**Please use this application if you are applying for an extension to a previously IRB approved study. The IRB’s mandate is to review protocols at least annually or as requested by the IRB, in order to re-assess the risk-benefit ratio and determine if a study may retain its approval.**

**It is important to complete and submit this form a minimum of *45 days prior to study approval expiry* in order to avoid any temporary hold on the initial protocol approval.**

**The Document Submission Checklist below provides a general guide regarding the required documents, as applicable, to be submitted with this application. For any assistance, please contact the IRB Office at** **irb@lau.edu.lb**

|  |
| --- |
| ***1. RESEARCH PROJECT INFORMATION*** |
| Name of Principal Investigator (PI):       | Department/School:        |
| Research Project / Study Title:      Research Approval Tracking Number:       Initial IRB Approval Date:       |

|  |
| --- |
| ***Document submission Checklist — Continuing review*** One **Original Hard Copy** of each of the following items are required:[ ]  Completed and signed Continuing Review Application[ ]  Progress Report and DSMB Reports, if any[ ]  Latest IRB-approved detailed protocol currently in use together with summary [ ]  Latest IRB-approved informed consent document(s) including any short forms and translations[ ]  Investigator Brochure *(if protocol involves use of any drugs or devices)*[ ]  Copies of any publications or external reports regarding findings of the study to date[ ]  Modifications to protocol or study documents that have not been previously approved by the IRB, if relevant to continuing review **(all modifications or amendments must be tracked)**[ ]  Additional reporting e.g. Serious Adverse Event Report, Major Violation Report, etc. *(if applicable)*[ ]  Human Subject protection training certificate for any additional investigator (s) or study personnel[ ]  Curricular Vitae for the Principal Investigator and any Co-investigator involved in subject contact, if not previously submitted with the Initial Protocol Application[ ]  Investigator Financial Disclosure Form completed and signed for any additional investigator (s) for funded or sponsored studies |

| ***2. PROTOCOL STATUS***  |
| --- |
| 1. **Enrollment**

 Open to Enrollment[ ]  Enrolling subjects [ ]  No enrollment to date, please specify reason:      [ ]  Closed to Enrollment; Date of Last Enrollment:       | 1. **Study Progress**

[ ]  Study treatment/intervention/procedures continues[ ]  Active or long term follow-up continues [ ]  Data analysis is ongoing[ ]  Subject re-consent necessary because of study amendments[ ]  Study on hold; reason:      1. **Expected End Date:**
 |
| Was any research activity conducted after protocol expiry/suspension/termination? [ ]  No [ ]  Yes, *If* ***yes****, please include a summary of all activities conducted, including subject recruitment, data collection, data analysis, and any other research-related activities, since the project expired/suspended/terminated.*      |
| ***No further research may be done until the project has been re-approved by the IRB.***  |

|  |
| --- |
| 1. ***SUMMARY OF INTERIM STUDY PROGRESS***

*(Please use the space below to give a brief summary of study progress, update and any findings to date)* |

| ***4. PROTOCOL MODIFICATIONS***  |
| --- |
| ***A. Protocol Amendments as part of the Continuing Review*** *(please check all that apply)* |
| **[ ]** No prior amendments have been made to this protocol since the original approval by the IRB**[ ]** Prior amendments were made to this protocol, and all have been previously approved by the IRB**[ ]** New protocol amendments are submitted as part of this continuing review submission. *Please refer to 4B for Informed Consent Form amendments* 🡪 *Please provide a description of the amendments below* 🡪 *Please submit copies of all documents that will be revised due to requested protocol amendments  (e.g. recruitment materials, surveys, etc)*🡪 *All amendments must be tracked or highlighted in the documents submitted****Description of Changes / Amendments (****Please describe each amendment and its effect on protocol integrity and the risk-benefit ratio. Provide a complete rationale and justification for each modification. Use a supplementary Description of Changes sheet, if necessary).**Amendment Category / Section:*            |
| *Amendment Category / Section:*            |
| ***B. Informed Consent / Assent Form(s) / Authorization*** |
| **[ ]** No changes have been made to the consent/assent form(s)/authorization 🡪 Please include a copy of the latest IRB-approved version of the consent form that is currently being used**[ ]** Changes have been made to consent/assent form(s)/authorization, including any addendums or patient information sheets and all have been previously approved by the IRB🡪 Please include a copy of the latest IRB-approved version of the consent form that is currently used**[ ]** Changes have been made to consent/ assent form(s)/authorization, including any addendums or patient information sheets that have not been reported to or approved by the IRB🡪 *Please indicate and explain the modifications below. Submit a copy of the new Informed Consent Form for IRB review and approval*      |
| ***C. Protocol Deviations / Violations*** |
| Have there been any Protocol Deviations / Violations since the last IRB review?**[ ]** No  **[ ]** Yes, if yes, have they been reported promptly to the IRB. **[ ]** Yes **[ ]** No, 🡪If no, please explain reason and submit immediately with this application:       |

| ***5. Subject Enrollment and Demographics***  |
| --- |
| ***A. General Enrollment Summary*** *(Please indicate below the number of subjects in each category)* |
| Subject Enrollment Target as specified in the Initial IRB application:         |
| Does the total number of study subjects to be recruited differ from that initially approved by the IRB?[ ]  No [ ]  Yes, Please clarify and give reason:       |
| ***B. Detailed Enrollment Summary*** *(Please indicate below the number of subjects in each category)* |
| **B1. Total number of pre-screened/screened subjects** |  |
| **B2. Number of subjects determined to be ineligible after consenting** |  |
| **B3. Number of subjects currently active on the study** |  |
| **B4. Number of subjects who completed the study** *(without early termination)* |  |
| **B5. Total number of subjects withdrawn from the study** *(sum of a-d)* |  |
| a. Number of subjects withdrew consent at subject’s request after enrollment |  |
| b. Number of subjects withdrawn due to toxicity/ adverse events |  |
| c. Number of subjects lost to follow-up |  |
|  d. Number of subjects no longer participating for other reasons (please explain reason):    |  |
| **Total number of subjects provided consent to date:***(Should equal to the sum of B2-B5)* |  |
| ***C. Descriptive Summary*** |
| Has enrollment proceeded as anticipated? [ ]  Yes [ ]  No🡪*If* ***no****, please explain below the problems/issues and the steps taken to address them, if any.*      |
| Have there been any subject or staff concerns or complaints? [ ]  No [ ]  Yes🡪*If* ***yes****, please specify:*        |
| Has there been any change in the risk/benefit ratio? [ ]  No [ ]  Yes🡪*If* ***yes****, please specify:*        |

| ***6. Events and Outcomes—Serious Adverse, Unexpected, and Unanticipated*** *(Please summarize and attach all reports submitted to the IRB)* |
| --- |
| Have all serious adverse events (expected or unexpected) or unanticipated problems involving risks to participants or others been reported previously to the IRB in a timely manner? [ ]  Yes, please specify the number:       [ ]  No*\**  [ ]  NA*\*If* ***no****, please complete and submit an* ***Adverse Event and UAP Reporting Form*** *with this form for each unreported incident* |
| Has the frequency or severity of adverse events been different than expected? [ ]  No [ ]  Yes🡪*If* ***yes****, please specify:*      |
| Have there been any other unanticipated problems involving risk? [ ]  No [ ]  Yes🡪*If* ***yes****, please specify:*      |

| ***7. Study Site Personnel*** *(Please indicate below any additional study personnel associated with this protocol not reported to the IRB previously. Use the supplementary Study Site Personnel Amendment sheet, if necessary.)* ***NOTE: Include copies of human subject research training certificate of completion.*** |
| --- |
| Study Personnel | Subject Interaction | ObtainsInformed Consent | Conducts data analysis, reviews medical records/ databases and/or handles biological specimens |
| Name:      School / Division:      [ ]  Added to the Protocol[ ]  Removed from the ProtocolName of Human Subject Training:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| Name:      School / Division:      [ ]  Added to the Protocol[ ]  Removed from the ProtocolName of Human Subject Training:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |

|  |
| --- |
| ***8. FUNDING SOURCES*** |
| Have there been any changes to the funding or sources of funding for this study?[ ]  No [ ]  Yes🡪*If* ***yes****, please specify below any amendments to the sponsor/funding source and a copy of the grant, financial funding progress report or any other funding applications/documents*      |

|  |
| --- |
| ***9. FINANCIAL / NON-FINANCIAL CONFLICT OF INTEREST*** |
| Have there been any changes to the financial/ non-financial conflict of interest of any current or proposed additional study personnel since the last IRB review that require disclosing to the IRB.[ ]  No [ ]  Yes🡪*If* ***yes, has this been disclosed.*** [ ]  Yes [ ]  No 🡪*If* ***No, please submit relevant documents.***       |

In the event there is finical or non-financial interest, please describe the type of conflict of interest and the methods of managing this risks and whether the informed consent document will be updated to highlight this.

| ***10. Progress report, interim findings and Publications*** *(Please indicate those that apply to this protocol and provide copies of all abstracts, articles, and reports)* |
| --- |
| * Is there any new information about study-associated risks: [ ]  Yes [ ]  No *If yes, please provide documentation*
 |
| * For interventional studiesthat are funded or sponsored:
* Is the study subject to oversight by a Data and Safety Monitoring Board (DSMB), Data Monitoring Committee (DMC) or any other similar committee/center responsible for review of interim findings and safety reporting

[ ]  No [ ]  Yes🡪*If* ***yes****, please attach copies of all relevant reports with this submission** Is the study monitored by a designated medical monitor from the sponsor? [ ]  Yes [ ]  No
* For PI initiated, interventional studies:
* Is the PI responsible for reviewing and monitoring the data collected based on the IRB approved protocol? [ ]  Yes [ ]  No
* Did the PI assign an independent Data and Safety Monitoring Committee or any other similar committee responsible for the review of interim findings and safety reports? [ ]  Yes [ ]  No
 |
| * Has this study been monitored/reviewed/audited/inspected by an outside monitor/sponsor/agency including Food and Drug Administration (FDA) or local regulatory authority?

[ ]  No [ ]  Yes🡪*If* ***yes****, please attach copies of all related reports/letters that have not yet submitted to the IRB* |
| * Since the last IRB review, have there been major changes or availability of any other relevant information

[ ]  No [ ]  Yes, *If Yes, Please explain and provide relevant documentation:*      * Since the last IRB review, please specify any limitations or obstacles encountered during the course of the study:

      |

|  |
| --- |
| ***12.* *PRINCIPAL* *INVESTIGATOR ASSURANCE*** |
| As Principal Investigator, by signing this application:* I accept ultimate responsibility for the protection of the rights and welfare of the human subjects and the conduct of this study including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki and Nuremberg Code
* I agree to comply with all applicable IRB policies and procedures, as well as with all relevant local and international laws regarding the protection of human subjects in research
* I will personally conduct or supervise this research within LAU and its affiliates and accept responsibility for adhering to the IRB-approved protocol
* I understand that I will not implement any modifications made to the protocol, study documents and/or informed consent documents prior to the IRB’s approval
* I understand that approval of this research could be suspended or terminated by the IRB
* I understand that any research-related material is subject to an audit by the IRB
* I certify that the proposed amendment(s) or continuing review of the research project is not currently being conducted and will not begin until IRB approval has been obtained
* I have completed the human subject protection education requirement and ensure that all investigators and personnel involved in this research have completed the human subject education requirements
* I certify that the information provided in this application is complete and accurate

             Signature of Principal Investigator Date |