**Please use this application if you are requesting exemption from IRB review as stated in exempt categories listed below. The “Document Submission Checklist” below provides a general guide regarding the required documents to be submitted with this application. For any assistance, please contact the Office of the IRB at** **irb@lau.edu.lb**

**Do not complete this form if the research involves pregnant women, fetuses, prisoners or children as the project does not fit exemption. It is important to note that the IRB makes the final determination of exempt status.**

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| ***1. RESEARCH PROJECT INFORMATION*** |
| Name of Principal Investigator (PI):       |  |
| Research Project / Study Title:       |
| Will data be collected at sites/locations other than LAU or its affiliates [ ]  Yes [ ]  NoIf yes, please provide necessary approvals, as applicable |
|  ***Research Personnel***  |
| *The PI must list the names of the personnel to be involved in the research in below space and include with this application the human subject research protection training “Certificate of Completion” for each personnel listed* |
|       |       |
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|       |       |
|  ***Study Administrator/Coordinator*** *(if different from PI and responsible for IRB submissions)* |
| Name:        | Title:        |
| Phone #:        | Email:        |
| ***Document submission Checklist — Protocol Exempt Application****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 Protocol Exempt Application – Signed by Advisor, if Submission is for a Student Project**[ ]  LAU Medical Center-Rizk Hospital Signature page - For research to be conducted at hospital**[ ]  Other study related material such as research proposal, data collection forms, informed consents, information sheet, questionnaire, survey, interview and/or telephone scripts, etc.**[ ]  Human Subject Research (HSR) 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)*)* |

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| ***2. Type of Research*** *(check only one)* |
| [ ]  **Departmental Research***(not externally sponsored)*[ ]  **Graduate Study Research***(Graduate thesis/dissertation)* |  **[ ]  Undergraduate Research***(Senior thesis/independent study)*[ ]  **Externally Sponsored Research** |

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| ***3. TARGETED POPULATION*** |
| ***A. Number of Participants*** |
| i) Expected number of participants **that will be enrolled** under your supervision:       ii) For collaborative research, **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.***  |
| **Age Range of Participants** 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)*:        |

| ***4. 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*** |
| ***5. RESEARCH METHODS AND ACTIVITIES****Check all research activities that apply.* ***Attach a copy of all materials to be used including oral scripts. Please note that for all prospective data collection, an information sheet or informed consent must be included.*** |
| [ ]  Retrospective Record review | [ ]  Specimen research *(existing at time of application)* |
| [ ]  Existing data, not publicly available[ ]  Existing data, publicly available[ ]  Focus groups[ ]  Interviews[ ]  Observation of participants | [ ]  Taste-testing[ ]  Audio recording[ ]  Video or image recording[ ]  Others, specify:       |
| [ ]  Surveys and questionnaires to be distributed as hard copy and to be completed manually[ ]  Surveys and questionnaires to be sent by email or social media as a link to an electronic platform, please specify:[ ]  LAU BLUE[ ]  Survey Monkey[ ]  Google Form[ ]  Others:       |
| **If the survey will be sent via an electronic platform, please provide the link to the uploaded survey, if available:** |
| **If the survey will be sent via an electronic platform by email or through social media, please include the content of the email or social media post that will accompany the link to the survey:**      |

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| ***6. Access for use - Survey or Questionnaire Tools*** |
| Please check the appropriate box for access to use the specific survey/questionnaire in your project. Documentation should be detailed and referenced in your research proposal or attached as part of this application[ ]  I created the survey / questionnaire[ ]  Survey / Questionnaire is available as Open Access [ ]  Survey / Questionnaire - I have received permission from the author to be able to use the Survey/ Questionnaire [ ]  Survey / Questionnaire - I have paid the author to be able to have access to the Survey / Questionnaire  |

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| ***7. PUBLICATION OR PRESENTATION OF STUDY RESULTS*** |
| Will research data be disseminated? (i.e. journal, dissertations, etc.) [ ]  Yes [ ]  No If yes, specify:       |

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| ***8. PROJECT SUMMARY (please complete all sections)*** |
| *Purpose of the study (briefly state the purpose of the study along with the objectives):*       |
| *Recruitment of Participants (describe who the targeted participants are):*       |
| *Describe how you will approach participants (face-to-face, email, flyer, links, etc.):*       |
| *Describe the tools that will be used, their validation and source; and specify the plan for data collection and recording.*       |
| *Describe the methods to be followed for the protection of participant information such as privacy, confidentiality and anonymity:*       |
| *Describe any foreseeable risks to subjects presented by the proposed study and the precautions you will take to minimize such risks:*       |

| ***9. EXEMPTION CATEGORIES*** *(Please select the category that exempts this study from continuing IRB review as per 45CFR 56.101b)* |
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| **[ ]  A. Research conducted in established or commonly accepted educational settings involving normal educational practices such as:**  (i) research on regular and special instructional strategies, or  (ii) research on the effectiveness of or the comparison between instructional techniques, curricula or classroom management methods. |
| **[ ]  B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement),  survey procedures, interview procedures or observation of public behavior, unless:** (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and(ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.***NOTE:*** *Survey or interview procedures or observations of public behavior involving children cannot be exempted, with the exception of observations of public behavior when the investigator(s) do not participate in the activities being observed.* |
| **[ ]  C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement),  survey procedures, interview procedures, or observation of public behavior that is not exempt  under part B. of this section, if:** (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter. |
| **[ ]  D. Research involving the collection or study of existing data, documents, records, pathological or  diagnostic specimens, if these sources are publicly available or if the information is recorded by the  investigator in such a manner that subjects cannot be identified, directly or through identifiers  linked to the subjects.** |
| **[ ]  E. Research and demonstration projects which are conducted by or subject to the approval of  Department or Agency heads, and which are designed to study, evaluate, or otherwise  examine:** (i) public benefit/service programs; (ii) procedures for obtaining benefits/services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in payment methods and/or levels of those programs. |
| **[ ]  F. Taste and food quality evaluation and consumer acceptance studies,** (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the U.S. Food and Drug Administration or approved by the federal health authority/food inspection agency. |

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| ***10.* *PRINCIPAL* *INVESTIGATOR ASSURANCE*** |
| As a Principal Investigator/ Student Principal Investigator, by submitting 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 accept responsibility for adhering to the project stated in this application, in the case of any changes that will impact the exemption status, I understand that I must re-submitted to the IRB for review
* I understand that any research-related material is subject to an audit by the IRB
* I certify that the proposed research is not currently being conducted and will not begin until IRB response / approval has been obtained
* 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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| ***11. PROJECT FACULTY ADVISOR ASSURANCE (if submission is by a Student Principal Investigator)*** |
| As the Project Faculty Advisor where the above research will be conducted, I have read the attached protocol submitted to the IRB and will ensure appropriate education and supervision of the student investigator.  **Name of Project Faculty Advisor Signature Date** |