**Please use this application if you are applying for a change / amendment to a previously IRB approved study or if you are adding new investigators to the project. Therefore, it is important to complete and submit this form in order to secure approval before any amendments can be made.**

**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)

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

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| ***Document submission Checklist — Protocol Amendment Application***  One **Electronic Copy** of each of the following items are required as applicable:  Completed and signed Protocol Amendment Application  Copies of all amended documents, **with tracked changes**  Informed Consent Form with proposed changes and assent forms, if applicable  Human Subject protection training certificate for any additional investigator  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 for funded/sponsored studies |
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| ***2. STATUS OF PROTOCOL*** *(please indicate below)* | |
| Open to Enrollment:  Currently enrolling subjects  No enrollment to date  Closed to Enrollment, however:  Study treatment/intervention/procedures continues  Active or long term follow-up continues  Data analysis is ongoing | Enrollment to date *(if any):*  State the number of participants recruited to date: |

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| ***3. RISK-BENEFIT ASSESSMENT***(*please check all that apply)* ***NOTE: Please explain how the risk-benefit ratio of subjects is affected in the Description of Changes.*** |
| Please indicate if the amendments you wish to propose affects the risk-benefit ratio towards the participants:  No change to risk  May increase risk  May decrease risk |

| ***4. AMENDMENTS*** | | | |
| --- | --- | --- | --- |
| ***A. Type of Amendment*** *(check all that apply)* | | | |
| Amendments requested to:  Study Protocol *(please complete Section 4B, 4C and 4D)*  Study Site Personnel *(please complete Section 5)* | | | |
| ***B. Protocol Components  NOTE: Changes to each selected component must be explained in Section 4D — Description of Changes.*** | | | |
| *Please indicate below the protocol components to be modified:* | | | |
| Sponsor  Study Site  Funding Source / Budget  Remuneration | Study Design  Interventions / Study Procedures  Duration of study  Use of specimen | Enrollment  Subject Eligibility   and/or Exclusion   Criteria  Study population | Other *(please specify in section D)* |
| ***C. Study Documentation and Procedures*** | | | |
| Do the proposed amendments involve modifications to: | | | |
| **1)** Informed Consent / Assent Forms  No  Yes\*🡪*if yes, re-Consent of previously enrolled subjects?*  *No  Yes, if yes, please explain process in section D and provide copy of amended Informed Consent Form.* | | | |
| **2)** Recruitment Materials?  No  Yes🡪*If* ***yes****, submit a copy of revised recruitment materials* | | | |
| **3)** Study Materials?  No  Yes🡪*If* ***yes****, please submit a copy of revised study materials   (e.g. surveys, questionnaires, study handouts, etc.)* | | | |
| **4)** Investigator Conflict of Interest?  No  Yes🡪*If* ***yes****, please submit a new Investigator Financial Disclosure form(s), as applicable* | | | |
| ***NOTE: Please include copies of all modified documents with this form. In addition, complete section D below*** | | | |
| ***D. 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:*    *Amendment Category / Section:*    *Amendment Category / Section:*    *Amendment Category / Section:*    *Amendment Category / Section:* | | | |

| ***5. 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 protection training certificate of completion.*** | | | |
| --- | --- | --- | --- |
| Study Personnel | Subject Interaction | Obtains  Informed Consent | Conducts data analysis, reviews medical records/ databases and/or handles biological specimens |
| Name:  School / Division:  Added to the Protocol  Removed from the Protocol  Name of Human Subject Research Training: | Yes  No | Yes  No | Yes  No |
| Name:  School / Division:  Added to the Protocol  Removed from the Protocol  Name of Human Subject Research Training: | Yes  No | Yes  No | Yes  No |
| Name:  School / Division:  Added to the Protocol  Removed from the Protocol  Name of Human Subject Research Training: | Yes  No | Yes  No | Yes  No |

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| ***6.* *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 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 |