Instructions:

The Faculty of Health Sciences' Human Subjects Research Committee accepts proposals for research that is **not** currently supported by external funding.

Given the research plans often include a series of similar experiments, there is no need to request separate approval from the ethics committee for each experiment, but rather for the entire research project.

The following forms and documents should be submitted:

1. This application form, filled out in its entirety
2. The research protocol:
	1. A full description of the project stages that pertain to the experimental method and all interaction with the human subjects.
	2. If the project contains a series of experiments, describe the variations;
	3. also include description of type and number of subjects and subject recruitment method.
	4. If this type of protocol is one commonly used and/or if a similar protocol and methods have been used and published in the literature, please add references indicating so.
	5. Please do not submit the complete project proposal that was submitted to the funding agency.
3. Copies of questionnaires and/or a description of interview questions (Appendix).
4. The informed consent form that the subjects will be asked to sign.
5. Instructions and/or explanations that subjects will receive before, during, or after the experiment.

**Ⅰ. General**

**Name of research project:**

**To which agency is the proposal being submitted (or has been submitted):**

**Principal investigator/s (or academic supervisor/s):**

|  |  |
| --- | --- |
| **Name:**  **Department:**  **Academic position:**  **University telephone:**  **Mobile phone:**  **University E-mail:**  **Other E-mail:**   | **Name:**  **Department:**  **Academic position:**  **University telephone:**  **Mobile phone:**  **University E-mail:**  **Other E-mail:**   |

**Name(s) of those conducting the research (if different from above):**

|  |  |
| --- | --- |
| **Name:**  **Department:**  **Academic position:**  **University telephone:**  **Mobile phone:**  **E-mail:**   | **Name:**  **Department:**  **Academic position:**  **University telephone:**  **Mobile phone:**  **E-mail:**   |

**Ⅱ. Consent to Participate**

1. Are the subjects able to legally consent to participate in the research? [ ] Yes /[ ]  No

If you answered ‘No’ to question 1, complete section Ⅱb

1. Will the subject be asked to sign a consent form? [ ] Yes /[ ]  No

If you answered ‘No’ to question 2, explain here:

**Ⅱb: Subjects who cannot legally consent (minors, mentally incapacitated, etc.):**

1. Will the subject’s legal guardian be asked to sign a consent form? [ ] Yes /[ ]  No

If you answered ‘No’ to question 3, please explain here:

1. Will the subject be asked to give oral consent? [ ] Yes /[ ]  No
2. Are the instructions appropriate to the subjects’ level of understanding? [ ] Yes /[ ]  No

Comments:

1. If informed consent forms will be signed, how will the informed consent forms be stored
 to ensure confidentiality?

**Ⅲ. Discomfort:**

1. Will the participant be subjected to physical discomfort? [ ] Yes /[ ]  No
2. Will the participant be subjected to psychological discomfort? [ ] Yes /[ ]  No

If you answered ‘Yes’ to question 7 or 8, add here a detailed explanation of the
circumstances:

**Ⅳ. Deception:**

1. Does the research involve deceiving the subjects? [ ] Yes /[ ]  No
2. Is the decision on the part of the subject to participate in the study based on deception?
(For example, if they are informed of their participation only after the event) [ ] Yes /[ ]  No

If you answered ‘Yes’ to question 9 or 10, add here a detailed explanation why deception
is necessary:

**Ⅴ. Feedback to the subject**

Note: Although feedback to the subject is recommended for *all* studies, it is required for studies
that involve discomfort or deception. Feedback entails providing the subject, upon completion
of experiment, explanation of the experiment and its aims.

1. Will the subjects be provided with post-experiment oral feedback? [ ] Yes /[ ]  No
2. Will the subjects be provided with post-experiment written feedback? [ ] Yes /[ ]  No If you answered ‘No’ to both questions 11 and 12, explain here:

**Ⅵ. Compensation for Participation**

1. Will the subjects receive compensation for their participation? [ ] Yes /[ ]  No

Detail here the type and amount of compensation:

If you answered ‘No’ to question 13, explain the basis for participation:

**Ⅶ. Privacy:**

1. Will audio and/or visual recordings be made of the subjects? [ ] Yes /[ ]  No
	1. If yes, are they informed of this fact in the informed consent form? [ ] Yes /[ ]  No
2. Will the data collected (apart from the informed consent form) contain identifying details about
the subjects? [ ] Yes /[ ]  No
	1. If the data contains identifying details, please answer here: (1) What steps will you take to ensure the confidentiality of the information? (2) How will the data be stored? (3) What will be done with identifying information or recordings of the subjects at the end of the research?

**Ⅷ. Withdrawal from the Study:**

1. Will subjects be informed that they may withdrew from the study at any time? [ ] Yes /[ ]  No
2. Will the subjects’ compensation for participation be affected if they withdraw from the study
before its completion? [ ] Yes /[ ]  No

a. If yes, are they informed of this fact in the informed consent form? [ ] Yes /[ ]  No

**Ⅸ. Research Equipment:**

1. Does the research entail the use of equipment other than standard equipment, such as computers, video recording equipment? [ ] Yes /[ ]  No
2. If yes, does the equipment being used meet safety standard for use with human subjects? [ ] Yes /[ ]  No

Please specify which standards (include documentation where appropriate):

Signatories:

**Name:**   **Position:**   **Name:**   **Position:**

**Signature:**  **Date:**   **Signature:**  **Date:**

This section is to be filled out by a member of the Human Subjects Research Committee only

**Decision of the Committee:**

Note: The decision of this committee pertains only to ethical considerations involved in the conduct of the research.

Application Number:

Title of Research Project:

Principal Investigator/s:

Approval for research: [ ] Granted / [ ] Denied

Comments to the researcher in the event that application has been denied:

Signature of committee:

**Name:**

**Signature:**  **Date:**