

IRB Guidelines Tokyo Metropolitan University, Arakawa campus
(Updated April 1, 2019)

- I . Basic rationale on research ethics
- II . Subjects of research ethics review
- III. Research ethics training
- IV. Documents required when applying for research ethics review
- V . Full board review application procedures
- VI. Full board meetings and departmental review meetings
- VII. Review outcomes
- VIII. Response to the review result
- IX. Changes to the research protocol, etc.
- X. Research period
- XI. Storage of research data
- XII. Submission of report

Annex

- Research protocol form for research ethics review
- Consent form for joint (or contributing) researchers

I . Basic rationale on research ethics

While it is self-explanatory that “research involving human subjects” must be conducted in compliance with law, such research must also be undertaken with appropriate ethical consideration for research subjects based on the Declaration of Helsinki and the Declaration of Lisbon, as well as other benchmarks such as “Ethical Guidelines for Medical and Health Research Involving Human Subjects” and “Ethical Guidelines for Nursing Research.” Accordingly, faculty members, graduate students, research students, etc. affiliated with the Arakawa Campus must, before conducting research involving human subjects, apply for and undergo review by the IRB at Tokyo Metropolitan University, Arakawa Campus(hereinafter, the committee) and receive approval from the committee. This will help to guarantee the safety of and ethical consideration for research subjects, while also protecting the position of the researchers themselves.

II . Subjects of research ethics review

The committee shall conduct reviews of research involving human subjects applied by faculty members and students (research students) affiliated with the Tokyo Metropolitan University Arakawa Campus. Should an individual wish to conduct research to which any of the following apply, they must receive the approval of the committee.

- Research when this university is the implementing entity
 - Research undertaken by students of this university (research students)
 - Research undertaken with a budget, expenses or research costs from this university
- Research undertaken by a full-time member of this university’s teaching staff as the research representative
 - Research undertaken as part of a degree course at this university
 - Research implemented by another entity but undertaken on the Arakawa Campus

Besides the above, applicants should consult a chairperson of departmental review committee(DRC) covering their own research department when unsure whether review is required or not, or when there is any uncertainty about an application.

III. Research ethics training

1. Purpose

In response to the stipulation in “Ethical Guidelines for Medical and Health Research Involving Human Subjects” (December 22, 2014, MEXT and MHLW) that training in research ethics must be provided, training will be implemented using the APRIN e-learning program “Research Involving Human Subjects: Fundamentals (HSR), Stage 1.” This will ensure that researchers who wish to conduct research involving human subjects and apply for research ethics review by the Arakawa Campus of Tokyo Metropolitan University will learn about ethics related to the research and the knowledge and technology required when conducting such research.

2. Course recipients

Researchers (including applicants, principal investigators, Co-Investigators and supervisors) who apply for research ethics review by the Arakawa Campus of Tokyo Metropolitan University.

Note: However, applicants other than staff, graduate students and research students at Tokyo Metropolitan University Arakawa Campus should read “Ethical Guidelines for Medical and Health Research Involving Human Subjects” instead of the e-learning mentioned above, and must then receive guidance on ethics concerning research involving human subjects from an applicant, research representative or joint researcher enrolled at this University.

Note: Applicants affiliated to Tokyo Metropolitan University Arakawa Campus must still attend the training even if they have already received e-learning from another institution or attended the “Responsible Research Conduct Digest” course offered by this University.

3. Method of course attendance

- Course recipients log in to the APRIN Home Page (<http://edu.aprin.or.jp/>) using the login Username (ID) and password provided by the Arakawa Campus Research ethics Secretariat (hereinafter, “the Secretariat”), then attend the course “Research Involving Human Subjects: Fundamentals (HSR), Stage 1.”
- After studying the research ethics course materials, course recipients take a comprehension test (quiz) to confirm understanding of the course content. A test score of at least 80% (four out of five questions answered correctly) signals course

completion, and a course completion certificate will be issued.

Note: The procedures for operating the system are as described in the procedures for taking the APRIN ON-Screen e-learning course “Digest on Research Involving Human Subjects.”

4. Research ethics review

At the time of the deadline for the submission of application documents to Secretariat, the Secretariat will confirm that individuals who have applied for review with the Committee have taken and completed the training program. The research protocols of applicants who have been confirmed to have taken and completed “Research Involving Human Subjects: Fundamentals (HSR), Stage 1” shall be accepted as matters for review by the committee.

5. Period of completion

In order to confirm completion of the training course as described in “4. Research ethics review” above, the applicant and any other researchers, etc. (research representative, joint researcher, supervisor) must have completed the training course before the submitting their application documents to the Secretariat.

6. Course frequency

The course must be re-taken every academic year.

IV. Documents required when applying for research ethics review

When applying for a review by the DRC and the committee applicants must submit the documents 1-12 listed below.

1. Application for research ethics review (separate form No.1)*
2. Research protocol for research ethics review (annexed prescribed form)
3. Research cooperation request form (for partnering institutes/facilities, free form, template available)
4. Explanation to research subjects (free form, template available)
5. Consent form for research subjects or legal representatives (free form, template available)
6. Form for record of provision of specimens and information (template available)
7. Form for notice of provision of existing specimens and information (template available)
8. Questionnaire and other documents for distribution (if distributed to research

subjects)

9. Literature, documents and others related to the research
10. Copy of approval certification issued by another institution's ethics review committee
11. Consent form for joint (or contributing) researchers (form specified in annex)*
12. (If re-applying based on assessment giving conditional approval or recommending changes) Assessment Notice*
13. Certificate of completion of the training on research ethics
14. Japanese manual of research ethics review

*Copies are acceptable when submitting documents 1, 11, and 12 to the DRC. However, the original documents must be used when submitting to the Secretariat.

Notes

- Application documents must be compiled in the above order, with documents 1 to 11 marked with their respective numbers in the bottom right corner.
- Documents 3 to 9 must be marked with a document number in the top right corner.
- When applying for review by the committee (submission to the Secretariat), the original copy of document 11 personally signed by joint (or contributing) researchers must be submitted.
- Regarding research requiring the approval of the ethics review committees of other institutes such as partnering and other research institutes, the documents that must be submitted to the committee will depend on whether the central institute involved in the research is TMU or another institute. In particular, in the event that the research topics and applicants (research representative) submitted to TMU differ from those listed on the approval certification from the ethics review committee of the other institute, make sure to include an explanation in the "Remarks" section of the application form that clarifies the research implementation system (how the research will be implemented).
- When the central entity conducting the research is TMU, such as research conducted in order to acquire a TMU degree (full board review), in addition to the documents listed above, make sure to attach documents showing consent has been received regarding both the provision of specimens and information acquired at other institutes to TMU and the publication of the results of the research in question.
- When the central entity conducting the research is another institute (expedited review is allowed in this case), make sure to attach copies of the application documents submitted to the ethics review committee of the other institute, as well

as of the approval certification.

- If the research is implemented by another entity that has no research ethics review committee, a request for ethics review from that institution (free format) and, if necessary, documents or similar (free format) clarifying the location of responsibility for implementing the research (research body, etc.) must be submitted in addition to the above documents.

V. Full board review application procedures

1. DRC review

- 1) Applicants are asked to submit copies of a full set of the application documents listed in “IV. Documents required for receiving a research ethics review” (printed on both sides and stapled once on the top left corner) to the laboratory postboxes of all the members of the DRC of the department with which they are affiliated and also email digital copies of the documents to the members.
- 2) If an application cannot be accepted (for example, if documents are missing, if the application clearly cannot be approved based on ethics principles, or if the application does not need to be considered by the committee), the DRC will return it to the applicant. If the application can be accepted, the DRC will notify the applicant of the review result as soon as possible after the review has been made.

Application deadline

- In principle, the deadline for submitting application documents to the DRC is 5 p.m. on the 4th Tuesday of every month. See the website of the Graduate School of Human Health Sciences for specific schedules.
- If an applicant is unavoidably prevented from submitting the application documents in person by the deadline above, they must be submitted by a supervisor on the applicant’s behalf.

2. Committee review

- 1) The applicant, or his or her agent, must submit a full set of application documents revised based on the DRC review to the Secretariat (submission by post is accepted) and When submitting to the Secretariat, original documents must be submitted. And the applicant email data of” Application for research ethics review (separate form No.1)*”and” Research protocol for research ethics review (annexed prescribed form)”.

Application acceptance times

Weekdays, 9 a.m. to 5:45 p.m. (excluding 12:30 p.m. – 1:30 p.m.)

- 2) The Secretariat will stamp the submitted “Application for Research ethics Review” and “Research Protocol for Research ethics Review” with an acceptance stamp and attach an acceptance number and return copies to the applicant.

Numbers attached to documents

- Serialized acceptance numbers are attached to the “Application for Research ethics Review” and “Research Protocol for Research ethics Review” in order of acceptance.

(Example) 19001-19999 (No. 1 in AY2019-No. 999 in AY2019)

- The acceptance number will be re-used as an approval number after an Assessment Notice has been issued.
- Applications for expedited review, when reapplying within the same academic year with research protocols that have already received an assessment of conditional approval, will be accepted using the same acceptance number as the original application.

Application deadline

- In principle, the deadline for submitting application documents to the Secretariat is 5:45 p.m. on the 2nd Tuesday of every month. See the website of the individual research department for specific schedules.
- There are the following three application methods:
 - 1) An applicant himself/herself, or his/her research collaborator, submits application documents to the Secretariat by the deadline.
 - 2) If an applicant is a graduate student, his/her supervisor submits application documents on his/her behalf.
 - 3) An applicant submits one set of application documents to the Secretariat by post.

When submitting by post, an applicant must submit to the mailing address listed below via trackable mailing services (e.g., registered post) a full set of application documents with a return-mail envelop with a sufficient amount of stamps affixed for receiving the full set of application documents with acceptance stamps.

[Mailing address]

Tokyo Metropolitan University Arakawa Campus Research Ethics Committee Secretariat 7-2-10 Higashi-Ogu, Arakawa City, Tokyo, Japan 116-8551

3. Animal experiments, gene recombination experiments

Reviews of animal experiments and gene recombination experiments are carried out by the Research Ethics Committee of the Minami-Osawa Campus. As such, applicants need not submit an application to the DRC and should instead confirm with the Secretariat regarding the submission deadline.

VI. Full board meetings and departmental review meetings

DRC meetings shall be held in each department and committee meetings shall in principle be held once a month.

VII. Review outcomes

1. Types of assessment

- 1) Approved
- 2) Conditionally approved
- 3) Changes recommended

Note: In principle, this committee only reviews research protocols in connection with ethics matters. However, an assessment of “Changes recommended” is sometimes made when the research method or other aspects are in conflict with other provisions, or when the research is deemed clearly inappropriate, for example because it would compromise the safety of research subjects, and it is judged that this part impacts the whole of the research protocol, which therefore cannot be implemented.

- 4) Not approved
- 5) Not applicable

2. Notification of assessment

An Assessment Notice drafted by a committee member from the applicant’s research department and finalized via the committee is issued by the dean of the graduate school. The review result is sent from the Secretariat to the email address of the applicant named in the Application Form for Research ethics Review.

Notifications are sent about 2-3 weeks after the date of the committee meeting.

3. Return of review documents

Application documents submitted to the DRC and the committee may be returned to the applicant if so desired, with the exception of the “Application for Research ethics Review” and “Research Protocol for Research ethics Review.” However, of documents submitted to the committee, copies of documents to be returned and electronic data are stored in the Secretariat.

4. Receipt of Assessment Notices

In principle, applicants shall receive Assessment Notices by going to the Secretariat in person on weekdays (in principle 9 a.m. to 5:45 p.m.). If the applicant is unable to attend in person during these hours, notices may be received by post if so desired. Applicants who wish to receive Assessment Notices must send to the Secretariat a return-addressed Letter Pack (a flat-rate package delivery service of Japan Post).

VIII. Response to the review result

1. If “Approved”

As soon as possible after receiving notification of the assessment, the applicant should use Microsoft Word or some other document creation tool to create a set of application documents with amendments marked in red in accordance with the issues flagged in the Assessment Notice, then send them as email attachments to the email address of the Secretariat (i.e. the source of the assessment result notification). In addition, the original of the “Application for Research ethics Review” (separate form No.1), marked with an outline of amendments in response to the issues flagged in the Assessment Notice, should be submitted to the Secretariat (students should submit to the Academic Affairs Section).

2. If “Conditionally approved”

The applicant should re-apply in accordance with the method given in “V. Full board review application procedures,” using the “Application for Research ethics Review” (separate form No.1) marked with an outline of amendments in response to the issues flagged in the Assessment Notice, and a set of application documents with amendments marked in red (specific details should be confirmed under “IV. Documents required when applying for research ethics review”).

3. If “Changes recommended”

Within one month starting from the day after the notification was received (i.e. after the date marked in the top right corner of the Assessment Notice), a set of application documents amended in line with the content of the Assessment Notice, a “Re-application for research ethics review” (separate form No. 5), and a copy of the “Changes recommended” Assessment Notice shall be submitted to the DRC members for DRC review. After the review, one set of originals of the above application documents shall be submitted by the applicant in person to the Secretariat in order to re-apply to the committee.

4. Objections to the assessment result

If an applicant has an objection to the committee’s assessment (including the content of flagged issues), the applicant may request a second review. Second reviews must be requested by submitting a “Request for second review of research safety ethics” (separate form No. 3) in person to the Secretariat.

A request for a second review must be made within two weeks starting from the day after notification was received (i.e. after the date marked in the top right corner of the Assessment Notice), and may only be made once per research protocol (one acceptance number).

IX. Changes to the research protocol, etc.

Should any change arise in the content of the research protocol after the assessment “Approved” has been received, the applicant must first confirm whether the content of the change falls under any of 1), 2) or 3) below. If the change falls under none of these, it shall be taken as a “minor change.”

- 1) Protection of the research subjects’ human rights
- 2) Method of obtaining the understanding and consent of research subjects
- 3) Disadvantage to research subjects and risks borne by them

1. When a change does not constitute a “minor change”

The applicant should consult with a chairperson of departmental review committee in their research department, and if necessary, apply for full board review. When doing so, the applicant should enter details of the change in the “5. Outline of amendments or changes” section of the “Application for Research ethics Review” (separate form No.1), as well as submitting the normal set of documents.

2. When a change constitutes a “minor change”

Electronic data of the set of documents, with changes marked in red, should be emailed together with a “Notification of Changes to Research Protocol” (separate form No.6) to the Secretariat.

3. When a research representative’s status (e.g. graduate course) changes during the research period

A new application for ethics review must be made to the committee. When changes are due to occur, the research completion date must be set to fall on or before the date of the scheduled change, and a new application must be made to the committee after the change.

X. Research period

Although no time limit is set on the validity of ethics review approvals, the committee chairperson must be consulted in cases of long-term research (lasting 5 years or so).

Moreover, when the research is likely to continue beyond the period specified in the “Research Protocol for Research ethics Review,” an application to change the research period must be made to the Secretariat by 30 days before the end of the period, following the procedure in paragraph 2. of “IX. Changes to the research protocol, etc.”

However, in situations such as when a degree thesis is due to be submitted, the need to submit the “Research Safety Ethics Report” (separate form No.4) as specified in “XII. Submission of report” while enrolled at the university should be taken into account when setting the research period.

XI. Storage of research data

The research representative must take responsibility for ensuring that data and other details concerning research approved by the Committee are stored for as long as possible. As a minimum requirement, the “Research Safety Ethics Report” (separate form No.4) related to the research in question must be appropriately stored using the method and in the location specified below for each research department, for five years from the date of submission or for three years from the date on which the announcement of the research results was finally reported, whichever is later.

Department of Nursing Sciences

- While enrolled: In principle, stored by research representative in the graduate student common room or research lab (however, may also be stored in a lockable desk in his/her private residence, as there are not enough desks or lockers for storage in the graduate student common room).

- After completion: Stored in a new storage location specified by the research representative in the “Research Safety Ethics Report” (separate form No.4).

Department of Physical Therapy

- While enrolled: Stored on a lockable shelf in the research lab if the research is internal to the university (in the case of students, stored in the supervisor’s room in future).
- After completion: Same as while enrolled

Department of Occupational Therapy

- While enrolled: In principle, stored in the graduate student common room
- After completion: Stored in supervisor’s research lab

Department of Radiological Sciences

- While enrolled: In principle, stored in the respective research lab
- After completion: Stored by research representative

Department of Frontier Health Sciences

- Stored as instructed by the supervisor

XII. Submission of report

When halting the research or after completion, the research representative must compile a “Research Safety Ethics Report” (separate form No.4) and email it as a PDF to the Secretariat within 60 days after completion of the research and while enrolled at this university. If leaving the university early, the report should be submitted provisionally even if the research is not yet complete.

Approved by Faculty Meeting, [insert date], 2019