Tokyo Metropolitan University Arakawa Campus Research Safety Ethical Review
Guidelines on Research Safety Ethics
(updated March 23rd, 2016)

Annex
・Research protocol form for research safety ethical review
・Consent form for joint (or contributing) researchers

I.   Basic rationale on research safety 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". For this reason, the staff of this campus, as well as its graduate students, research students and others, must apply for review by the Research Safety Ethics Committee of this campus and receive its approval before engaging in "research involving human subjects". This will help to guarantee the safety of and ethical consideration for research subjects, while also protecting the position of the researchers themselves.

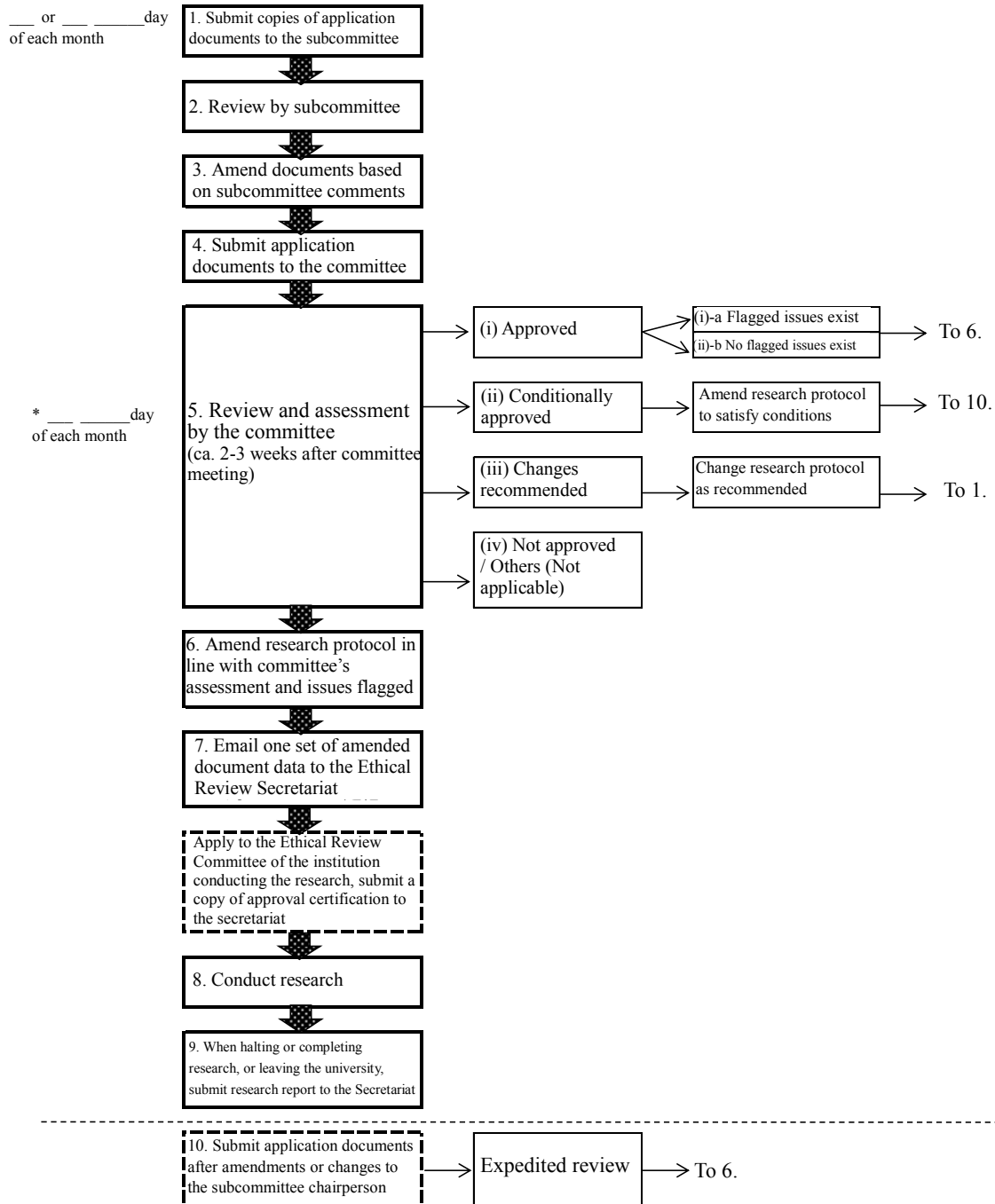II.   Research requiring research safety ethical review

When full-time staff or students (research students) affiliated to Tokyo Metropolitan University Arakawa Campus engage in the following kinds of research involving human subjects, they must first undergo Arakawa Campus research safety ethical review to obtain approval for such research.

・Research when this University is the implementing entity
    ・Research undertaken independently 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 campus

Besides the above, applicants should consult the subcommittee chairperson covering their own research department when unsure whether review is required or not, or when there is any uncertainty about an application.

III. Flow of review

Flow of Research Safety Ethical Review at the Arakawa Campus of Tokyo Metropolitan University

___ or ___ _____day
of each month

| 1. Submit copies of application documents to the subcommittee |

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| 2. Review by subcommittee |

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| 3. Amend documents based on subcommittee comments |

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| 4. Submit application documents to the committee |

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* ___ _____day
of each month

| 5. Review and assessment by the committee (ca. 2-3 weeks after committee meeting) |

→ (i) Approved → (i)-a Flagged issues exist / ii-b No flagged issues exist → To 6.

→ (ii) Conditionally approved → Amend research protocol to satisfy conditions → To 10.

→ (iii) Changes recommended → Change research protocol as recommended → To 1.

→ (iv) Not approved / Others (Not applicable)

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| 6. Amend research protocol in line with committee's assessment and issues flagged |

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| 7. Email one set of amended document data to the Ethical Review Secretariat |

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| Apply to the Ethical Review Committee of the institution conducting the research, submit a copy of approval certification to the secretariat |

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| 8. Conduct research |

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| 9. When halting or completing research, or leaving the university, submit research report to the Secretariat |

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| 10. Submit application documents after amendments or changes to the subcommittee chairperson | → Expedited review → To 6.

IV.   Research ethics training

1.   Purpose

In response to the stipulation in "Ethical Guidelines for Medical and Health Research Involving Human Subjects" that training in research ethics must be provided, training will be implemented using CITI Japan ON screen e-learning. This will ensure that researchers who wish to conduct research involving human subjects and apply for research safety ethical 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, research representatives, joint researchers and supervisors) who apply for research safety ethical review by the Arakawa Campus of Tokyo Metropolitan University.

*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.

*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 CITI Japan Home Page (http://edu.citiprogram.jp/) using the login Username (ID) and password provided by the Ethical Review Secretariat, then attend all 5 courses that are indicated in English as optionals.
- ・The History and Principles of Bioethics, and the Development of Its Rules
- ・Review by an Independent Ethics Committee (IEC)
- ・Handling Personal Information in Research
- ・Informed Consent in Research
- ・Research Subjects Who Merit Special Considerations

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 (the certificate need not be submitted).

4. Research safety ethical review

Applicants and other researchers (including research representatives, joint researchers and supervisors) must complete the course before submitting application documents to the secretariat.

5. Course frequency

The course must be re-taken every academic year.

V. Documents required when applying for research safety ethical review

When applying for review by the subcommittee and committee, documents 1 to 9 below must be submitted in accordance with the "Document Preparation Manual".

1. Application for Research Safety Ethical Review (Separate Form No.1)*
2. Research Protocol for Research Safety Ethical Review (form specified in Annex)
3. Research Cooperation Request Form (to cooperating institution or facility, free format)
4. Explanation to Research Subjects (free format)
5. Consent Form for Research Subjects or Legal Representatives (free format)
6. Questionnaire and other documents for distribution (if distributed to research subjects)
7. Literature, documents and others related to the research
8. Copy of approval certification issued by another institution's Ethical Review Committee
9. Consent Form for Joint (or Contributing) Researchers (form specified in Annex)*
10. (If re-applying based on assessment giving conditional approval or recommending changes) Assessment Notice*

*Copies of 1., 9. and 10. may be used when applying to the subcommittee. 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 9. marked with their respective numbers in the bottom right corner.
・ Documents 3.-7. 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 9. personally signed by joint (or contributing) researchers must be submitted.

・ If the research is implemented by another entity that has no research safety Ethical Review Committee, a request for ethical 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.

VI. Application procedure

  1. Subcommittee review

    1) Applicants must submit copies of the set of application documents specified in "V. Documents required when applying for research safety ethical review" to the research lab postbox of a subcommittee member covering their particular research department.

    2) If an application cannot be accepted (for example, if documents are missing, if the application clearly cannot be approved based on ethical principles, or if the application does not need to be considered by the committee), the subcommittee will return it to the applicant. If the application can be accepted, the subcommittee 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 subcommittee is 17:00 on the 4th Tuesday of every month. See the home page of the individual research department 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) Applicants must submit one set of application documents, amended in accordance with the subcommittee's review, in person to the Planning Officer, Administrative Affairs Section (students should submit to the Academic Affairs Section). When submitting to the secretariat, original documents must be submitted.

Application acceptance times

In principle: weekdays, 9:00-17:00

*If requested in advance, the closing time may be extended to 20:00 in term time only (but on

the deadline date, applications may not be submitted after 17:00).

2) The Planning Officer will stamp the submitted "Application for Research Safety Ethical Review" and "Research Protocol for Research Safety Ethical Review" with an acceptance stamp and attach an acceptance number before returning copies to the applicant.

3) The applicant should then submit copies of the set of application documents marked with the respective acceptance numbers and acceptance stamps as soon as possible to the research lab postbox of a Research Safety Ethics Committee member.

Numbers attached to documents
・ Serialized acceptance numbers are attached to the "Application for Research Safety Ethical Review" and "Research Protocol for Research Safety Ethical Review" in order of acceptance.
(Example) 16001-16999 (No. 1 in 2016-17 - No. 999 in 2016-17)
・ The acceptance number will be re-used as an approval number after an Approval 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 17:00 on the 3rd Tuesday of every month. See the home page of the individual research department for specific schedules.
・ If an applicant is unavoidably prevented from submitting the application documents in person to the Planning Officer, Administrative Affairs by the deadline above, they must be submitted by a supervisor on the applicant's behalf, or else, if requested in advance, one set of application documents must be promptly mailed to the Planning Officer, Administrative Affairs (to arrive without fail by the application deadline). In such cases, the Planning Officer, Administrative Affairs will attach an acceptance number after receiving the application documents and receiving the supervisor's signature. The submission will be deemed to have been made once the documents have been posted in the mail boxes (offices) of the various Research Safety Ethics

Committee members.

- ・ Applicants who submit application documents by the deadline shown above will have their application reviewed upon confirmation that they have attended and completed the CITI Japan e-learning.

3.　　Animal experiments, gene recombination experiments

Reviews of animal experiments and gene recombination experiments are carried out by the Research Safety Ethics Committee of the Minami-Osawa Campus. In this case, applicants do not apply to the subcommittee but to the Planning Officer, Administrative Affairs, after first confirming the deadline for submissions to the same.

VII.　Expedited review

1.　　Expedited review judgment criteria

Matters that may be reviewed using expedited review procedures are as follows.

1) Reviews of condition fulfillment for research that has received conditional approval.

2) Reviews of research implemented jointly with another research institution, when the whole of the research in question has already been reviewed by the Ethical Review Committee of the joint research institution and the implementation has been approved.

3) Cases when the research protocol has been changed after receiving approval.

4) Other matters deemed subject to expedited review by agreement of all committee members in attendance at a committee meeting.

2.　　Subcommittee review

1) Applicants must submit copies of the set of application documents specified in "V. Documents required when applying for research safety ethical review" to the research lab postbox of a subcommittee member covering their particular research department.

2) If the subcommittee chairperson judges that the submitted content should be subject to expedited review procedures, subcommittee review will be carried out. If judged not applicable to expedited review procedures, the application will be accepted for normal review.

Application deadline

- ・ In principle, the deadline for submitting application documents (expedited review) to the subcommittee shall be twice a month, on the 2nd and 4th Tuesday of each month (by 17:00 in each case).
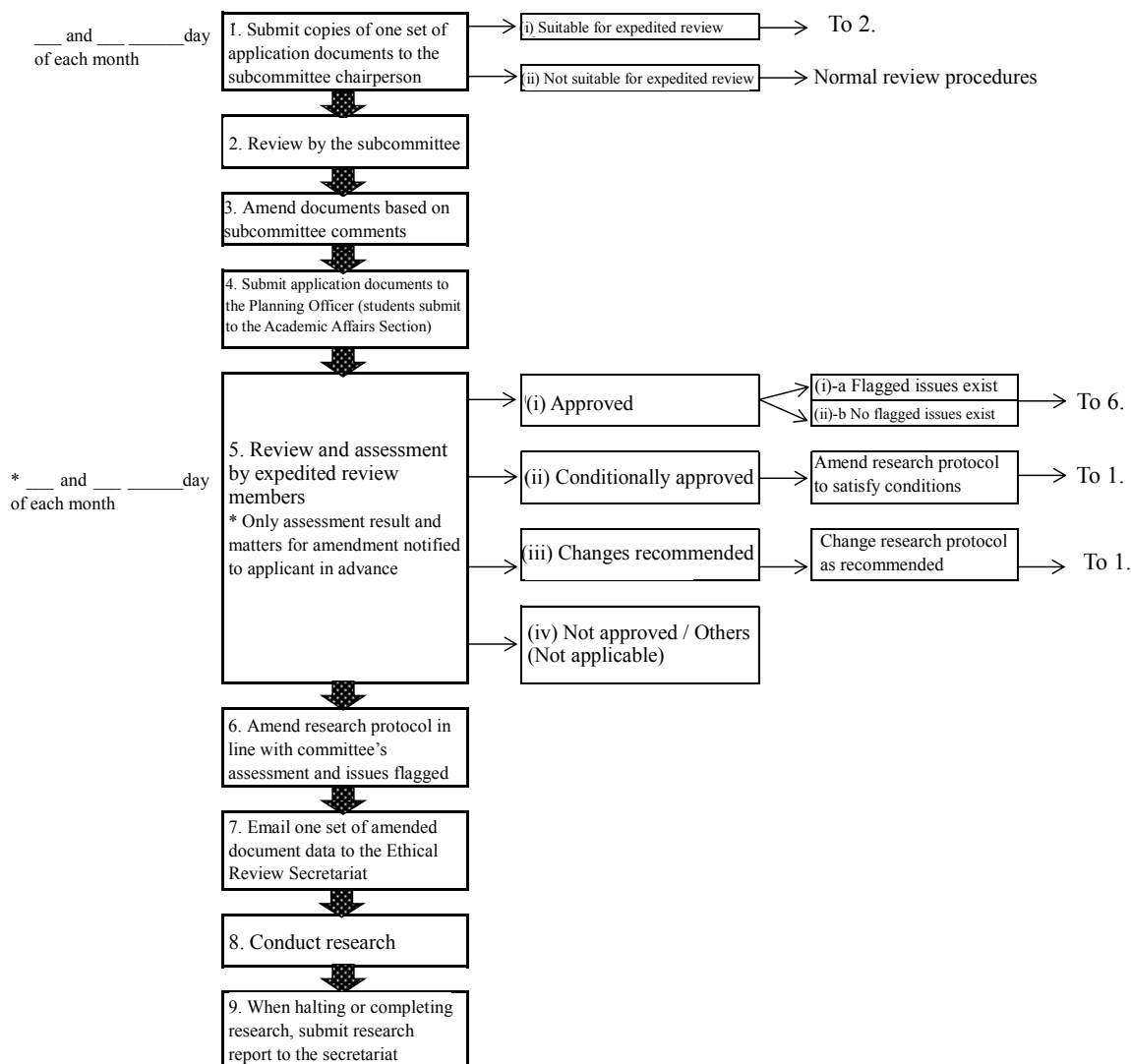
3. Committee review

Applicants must amend documents in accordance with matters pointed out as a result of the subcommittee review, and must submit one set of documents in person to the Planning Officer, Administrative Affairs (students should submit to the Academic Affairs Section). After accepting the application documents, the Planning Officer will distribute copies thereof to the expedited review members.

Application deadline

- In principle, the deadline for submitting application documents (expedited review) to the committee (secretariat) shall be twice a month, on the 3rd and 5th Tuesday of each month (by 17:00 in each case).
- Applicants who submit application documents by the deadline shown above will have their application reviewed upon confirmation that they have attended and completed the CITI Japan e-learning.

Flow of Expedited review

___ and ___ _____day
of each month

1. Submit copies of one set of application documents to the subcommittee chairperson

→ i) Suitable for expedited review → To 2.

→ ii) Not suitable for expedited review → Normal review procedures

2. Review by the subcommittee

3. Amend documents based on subcommittee comments

4. Submit application documents to the Planning Officer (students submit to the Academic Affairs Section)

* ___ and ___ _____day
of each month

5. Review and assessment by expedited review members
* Only assessment result and matters for amendment notified to applicant in advance

→ (i) Approved
  → (i)-a Flagged issues exist
  → (ii)-b No flagged issues exist → To 6.

→ (ii) Conditionally approved → Amend research protocol to satisfy conditions → To 1.

→ (iii) Changes recommended → Change research protocol as recommended → To 1.

→ (iv) Not approved / Others (Not applicable)

6. Amend research protocol in line with committee's assessment and issues flagged

7. Email one set of amended document data to the Ethical Review Secretariat

8. Conduct research

9. When halting or completing research, submit research report to the secretariat

VIII. Committee and subcommittee meetings

1. Subcommittee meetings

In principle, subcommittee meetings are held once a month, approximately two weeks before the committee meetings for each research department.

2. Committee meetings

In principle, committee meetings are held once a month. When a quorum (attendance of at least two-thirds of committee members) cannot be reached owing to the absence of a member from a research department subject to a review application, a subcommittee member from the absent member's research department shall be drafted in as a proxy member. If a subcommittee

member has difficulty in attending, a professor or associate professor responsible for graduate student education in said research department shall be drafted in as a proxy member.

IX.   Review assessment
1.   Types of assessment
1)   Approved
2)   Conditionally approved
3)   Changes recommended
*In principle, this committee only reviews research protocols in connection with ethical 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 head of the research department. The review result is published on the Faculty of Health Sciences and Graduate School of Human Health Sciences home pages, and is sent from the Ethical Review Secretariat (Planning Officer, Administrative Affairs) to the email address of the applicant named in the Application Form for Research Safety Ethical 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 subcommittee and committee may be returned to the applicant if so desired, with the exception of the "Application for Research Safety Ethical Review" and "Research Protocol for Research Safety Ethical Review". However, of documents submitted to the committee, copies of returned documents and electronic data are stored in the secretariat.

4.   Receipt of Assessment Notices
In principle, applicants shall receive Assessment Notices by going to the Academic Affairs Section in person on weekdays (in principle 9:00-17:00). If the applicant is unable to

attend in person during these hours, notices may be accepted outside hours in term times only (but only up to 20:00 on weekdays) by reserving a time in advance.

X.   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 Planning Officer, Administrative Affairs (i.e. the source of the assessment result notification). In addition, the original of the "Application for Research Safety Ethical 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 Planning Officer, Administrative Affairs (students should submit to the Academic Affairs Section).

2.   If "conditionally approved"

The applicant should re-apply in accordance with the method given in "VII. Expedited review", using the "Application for Research Safety Ethical 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 "V. Documents required when applying for research safety ethical 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 safety ethical review" (Separate Form No. 5), and a copy of the "Changes recommended" Assessment Notice shall be submitted to the subcommittee members for subcommittee review. After the review, one set of originals of the above application documents shall be submitted by the applicant in person to the Planning Officer, Administrative Affairs (students should apply to the Academic Affairs Section) 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 Planning Officer, Administrative Affairs (students should apply to the Academic Affairs Section).

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).

XI.   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 the subcommittee chairperson in their research department, and if necessary, apply for expedited 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 Safety Ethical 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 Ethical Review Secretariat (rinri-hs@tmu.ac.jp).

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

A new application for ethical 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.

XII.   Research period

Although no time limit is set on the validity of ethical 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 Safety Ethical Review", an application to change the research period must be made to the Planning Officer, Administrative Affairs (students should apply to the Academic Affairs Section) by 30 days before the end of the period, following the procedure in paragraph 2. of "XI. 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 "XIV. Submission of report" while enrolled at the university should be taken into account when setting the research period.

XIII.　Storage of research data

The research representative must take responsibility for ensuring that data and other details concerning research approved by the Arakawa Campus research Safety Ethics 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 the desk of lockable accommodation, 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.

XIV. 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 Ethical Review Secretariat (rinri-hs@tmu.ac.jp) 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, and once again after completion of the research.

Approved by Faculty Meeting, February 18, 2016