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APPLICATION FOR EXEMPTION/

LIMITED REVIEW

**INSTRUCTIONS**

This form can be used to apply for Exemption/Limited Review. It is not for applying for Full Committee Review or Expedited Review.

Please complete this form. The completed Application for **Exemption/Limited Review** may be submitted electronically.

Research activity should fit at least one of the following categories 1-6; please tick the applicable category (to know more about exempt research categories, see APPENDIX I)

|  |  |
| --- | --- |
| Category 1 |  |
| Category 2 |  |
| Category 3 |  |
| Category 4 |  |
| Category 5 |  |
| Category 6 |  |
| Category 7 | AUB IRB does not plan to implement this category at this time. |
| Category 8 | AUB IRB does not plan to implement this category at this time. |

**How to complete your application and begin the IRB review process:**

This form must not be handwritten.

1. Fill out **all the sections** on this form completely.
2. Fill out and attach the appropriate documents as required by this application.
3. Studies that involve pregnant women, fetuses, and neonates are not eligible for exemption under all categories.
4. Exemption DOES NOT APPLY to **research involving prisoners.**
5. **Studies involving children** are allowed in categories 1, 4, 5, 6, 7 & 8 only. **Limited review:** It is a process that is required only for certain exemptions, including categories 2 (iii), 3 (C), 7 and 8. In limited IRB review, the IRB must determine that certain conditions that are specified in the regulations, are met. Continuing IRB review should be submitted for Limited Review studies. Limited IRB review is done by the chair/co-chair or an experienced IRB member designated by the chair (although it can also be conducted by the full IRB).
6. Continuing review is not required for Exemption Review.
7. AUB IRB does not plan to implement exemption categories 7 & 8 at this time. Few exceptions may be considered.
8. Research on sensitive or personal topics which may cause stress to participants are **not** exempt from review.

**CONTENTS OF APPLICATION FORM**

|  |
| --- |
| [1. PROJECT IDENTIFICATION 4](#_Toc146108184)  [2. COLLABORATORS 5](#_Toc146108185)  [3. FUNDING 6](#_Toc146108186)  [4. PROPOSAL 6](#_Toc146108187)  [Appendix I 9](#_Toc146108188)  [Appendix II 12](#_Toc146108189) |

**DATE OF SUBMISSION TO INSTITUTIONAL REVIEW BOARD:**

**EXPECTED STARTING DATE OF STUDY:**

# PROJECT IDENTIFICATION

* 1. **Project Title**

(Project title on application must match title added to **all** corresponding documents):

Click or tap here to enter text.

* 1. **Is This a student project?**

Yes No

|  |  |  |
| --- | --- | --- |
| 1.3 Principal Investigator: | | |
| **Name:** | **Department:** | |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:**  ☐ Yes ☐ No ☐ Pending | **Course module:** | **Expiry date:** |

|  |  |  |
| --- | --- | --- |
| 1.4 Co-investigator/Staff/Student: (Copy and paste table if necessary) | | |
| **Name:** | **Department:** | |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:**  ☐ Yes ☐ No ☐ Pending | **Course module:** | **Expiry Date:** |
| **Position:** | Professor Associate Professor Assistant Professor Instructor Research Assistant Research fellow Student Other  If other, please indicate the position:  Click or tap here to enter text. | |
| **Role in study:** | Recruitment Consenting Blood withdrawal  Data collection Study Coordinator Other  If other, please indicate the role:  Click or tap here to enter text. | |

|  |  |  |
| --- | --- | --- |
| 1.5 Collaborators: Collaborators and IRB involvement at other institutions outside AUB (Copy and paste table if necessary) | | |
| **Name:** | **Department or Affiliation:** | |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:**  ☐ Yes ☐ No ☐ Pending | **Course module:** | **Expiry date:** |
| **Role in study:** | Recruitment Consenting  Data collection Other  If other, please indicate the role:  Click or tap here to enter text. | |

# COLLABORATORS

* 1. **Will you send participants’/subjects’ research data information to any of the collaborator(s)?**

Yes  No  Not Applicable

* *If yes, submit a Non-Disclosure Agreement (NDA) signed by AUB and each collaborating individual or institution with whom or with which data will be shared. (Please contact Office of Grants and Contracts (OGC) for setting the agreement.)*
* *Submit copies of IRB approvals from all collaborating institutions, if available. If not, please specify the timeline for obtaining and submitting this information.*

Click or tap here to enter text.

# FUNDING

* 1. **Is this research funded?**

Yes, please fill the below table and copy the same table for more than one source of funding if applicable.

|  |  |
| --- | --- |
| Source of funding/Sponsor name |  |
| Status | Funded Pending |
| Proposed annual budget |  |
| Role of funding agency |  |
| Federal money (for example: NIH) | Yes No |

No, explain how costs of research will be covered, if any: Click or tap here to enter text.

# PROPOSAL

Please complete the below fields. (You do not need to submit a separate proposal.)

* 1. **State your research question/hypothesis.**

Click or tap here to enter text.

* 1. **Provide a brief overview of the research activities.**

Click or tap here to enter text.

* 1. **Specify the research method/procedure that will be applied as part of this study (provide the sample size).** Click or tap here to enter text.

*If the study ONLY involves secondary use of data/biospecimens, then there is no need to fill the rest of the application. Submit a complete form of the “Request to create a de-identified dataset from research data, clinical data or other identified data source”* <https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx> *. Otherwise, please continue.*

* 1. **Recruitment of research participants**

Provide a thorough description of the recruitment strategy, participants’ identification, and invitation to the research. Click or tap here to enter text.

* 1. **Consenting research participants**

*Informed consent process should be described even if it will be an oral consent (a script of the consent information is required for review upon submission of the proposal). You can use verbal scripts, online scripts, emails, etc.* [*https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx*](https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx)

*The script should explain that participation in the study is completely voluntary and that the subject has the right to discontinue his/her participation, skip certain sensitive questions, etc.*

Click or tap here to enter text.

* 1. **Indicate the time involvement for participants in the research (for each research activity if applicable).**

Click or tap here to enter text.

* 1. **Provide form(s) of compensation, if any.**

Click or tap here to enter text.

* 1. **Describe how and when compensation is provided to participants, if any.**

Click or tap here to enter text.

* 1. **Describe all potential research risk or discomfort to participants resulting from study procedures.**

Click or tap here to enter text.

* 1. **Describe any potential direct benefits of the research to participants.**

Click or tap here to enter text.

* 1. **Describe how privacy will be protected and confidentiality maintained.**

*[Exempt studies may have identifiers but be sure to explain how participants will be informed about protection of privacy, confidentiality, etc.]*

Click or tap here to enter text.

* 1. **Outline the procedure for data analysis and disposal of data collected (including audio or video recordings) at the end of the study.**

Click or tap here to enter text.

* 1. **Describe the strategy for report preparation and specify objectives for the dissemination of findings.**

Click or tap here to enter text.

**NB. PLEASE NOTE THE FOLLOWING IMPORTANT INFORMATION**

The determination that a research study meets the requirements for exempt status is based solely on the written information provided in the application. Any amendment to a research project that the IRB has determined to be exempt (recruitment of participants, changes in the consent process, amendments to or addition to research instruments, etc.) may cause the research to become non-exempt and subject to IRB review and oversight. Any proposed modification to an Exempt study must be re-submitted to the IRB office for review. Depending on the extent of the change, an Expedited or Full Committee review may be required. The responsible principal investigator should be aware of these requirements. Please note, a research study that has been determined by the IRB to be exempt does not require continuing reviews or a final study report.

|  |  |
| --- | --- |
| I certify that the above information is correct | |
| Printed Name of Principal Investigator:  Date:Click or tap to enter a date.  Signature: |  |

|  |
| --- |
| As Chairperson of the Department / Dean of the Faculty or Representative, I acknowledge that this research is in keeping with the standards of my department and I assure that the principal investigator has met all departmental requirements for review and approval of this research.  Printed name of Chairperson of Department / Dean of the Faculty or Representative  Date: Click or tap to enter a date.  Signature: |

# Appendix I

**Exempt and Limited Review** §46.104

|  |  |
| --- | --- |
| **Check the box corresponding to the eligibility for exemption category which best describes the proposed research: 󠆶** | |
| **Exemption 1**  §46.104(d) | Research, conducted in established or commonly accepted [educational setting](#_Educational_Setting:_The), that specifically involves [normal educational practices](#_Normal_Educational_Practices:) that are not likely to [adversely impact students’ opportunity to learn](#_Adversely_Impact_Students’) required educational content or the [assessment of educators](#_Adversely_Impact_Assessment) who provide instruction.  **This research includes but is not limited to:**   1. Research on regular and special education instructional strategies. 2. Research on the effectiveness of, or the comparison of, instructional techniques, curricula, or classroom management methods. |
| **Exemption 2**  §46.104(d)(2) | Research that **only includes interactions** involving educational tests (cognitive, diagnostic, aptitude, achievement), OR survey procedures, OR interview procedures, OR [observation of public behavior](#_Observation_of_Public) **(including visual or auditory recording),** OR focus groups if at least one of the following criteria is met:   1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects. 2. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, [educational advancement](#_Educational_Advancement:_Examples), or reputation. 3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, andan IRB conducts a limited review to make the determination required by §46.111(a)(7) which relates to there being adequate provisions for protecting privacy and maintaining confidentiality. |
| **Exemption 3**  §46.104(d)(3)(i) | Research involving [benign behavioral interventions (BBI)](#_The_term_benign) through [verbal or written responses](#_Verbal_or_Written) (including data entry) or audiovisual recording if the adult subject prospectively agrees to the intervention and information collection and at least one of the following below criteria is met:   1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects. 2. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation. 3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to make the determination required by §46.111(a)(7), which relates to there being adequate provisions for protecting privacy and maintaining confidentiality. |
| **Exemption 4**  §46.104(d)(4) | Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:   1. The identifiable private information or identifiable biospecimens are publicly available. 2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects (Fill forms “**Request to create a de-identified dataset from research data, clinical data, or other identified data source**”. 3. Research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes as those terms are defined in HIPAA. **(DOES NOT APPLY OUTSIDE THE UNITED STATES.)** 4. The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information, it is subject to specified privacy laws. |
| **Exemption 5**  §46.104(d)(5) | Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.  SUCH PROJECTS INCLUDE, BUT ARE NOT LIMITED TO:   * Internal studies by federal employees, * Studies under contracts or consulting arrangements, * Cooperative agreements or grants.   **Important note:** Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal website, or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. |
| **Exemption 6**  §46.104(d)(6) | Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture. |
| **Exemption 7**  §46.104(d)(7)  Limited review | Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use for which broad consent is required. **AUB IRB does not plan to implement this exemption category at this time. Limited exceptions may be considered.** |
| **Exemption8**  §46.104(d)(8)  Limited review | Secondary research involving the use of identifiable private information or identifiable biospecimens for potential secondary research use for which broad consent is required.  **AUB IRB does not plan to implement this exemption category at this time. Limited exceptions may be considered.** |

# Appendix II

**Descriptions**

**EXEMPTION CATEGORY 1**

## Educational Setting: The consistent interpretation of this term is that commonly accepted educational settings can be almost anywhere, as long as the setting is one where specific educational offering normally take place or a setting where one would go in order to have an educational experience. Examples include K-12 schools and college classrooms, after-school programs, preschools, vocational schools, an alternative education programs; professional development seminar for school district personnel; soccer practice field; Boy/Girl Scouts meeting; Medical school; Religious education settings; Training simulators (e.g., medical simulators, flight simulators, etc.).

## Normal Educational Practices: Normal educational practices are those activities that are routinely used in similar educational settings and/or are considered proven educational practices with the population under study.

## Adversely Impact Students’ Opportunity to Learn: Consider whether the proposed activity requires students to deviate from a curriculum that is aligned with any national or state-level indicators of student achievement (eg., state end of grade testing) or if the activity will take instructional time away from students.

## Adversely Impact Assessment of Educators: Will participation, or the refusal to participate in the research be a factor in the assessment of educators? Will the outcomes of the research be a factor in the assessment of participating instructors?

**EXEMPTION CATEGORY 2**

## Educational Advancement: Examples of damaging the educational advancement would be information learned in the study that would disqualify an individual from advancement.  For example, in a survey that collects data about academic integrity where respondents indicate whether they have engaged in misconduct (eg., cheating on exams, plagiarism, etc.), the disclosure of the subjects’ responses outside the research could be damaging to the subjects’ educational advancement.

## Observation of Public Behavior: Observation of public behavior without intervention or interaction can be human subjects research when it satisfies the definitions of human subject and research. Within the framework of this exemption, it is possible that an investigator may be observing individuals in a setting where, while public, there is an expectation of privacy (eg., public restroom and online groups).  It is also possible under the exemption that an investigator engaged in public observation would capture information that would allow for the identification of observed individuals, provided that an IRB conducts a limited IRB review to make the determination required.

**EXEMPTION CATEGORY 3**

## Benign Behavioral Intervention: The term is used in the language of the regulations to define research procedures that are employed in the study of psychological states and processes, cognition, ideas and attitudes, or behavior, and do not include physical (bodily) tasks or physical manipulations (eg., range of motion activities and physical exercise), unless these are minor activities that are incident to the behavioral intervention and do not increase risk. For example, manipulating a keyboard, doing a puzzle, or walking while listening to music would be physical activities that could be considered minor activities that are taking place incident to the benign behavioral intervention. Physical interventions that are physically invasive, or those that could be harmful or painful would not meet the exemption. Alterations in the subject’s physical or sensory environment may be considered behavioral interventions to this exemption.  Such interventions may not be harmful, painful, or distressing, such as exposure to extremes of heat, cold, noise or light. In addition, the benign intervention is not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive.  Ordinary, mild, transient forms of discomfort, such as the stress associated with completing a timed cognitive task, anxiety about performance, and boredom, are consistent with the intent of the exemption.  Similarly, while research cannot meaningfully eliminate all risk of embarrassment or offense, the research should include only interventions that the researcher has no reason to think subjects will find offensive or embarrassing considering the characteristics of the subject population, the research context, and how they might impact the subject’s experience of the research intervention.

## Verbal or Written Responses (including data entry): This category defines a narrow set of the allowable means by which data can be collected.  Even very low risk physical procedures such as the application of sensors to the body (eg., blood pressure monitoring, electroencephalogram, and wearable activity trackers), minimally invasive procedures (eg., blood drawing), and the collection of bodily fluids via introduction of a tool or sensor into the body (eg., buccal swab) would not be consistent with the language of this exemption. Data entry by a device (eg., a Fitbit) would not meet this exemption.

**REFERENCES**

Exempt categories for research involving human subjects are defined in the US Code of Federal Regulations for the Protection of Human Subjects (45CFR46)

* <https://www.hhs.gov/ohrp/regulations-and-policy>
* <https://www.ecfr.gov/cgi-bin/text-idx?SID=300df04ebff09c7b23735d902a3f645a&mc=true&tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl>
* <https://www.hhs.gov/ohrp/sachrp-committee/index.html>

