**Please use this application if you are applying for a new research project involving human participant that require Full or Expedited Review. *In order to check if your project might be Exempt from IRB review, please check the Exempt Criteria detailed in the IRB Protocol Exempt Application.***

**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): | |  | |
| Research Project / Study Title: | | | |
| Location (s) where the study will be conducted:  *(identify all locations where the study will be conducted under your supervision)* | | | |
| Will data be collected at sites/locations other than LAU or its affiliates  Yes  No  If yes, please provide necessary approvals, as applicable | | | |
| ***Study Administrator/Coordinator*** *(if different from PI and responsible for IRB submissions)* | | | |
| Name: | Email: | | Phone: |
| ***Document submission Checklist — Initial Protocol Submission***  *One* ***Electronic Copy*** *of each of the following items are required, as applicable (study documents in Word editable form):*  *Completed and signed* ***Research Project Submission Form*** *(GSR) – Only for Faculty Research Projects*  *Completed* ***IRB Initial Protocol Application*** *– Signed by Advisor, if Submission is for a Student Project*  *LAU Medical Center-Rizk Hospital Signature page - For research to be conducted at the hospital*  *LAU Medical Simulation Center – For research to be conducted at the Simulation Center*  *A detailed protocol or research project proposal*  *Protocol Summary for Sponsored research projects is mandatory*  *Grant Application / study contract and/or Clinical Trial Agreement (CTA) including detailed budget information*  *Informed consent form(s) including any short forms and translations*  *Recruitment materials (cover letters, brochures, email notices /referrals, advertisements including translations)*  *Research Instruments e.g. diaries, surveys, questionnaires, Quality of Life handouts, telephone scripts, etc.*  *Educational materials including information sheets, study guides*  *Investigator’s Brochure, Product Monograph, Package Insert, or Device Manual – for Drug and Device trials*  *Product - New Drug Application or Investigational Device Application*  *Indemnification documentation, if applicable (for drug and device studies)*  *Study material including case report form and data collection tools*  *Human Subject Protection training certificate for all study personnel, valid within 3 years from date on certificate (*[*Protecting Human Subject Research Participants*](http://gsr.lau.edu.lb/irb/education-training.php)*)*  *Curricular Vitae for the Principal Investigator and any Co-investigator involved in participant contact*  *Investigator Financial Disclosure Form completed and signed for all PI and other investigators (only for funded/sponsored studies)* | | | | |

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| ***2. Type of Research*** *(check the one that applies from each column)* | |
| **Departmental Research**  *(not externally sponsored)*  **Graduate Study Research**  *(Graduate thesis/dissertation)*  **Undergraduate Research**  *(Senior thesis/independent study)*  **Externally Sponsored Research** | ***Investigational Product Study:***  Drug  Medical Device  Biologic *(vaccines, gene therapy, etc.)*  ***If any of the above is checked, then please specify study phase***  Phase I Phase II  Phase III  Phase IV |
| ***Epidemiological/ Observational Study*** *(including social/behavioral)*  ***Genetic Studies***  ***Other*** *(please specify)*: |

| ***3. Study Site Personnel*** *(All personnel involved in the study including the* ***Principal Investigator/Co-Investigators*** *must complete the CITI Protection of Human Subjects as a condition for IRB Approval. Use the supplementary Study Personnel sheet, if necessary.)* ***NOTE: Include copies of each human subject research protection training certificate of completion.*** | | | |
| --- | --- | --- | --- |
| Study Personnel | Participant Interaction | Obtains  Informed Consent | Conducts data analysis, reviews medical records/ databases and/or handles biological specimens |
| Name:  School / Division  Name of Human Subject Research Training: | Yes  No | Yes  No | Yes  No |
| Name:  School / Division  Name of Human Subject Research Training: | Yes  No | Yes  No | Yes  No |
| Name:  School / Division  Name of Human Subject Research Training: | Yes  No | Yes  No | Yes  No |
| Name:  School / Division  Name of Human Subject Research Training: | Yes  No | Yes  No | Yes  No |
| Name:  School / Division  Name of Human Subject Research Training: | Yes  No | Yes  No | Yes  No |

| ***4. Research Protocol Summary*** |
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| *This section should be written in lay terminology and must cover the following:*   * *Study Rationale* * *Purpose and Objective* * *Study population inclusion/exclusion criteria* |
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| ***5. Human Participant Recruitment*** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***A. Number of participants*** | | | | | | | |
| i) Expected number of participants **that will be enrolled** under your supervision:  ii) For multi-center study, the **total number** of participants to be enrolled (including (i) above): | | | | | | | |
| ***Note: Please note that the expected number of participants noted above to be enrolled under your supervision will be for which the LAU IRB approval will be granted.*** | | | | | | | |
| ***B. Targeted Population*** | | | | | | | |
| **Age Range of Participants** *(check all that apply)*  Newborns/Infants (0-2yrs)  Children (2-7yrs)  Children (8-17yrs)  Adults (18 yrs+),  Age range :       yrs to       yrs) | | | | | **Gender**  Females/Males  Females only  Males only | | |
| **Type of Participants** *(check all that apply)* | | | | | | | |
| Inpatients  Outpatients  Healthy volunteers, Non LAU | | | LAU Students  LAU Faculty  LAU Staff | | LAUMC-RH Staff  Other *(please specify)*: | | |
| **Special Populations** (*indicate any special populations that will be targeted in the research)* | | | | | | | |
| Children *(<18 yrs incl. viable neonates)\**  Nonviable neonates  Fetus/Fetal tissue  Other *(please specify):* | | | | Pregnant women  Impaired decision making  Illiterate  Employees of participating sites | | | |
| *Please provide the rationale for using the special population(s) noted above:* | | | | | | | |
| ***C. Recruitment Methods*** *(check all that apply):* | | | | | | | |
| Brochures  Recruitment letter  Study personnel  Internet / Email | | Flyers/Posters  Physician referral  Medical records/Chart review  Media Outlet: TV, Radio ads | | | | Telephone conversation text  Database/Registry  Other (please specify): | |
| ***Note: Please note that the text of all advertisement and letters used for recruiting participant must be submitted to the IRB for review and approval.*** | | | | | | | |
| ***D. Payment to Participants for taking part in the Research Project*** | | | | | | | |
| Will participants receive any payments?  No  Yes🡪if yes, *please indicate the type and amount for each:* | | | | | | | |
| Cash; LL: | Parking; LL:      ; | | | Transportation LL:      ; | | | Other, explain; LL: |
| Please provide reason for payment: | | | | | | | |

| ***6. Informed Consent and Participant’s diaries/questionnaires*** *(check all that apply)* | |
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| **Informed Consent will be obtained from:**  Participant  Parent/Guardian for child  Assent from Child  Legally Authorized Representative | |
| **Written Informed Consent**  Informed consent will be obtained and documented through use of written **Informed Consent Form** approved by the IRB and signed by the participant or participant’s representative | **Request for Waiver Requirement to obtain a Signed written Informed Consent Form**  Informed consent will be obtained and documented as follows (check all that apply):  Oral /Verbal Consent will be obtained and documented in the research record  A written statement or information sheet describing the research will be given to all participants and documented in the research record  Consent will be implied by voluntary completion of questionnaire or surveys  Request for waiver of informed consent for research that involves **No Contact With Participant**, e.g. retrospective/prospective chart review, excess tissue studies, some behavioral studies where data will remain anonymous |
| ***Note: Attach the relevant written Informed Consent Form, Information Sheet, or script for verbal consent to be used in this study and any translations. Verbatim translation is required. Back translations may be done to ensure accuracy*** | |

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| ***Participant Diaries/Questionnaires*** *(Please include copies with submission)* |
| Participant Diary (e.g. follow up, symptoms, medication, etc)  Questionnaires/Quality of Life Instruments |
| **Language to be used** *(check all that apply and provide copies of all translations):*  English  Arabic  Other: |

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| ***7. COSTS*** |
| Will the participants be charged for research-related procedures?  No  Yes🡪*please explain:* |
| Will any routine costs be billed to the participants or third party payor?  No  Yes🡪*please explain:* |
| ***NOTE: In general, participants should not be charged for research procedures that are not part of their standard of care. The consent form must disclose to participant that there may be charges for experimental procedures that cannot be billed to or be reimbursed by their insurance.*** |

| ***8. Medications, Supplements, Devices or Biologics*** |
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| ***A. Approvals*** |
| Does this study involve the use of a medication, supplement, device or biologics?  No  Yes, *if yes, please complete the following section* |
| **Medications, Supplements and Biologics** |
| Approved by the Ministry of Health, Lebanon  Approved by the FDA/EU Investigational New Drug  *(marketed product) (marketed product) (un-marketed product)*  *Please submit a copy of the Confidential Investigator Brochure, Product Monograph, and/or IND application, CT Registration documentation, as applicable, as well as any approval from above regulatory agencies* |
| **Devices** |
| **Type of Device**:  Significant Risk Device  Non-Significant Risk Device  Approved by the Ministry of Health, Lebanon  Approved by the FDA/EU  Investigational Medical Device  *(marketed product) (marketed product) (un-marketed product)*    *Please submit a copy of the Device Manual, IDE application and/or 510k application, Clinical Trial Registration documentation, as applicable, as well as any approval from above regulatory agencies* |
| ***B. Use of Investigational Products*** *(please check all that apply)* |
| **Name of Product**:       **Manufacturer**:  Investigational Product administered to participants under standard clinical care and for the approved indication  Investigational Productadministered to participants for a new or unapproved indication    Investigational product given to participants in a combination that is not considered standard of care. |

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| ***9. OTHER STUDY PROCEDURES*** | |
| ***A. Use of Radiation*** | |
| Does this research involve use of radioisotopes or radioactive agents (ionizing and non-ionizing) on participants?  No  Yes 🡪 *If yes, please specify type:* | |
| ***B. Gene Therapy*** | |
| Does this research involve gene transfer (including all vectors) to human participants?  N/A  No  Yes🡪*If* ***yes****, please contact the IRB for submission requirements.* | |
| ***C. Biological Materials*** | |
| Does this research include collection or use *(including genetic analysis)* of human material *(i.e. human blood, blood products, tissues, or body fluids)*?  No  Yes🡪*If* ***yes****, Will the material be used for Genetic Analysis. If yes, please also complete Section 10. of this application “Genetic Studies”* | |
| Will the samples be coded?  No  Yes  *Please explain what the coding method is to maintain confidentiality of the samples, if any:* | |
| Will any identifiers be maintained?  No  Yes🡪*If* ***yes****, please explain:* | |
| Do stored samples currently exist from previously approved studies which will be used for the purpose of this project?  No  Yes🡪I*f* ***yes****,* *did participants consent to the use of their stored sample(s)?*  No  Yes | |
| Are existing samples de-identified?  No  Yes | |
| Will samples for this study be collected as part of a routine clinical procedure?  No  Yes | Will samples be collected specifically for this study?   No  Yes |
| Will the samples be discarded?  No  Yes | Will this information be kept confidential from third parties such as employees and/or insurance companies?  No  Yes |
| ***10. GENETIC STUDIES***  ***Note: The informed consent form should include all the following considerations.*** | |
| What is the source of genetic material to be studied (blood, tissue, DNA)? | |
| Is there a possibility of an incidental finding of a genetic condition?  No  Yes\*  \*If ***yes***, is there a plan to disclose this to the individual?  No  Yes  *Please explain*: | |
| Are any of the diseases being studied considered known genetic diseases?  No  Yes🡪*If* ***yes****, please explain:* | |

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| ***REASONABLY ANTICIPATED BENEFITS*** | | |
| 1. List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants. ***Compensation is not to be considered a benefit.*** | | |
| 1. List the potential benefits that society and/or others may expect as a result of this research study. | | |
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| ***RISKS, HARMS, & DISCOMFORTS*** | | |
| 1. Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Consider the range of risks, including physical, psychological, social, legal, and economic. As applicable, discuss severity and likelihood of occurrence. |
| 1. Describe how risks, harms, and/or discomforts will be minimized. | | |
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| ***13. DATA SAFETY AND DATA HANDLING*** | | |
| ***A. Data Safety and Monitoring*** | | |
| Provide a general description of the data and safety monitoring plan which must include, at least, a description of the reporting mechanism of serious/unexpected adverse events to the IRB, the study sponsor(s), principal investigator(s) or FDA (as applicable).    Is there a Data Safety Monitoring Board/Committee to review this study for safety and adherence to the study protocol?  No  Yes🡪If Yes, please specify the DSMB composition and how often they will review the data | | |
| ***B. Data Handling*** | | |
| Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records.    What will happen with the data after completion of the study? | | |

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| ***14. PUBLICATION OR PRESENTATION OF STUDY RESULTS*** |
| Will research data be disseminated? (i.e. journals, dissertations, etc)  Yes  No  If yes, specify: |

| ***15. PRIVACY AND CONFIDENTIALITY*** |
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| a. Describe the provisions to protect the privacy of the participants    b. Does the research require access to personally identifiable private information?  No  Yes\*  *If yes, please describe e.g., educational records, surveys, medical records, etc.*    c. Will medical history/ clinical information be obtained from participant’s health/medical records for the study purpose?  No  Yes\*  *\*If yes, explain the information you intent to access from the Medical Records (to prior approval)*    d. What specific safeguards will be employed to protect confidentiality of data **during the course of the research study**, e.g. coding or removal of identifiers when sending participant related information to sponsor, limitation of access of data, use of locked file cabinets, and protection of computer based data systems etc?  No  Yes\*  *\*If yes, please explain*: |

| ***16.* *PRINCIPAL* *INVESTIGATOR ASSURANCE*** |
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| As the Principal Investigator, by submitting this application:   * I accept full responsibility for the protection of the rights and welfare of the human  participants 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 participants in research * I am responsible for the overall conduct of the study and 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 the requirement to report all serious and unexpected adverse events to the IRB within **10 calendar days** of the occurrence * I understand that any research-related material is subject to an audit by the IRB * I understand that I am required to submit a Continuing Review Application as an annual update if my research extends beyond the final approval period. * If I am a student principal investigator, I am responsible for obtaining review and approval for this research proposal from my faculty advisor. * I have completed the human subject protection training requirement and ensure that all investigators and personnel involved in this research have completed the human subject training requirements * I certify that the information provided in this application is complete and accurate |

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| ***17. PROJECT FACULTY ADVISOR ASSURANCE (if submission is by a Student Principal Investigator)*** |
| **As the Project Faculty Advisor for the above noted student, I have read the attached research project submitted to the LAU IRB and will ensure appropriate supervision of the student’s work.**    **Name of Project Faculty Advisor Signature Date** |