GUIDE

For IIMB IRB Ethics Application and Related Documents March 12, 2019

[Updated on January 30, 2023]

Ethics Application Form

(Downloadable from Venus)

- 1. To start a new application for a research study, please download this ethics application form from Venus and fill in your responses and email to irb@iimb.ac.in with the related documents (See appendices in the ethics application form). Clear instructions have been provided in the form itself.
- 2. All questions with an asterisk* are compulsory. Incomplete applications will be returned, and it will delay the review process.
- 3. <u>Level of review</u>: You have to select one of the following options- excused, expedited, or full. Excused level should be selected if your interaction is benign and/or quite similar to everyday life events. Expedited level should be selected if the interactions are not necessarily benign and may induce discomfort physically or psychologically. Full review should be selected if the potential participants are going to be exposed to more than a minimal risk and these risks cannot be reduced through risk-minimizing procedures.
- 4. For all questions with multiple options in this form, it has been clearly stated whether you need to pick one option or more.
- 5. Guidelines for determining risk are provided in the application form on page 4. Please read carefully before filling in your response.
- 6. You can add your scanned signature under Principal Investigator's assurance on page 6.
- 7. Please make sure you have attached files with all the research study material, including study stimuli, video, or audio recordings (if applicable).
- 8. Submission of the research proposal is strongly recommended for applicants along with the ethics application.

Research Status and Amendment Forms

(Downloadable from Venus)

- 1. These forms are not for first-time applicants. They are for applicants whose ethics application has been approved at least once by the IRB Committee.
- 2. Please download these forms from Venus and fill in your responses and email to irb@iimb.ac.in with the related documents mentioned in the forms.
- 3. **Research Status Form**: This form is needed post approval of your ethics application by the IRB Committee. The IRB committee will approve your research study for a certain period of time during which you can engage in data collection. After the expiration date of this time period, you should fill out this form. You will have three options in this form:
 - a. Ongoing study/Extension request (Section A): If you need more time for data collection beyond the time approved by the IRB Committee, you should fill out this section.

- b. Completed study (Section B): If you have finished data collection successfully, you should fill out this section.
- c. Terminated study (Section C): If you decide to end the study without completing data collection for some unforeseen reason/s, you should fill out this section.
- 4. **Amendment Form**: This form is needed post approval of your ethics application by the IRB Committee if you want to make any minor or major change in your research study. Examples of major and minor amendments are provided in the form itself. The IRB Committee has the discretion to decide whether or not a proposed amendment is major or substantial and requires ethical review.

If you have any questions, please write to <u>irb@iimb.ac.in</u>.