

Ethics Review Committee on Experimental Research with Human Subjects

In order to ensure the proper consideration of ethical issues concerning people who directly participate in research projects (hereafter, the participants) such as ensuring their safety, respecting their human rights, and protecting their personal information, the University of Tokyo's Graduate School of Arts and Sciences and the College of Arts and Sciences (hereafter, the Graduate School) has established the Ethics Review Committee for Experimental Research with Human Subjects (hereafter, the Ethics Committee). Researchers affiliated with the Graduate School, if undertaking applicable research, are strongly recommended to submit their research for an ethics review during the planning stages. Recently, academic journals across the disciplines require, at minimum, that research papers submitted for publication include proof that the research was approved by an ethics review committee. Therefore, for all practical purposes, approval of the Ethics Committee has become a requirement.

Researchers who would like an ethics review may, by gathering the required application materials and following the procedures explained below, receive a review. As an ethics review can take up to 2 months, it is advised that the researchers start preparing the application well in advance.

Ethics Review Applicability

Ethics review is applicable to all research conducted in the Graduate School that undertakes experiments or investigations on human beings. It is preferable to undergo ethics review during the planning stages, but research that is already underway can also be reviewed.

Procedure

When you submit an application to the Ethics Review Committee, you must gather each of the following materials and submit them to the administrative division's research support office.

- (1) Application for ethics review (issued by the research support office): One set
- (2) Documents applicable to ethics review (Research proposal, or manuscript to be published): Seven sets (If the research proposal or manuscript to be published is written in a language other than Japanese or English, attach an explanatory text in Japanese or in English to the parts that require ethics review.)
- (3) Sample explanation of the experimental research and consent form for participants: Seven sets (only for cases where a research proposal is to be reviewed)

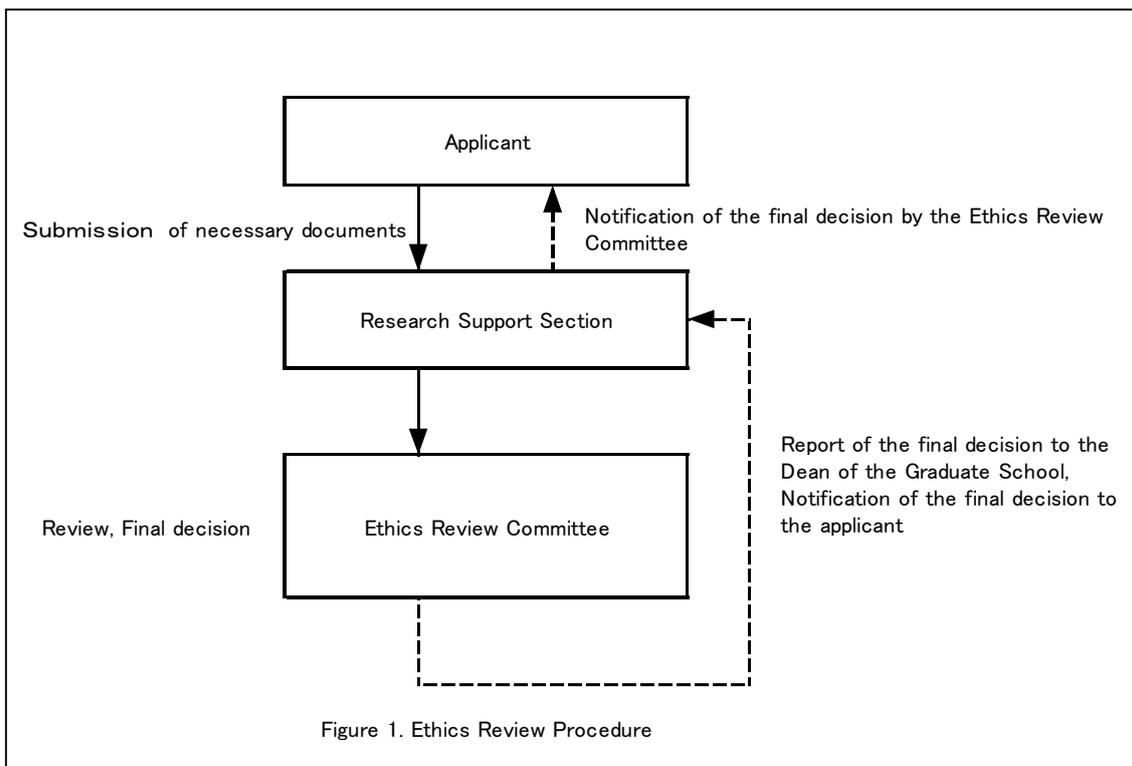
On portrait-oriented A4 paper with horizontal text, include the following information:

1. Title of the research
2. Name(s) of the actual researcher(s) as well as name(s) of the person(s) in charge of the research. (If the actual researchers are students, give the name of the academic advisor.)

3. The research period and the actual location where the research will take place
4. Content of the research
 - (1) Research goals and expected results
 - (2) Outline of the research
5. Research methods (equipment, chemicals, instruments, procedures, participants' tasks, detailed description of what participants will do in the experiment etc.)
6. Participants (detailed description of participants including their number)
7. Provisions to protect participants' human rights and personal information
8. Methods of acquiring research participation consent forms from respondents
9. Measures to ensure participants' safety
10. Remarks (1) funding or equipment received from private companies (2) any payment or other compensation provided to participants (3) other

Notifications from the Ethics Committee

Applicants will be informed of the results of the ethics review by letter from the committee chair. A report will be made to the dean of the Graduate School at the same time. If an applicant objects to the notified result as decided by the committee, he or she may file a notice of objection to the committee or apply again.



Proof of Ethics Review

Academic journals and other entities may require proof or certification of ethics review. In cases where the Ethics Committee granted approval based on a research proposal, the committee will issue this certification after evaluating and confirming that the actual research conducted, as described in the research paper, is identical to that described in the proposal. Also, for researchers who desire proof of ethics review who conducted their research before the committee was established, or who, for whatever reason, conducted research before receiving ethics approval from the Ethics Committee, the committee will conduct a standard ethics review based on a new research proposal submitted at the time an application to the committee is made.

Ethics Review Methods and Key Points for Review

The following summarizes the structure of the Ethics Committee and the key points in the conduct of ethics reviews.

Structure of the Ethics Committee

The committee is composed of six members, including the committee chair. The committee members includes the following: one faculty member each from these groups in the Department of Multi-Disciplinary Life Sciences: (1) Science of Human Movement and Fitness, (2) Cognitive and Behavioral Sciences, and (3) Basic Biological Sciences; one faculty member from the Department of Multi-Disciplinary Sciences-General Systems Studies; one faculty member from the Department of Multi-Disciplinary Sciences-Basic Science; and one faculty member from any one of the Departments of Language and Information Sciences, Interdisciplinary Cultural Studies, Area Studies, or Advanced Social and International Studies. In addition, if a committee member deems it to be particularly necessary, additional committee members may be added.

Ethics Review Methods

The committee holds a meeting once a month to implement reviews and issue final decisions. The committee considers the following points to determine, based on the application materials submitted to it, if there are any ethical issues with the research.

Key Points for Review

In accordance with the spirit of the Helsinki Declaration, the ethics review committee considers the following points:

- (1) Human rights protections for the research participants
- (2) Suitability of methods for obtaining participant consent
- (3) Provisions to protect participants from dangers that may arise during the research

You will be asked to address these points directly in items seven to nine of the application form's research proposal form. These items are explained in more detail below.

(1) Human rights protections for individuals participating in research

The human rights of research participants must be prioritized above all else. The Ethics Committee will confirm that appropriate measures have been taken in the research to do this; if it decides these measures are insufficient, it will recommend changes.

(2) Validity of methods of obtaining participant consent

Consent forms should be obtained as follows. First, explain the research clearly in writing. At a later date, researchers should collect consent forms from participants. The form explaining the research must be written in clear language that is easy for a nonspecialist to understand. Sometimes research planning documents used in internal laboratory meetings, etc., are submitted as research explanation documents for participants; in such cases, the researchers may be asked to edit the text so that it is clear and easy for nonspecialist to understand.

(3) Provisions to protect participants from dangers that may arise during the research

In this section, researchers should state any dangers that may arise during the research, and explain in detail countermeasures to be taken if any harm occurs. For example, list in detail the names of medical facilities and how to contact them if participants are injured or become unwell during the research.

Ethics Review Decisions

Ethics Committee decisions are, as a rule, made based on the agreement among all committee members in attendance (including attendance by proxy) and will be one of the following:

- (1) Approved
- (2) Conditional approval
- (3) Changes recommended
- (4) Not approved
- (5) Not applicable

Notes

Please consult the websites below when necessary for information on completing application forms:

- Application documents: Experimental Research with Human Subjects (Internal website)
<http://www.c.u-tokyo.ac.jp/faculty/ken9/experiments/humansubjects/> (in Japanese)
- Ministry of Education, Culture, Sport, Science, and Technology: Bioethics and Safety
<http://www.lifescience.mext.go.jp/bioethics/index.html> (in Japanese)
- Ministry of Health, Labour, and Welfare: List of Research Guidelines
<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/hokabunya/kenkyujigyou/i-kenkyu/index.html> (in Japanese)