**Please use this form if you are notifying the IRB of study termination, closure, or completion. Complete all sections of this application as applicable. Study closure means that all research related interventions and interactions with human subjects have been completed, and all data collection and analysis has been finished.**

**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**](mailto:irb@lau.edu.lb)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | ***1. RESEARCH PROJECT INFORMATION*** | | | | Name of Principal Investigator (PI): | Department/School: | | | Research Project / Study Title: | | | | IRB Approval Tracking number: | | Initial IRB Approval date: |   ***Document submission Checklist — Request for Protocol Closure***  One **Electronic Copy** of each of the following items are required as applicable:  Completed and signed Protocol Closure Form  Progress Report and DSMB Reports, if any  Copies of any publications or external reports regarding findings of the study to date |

| ***2. PROTOCOL STATUS*** |
| --- |
| Why is this study being Closed:  Completed; Date of Completion:  Terminated; Date of Termination:       , Reason:    Never Commenced, Reason:  Suspended; Date of Suspension:       , Reason: |
| Was any research activity conducted after protocol 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.* |

|  |  |  |  |
| --- | --- | --- | --- |
| ***3. PROTOCOL DEVIATIONS / VIOLATIONS*** | | | |
| Have there been any Protocol Deviations / Violations since the last CHSR review?  No    Yes, if yes, please explain: | | | |
| ***4. Subject Enrollment and Demographics*** | | |
| ***A. General Enrollment Summary*** *(Please indicate below the number of subjects in each category)* | | |
| **Subject Enrollment Target as per Initial Application**  LAU Campuses/ Affiliates: | Study- wide: | |
| ***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:* | | |

| ***5. 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:* |

|  |
| --- |
| ***6. FUNDING SOURCES*** |
| Have there been any changes to the funding sources 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* |

| ***7. Progress report, interim findings and Publications***  *(Please indicate those that apply to this protocol and* ***provide copies of all abstracts, articles, and reports****)* | |
| --- | --- |
| * Interim analysis/ findings / Progress reports:   Yes  No | Resulting publications:  Yes  No |
| * Information about study-associated risks:   Yes  No | Multi-center trial reports *(if multi-center study*):  Yes  No  N/A |
| * 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* | |
| * 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: | |

| ***8. Summary of Study Outcome***  *(Please use the space below to give a brief summary of study findings)* |
| --- |
|  |

| ***9.* *PRINCIPAL* *INVESTIGATOR ASSURANCE*** |
| --- |
| As Principal Investigator, by signing this application:   * I certify that I have accepted 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 have complied 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 have personally conducted or supervised this research within LAU and its affiliates and accepted responsibility for adhering to the IRB-approved protocol * I understand that any research-related material is subject to an audit by the IRB, even after study closure * I certify that the information provided in this application is complete and accurate            Signature of Principal Investigator Date |