this interest to AUB or which may require disclosure of interest in the consent documents or prohibit them from serving as key personnel for this study, based on the AUB Conflict of Interest Policy (COI).** |
| Yes  No |
| If the answer is “**Yes”**, has this been disclosed to AUB IRB?  Yes  No  If the answer is **“No”,** please justify the reason and fill the **AUB COI form** <https://aub.policytech.eu/dotNet/documents/?docid=2071>which must be available for the IRB's consideration during the continuing review.  Click or tap here to enter text.  Attached |
| **AND**  Describe these interests and how they are being managed to mitigate risks to participants and whether the consent must be revised to reflect this interest.  Click or tap here to enter text. |

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| 1. **Which type of funding is this research receiving? (You may select more than one):** | |
| AUB funding | URB Other, specify: |
| Commercial sponsorship | Specify: |
| US Federal funding | NIH NSF USAID DOD Other specify: |
| Non-federal US funding | Specify: |
|  |  |
| Funding from external sources | Specify: |
| Lebanese National Council for Scientific Research (LNCSR) |  |
| No Funding |  |

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

*Note: Studies designated at minimal risk either through an earlier expedited review process or by a full board committee assessment may be eligible for expedited review at the time of continuing review. Substantial modifications in protocol recruitment, design, consent process, and/or risk/benefit ratio may require full IRB committee review.*

