# To: Faculty Committee for the Evaluation of Studies on Human Subjects

**Application for Approval of Study**

**Title of research proposal:** Press or type here to enter text

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** Press or type here to enter text**:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**By (name of advisor / chief investigator / investigator in charge):**

בחר פריט.Press or type here to enter text

Select item
Dr.
Prof.

בחר פריט.Press or type here to enter text

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Mobile phone number:** Press or type here to enter text

**Email address:** Press or type here to enter text

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Department / school (of Investigator A):** Press or type here to enter text \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Department / school (of Investigator B):** Press or type here to enter text

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name of additional investigator / student:** Press or type here to enter text

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Mobile phone number:** Press or type here to enter text

**Email address:** Press or type here to enter text

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **General**

**Please check one of the following if applicable:**

** Approval of exemption from Ethics Committee proceeding**

 **Reason for request:** Press or type here to enter text

** Expedited review proceeding**

 **Reason for request:** Press or type here to enter text

** Exemption from having participants sign a consent form for their participation in the study**

 **Reason for request:** Press or type here to enter text

**2. Concise general description of the study (up to 200 words)**

 Press or type here to enter text

**3. General evaluation of risk in the study**

** To the best of my knowledge, the proposed study poses no risk of harm to participant/s or their surroundings.**

** It is my opinion that the extent of risk to people in the proposed study is less than the minimal risk and the requisite measures to mitigate said risk have been taken.**

* **“Minimal risk:” The severity and/or probability of risk of harm or discomfort expected in the study do not exceed those to which a reasonable person is exposed in his/her daily conduct or in the course of taking routine psychological or physical exams or checkups.**

** It is my opinion that the level of risk to people in the proposed study exceeds the minimal risk, and the requisite measures have been taken to protect the participant/s to the greatest extent possible.**

**4. Research Participants**

**4.1 Number of participants:** Press or type here to enter text

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | **Yes** | **No** | **Comments / details** |
| **4.2** | **Age range**: | Minors (under age 18)—a parental consent form and, if the minor is an adolescent, his/her consent is needed |  |  |  |
| **4.3** | **Type of population** | Pupils / their parents, recruited by means of the educational system |  |  |  |
|  |  | Students at the University of Haifa and/or members of their families |  |  |  |
|  |  | Adult population without weaknesses |  |  |  |
|  |  | Sensitive population groups (e.g., wards, prisoners, individuals with cognitive disorders; mental illness, etc.) |  |  |  |

**4.4 Process used to recruit research participants (explain in detail, including how they are located, screened, by whom contacted, in what manner, etc.)**

 Press or type here to enter text

**5. The study includes one or more of the following research methods. If answering in the affirmative, please provide a detailed explanation in the study abstract.**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Yes** | **No** |
| **1.** | **Questionnaire (participants identified to investigator)** |  |  |
| **2.** | **Anonymous survey (participants not identified to investigator)** |  |  |
| **3.** | **Interview** |  |  |
| **4.** | **Observation** |  |  |
| **5.** | **Video or camera recording, etc. (if “yes” please specify below how it will be saved)** |  |  |
| **6.** | **Audio recording (if “yes,” please specify below how it will be saved)** |  |  |
| **7.** | **Use of existing documents or data (including information from medical records, databases, etc.)** |  |  |
| **8.** | **Structured tests (e.g., behavioral test / behavioral task)** |  |  |
| **9.** | **Experimental set-up (experimental manipulation)** |  |  |

**5.1 If the study includes the use of transcribed audio and/or video and/or interviews, explain in detail whether and how the materials will be saved, when they will be deleted, whether they will be returned to the participants, and how anonymity/confidentiality will be preserved:**

 Press or type here to enter text

**6. The study includes one or more of the following elements (please provide details in the right-hand column):**

|  |  | **Yes** | **No** | **Comments** |
| --- | --- | --- | --- | --- |
| **1.** | **Misleading or inadequate explanation** |  |  |  |
| **2.** | **Collection of sensitive information** |  |  |  |
| **3.** | **Exposure to stimuli that may be experienced as threatening, insulting, triggering anxiety, triggering traumatic memories, etc.** |  |  |  |
| **4.** | **Exposure to physical stimuli (e.g., high levels of noise or visual stimuli that exceed routine daily levels of irritation or pain)** |  |  |  |
| **5.** | **Collection of biological and/or physiological indicators (e.g., blood, saliva, pulse, blood pressure, other physiological indicators)** |  |  |  |
| **6.** | **Use of pharmaceuticals (describe the pharmaceuticals and the measures taken to maintain participants’ safety)** |  |  |  |
| **7.** | **Physical effort exceeding accepted daily levels (describe the task and the measures taken to protect participants)** |  |  |  |
| **8.** | **Social, legal, or economic risk to participants (e.g., creation of stigma, risk to status, risk to employment, or criminalization of participants)** |  |  |  |
| **9.** | **Appeal to participants by means of person of authority (teacher, caregiver, employer)** |  |  |  |
| **10.** | **Monetary recompense, scoring, or other means of encouraging participants (describe in the Comments)** |  |  |  |

**6.1 If you answered “yes” to any of the above, please detail here in what way/s the study will deal with the ethical complexity or the potential damage of the cited element:**

 Press or type here to enter text

**6.2 If you answered “yes” to any of the above, please elaborate on the relevant investigators’ training and background for dealing with the ethical complexity of the cited element.**

 Press or type here to enter text

**7. Inclusive explanatory letter to potential participants (if “no”—explain why in the Comments section)**

|  |  | **Yes** | **No** | **Comments** |
| --- | --- | --- | --- | --- |
| **1.** | **Description, title, and purpose of the study. Please note if the study is part of a seminar, a thesis, or a dissertation.** |  |  |  |
| **2.** | **Benefit/s of the study** |  |  |  |
| **3.** | **Opportunities and/or risks to the participant** |  |  |  |
| **4.** | **Tasks assigned to the participant/s** |  |  |  |
| **5.** | **Affirmation of voluntary participation and participants’ right to withdraw from the study at any time without adverse consequences** |  |  |  |
| **6.** | **Assurance of confidentiality, anonymity, and privacy (including how the data are retained and destroyed in cases of research on identified persons)** |  |  |  |
| **7.** | **Expected duration of participation in the study** |  |  |  |
| **8.** | **Source of funding of the study (if there is a source outside the university)** |  |  |  |
| **9.** | **Name of investigator and telephone number or other contact information. If the study is part of a thesis or dissertation, advisors’ names should be noted as well.** |  |  |  |
| **10.** | **Voluntary participation consent form** |  |  |  |
| **11.** | **Verification of signature in presence of investigator**  |  |  |  |

**8. Safeguarding of confidentiality of information collected**

|  |  | **Yes** | **No** | **Comments** |
| --- | --- | --- | --- | --- |
| **1.** | **Will the voluntary participation consent form be kept separate from the participants’ results?** |  |  |  |
| **2.** | **Will the participants’ identities be disclosed?** |  |  |  |
| **3.** | **Identifying details will be available to the research team only.** |  |  |  |

**8.1 Please describe the measures that will be taken to protect the participants’ identities and secure the data obtained / collected:**

 Press or type here to enter text

**I hereby affirm that the foregoing information is correct and accurate, that the research proposal complies with international and the university’s standards for the ethical conduct of research, and that the study will be carried out in accordance with said standards.**

**I am aware that the responsibilities of the chief investigator include reviewing the rules of ethics and the conduct of the different bodies operating in the study (e.g., students employed in the study, research assistants, information-gathering companies, various professional entities, and so on). The review of and compliance with the ethics of these bodies is not examined directly by the Ethics Committee.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Chief investigator’s name |  | Investigator’s name |  | Investigator’s name |
| Date |  | Date |  | Date |
| Signature |  | Signature |  | Signature |

\* **This application should not be submitted without the signature of the chief investigator, who has confirmed that it satisfies the academic requirements and is fit for submission.**