Tokyo Metropolitan University, Arakawa Campus
Guidelines for Research Ethics

*This is a reference English translation. Please refer to “東京都立大学荒川キャンパス研究倫理の指針“.

(April 1st , 2025 version)

Research Ethics Committee of Arakawa Campus

Tokyo Metropolitan University

Contents

Chapter 1 Basic Rationale on Research Ethics

It is obvious that research must be conducted in compliance with laws and regulations. Furthermore, when conducting "research involving human subjects," it must be undertaken with appropriate ethical consideration for research subjects in accordance with the "Declaration of Helsinki," "Declaration of Lisbon," "Ethical Guidelines for Nursing Research," and "Ethical Guidelines for Medical and Biological Research Involving Human Subjects."

Accordingly, faculty members, graduate students, research students, etc., affiliated with the Tokyo Metropolitan University, Arakawa Campus (hereinafter referred to as the "Arakawa Campus") must, before conducting "research involving human subjects," apply for and undergo review of their study plan by the Research Ethics Committee of Tokyo Metropolitan University, Arakawa Campus (hereinafter, the "Committee") and obtain approval (or a research implementation permission at the University if ethics approval is obtained in the collective review for a multi-institutional collaborative research) 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.

Chapter 2 Subjects of Research Ethics Review

The following research projects "involving human subjects" conducted by faculty members and students (research students) affiliated with and enrolled in the Arakawa Campus are subject to the review (students affiliated with the Department of Health Promotion Sciences are not eligible because they are affiliated with the Minami-Osawa Campus).

(1) Research when the University is the implementing entity
  [1] Research undertaken by students of this university or research students
  [2] Research undertaken with a budget, expenses, or research costs from this university
(2) Research undertaken by a full-time member of this university's teaching staff as the principal investigator
(3) Research undertaken as part of a degree course at this university
(4) Research implemented by another entity but undertaken on the Arakawa Campus

* In addition, consult a subcommittee of the applicant's affiliated department if there is any uncertainty about whether the review is necessary or not, and when unsure about the application.

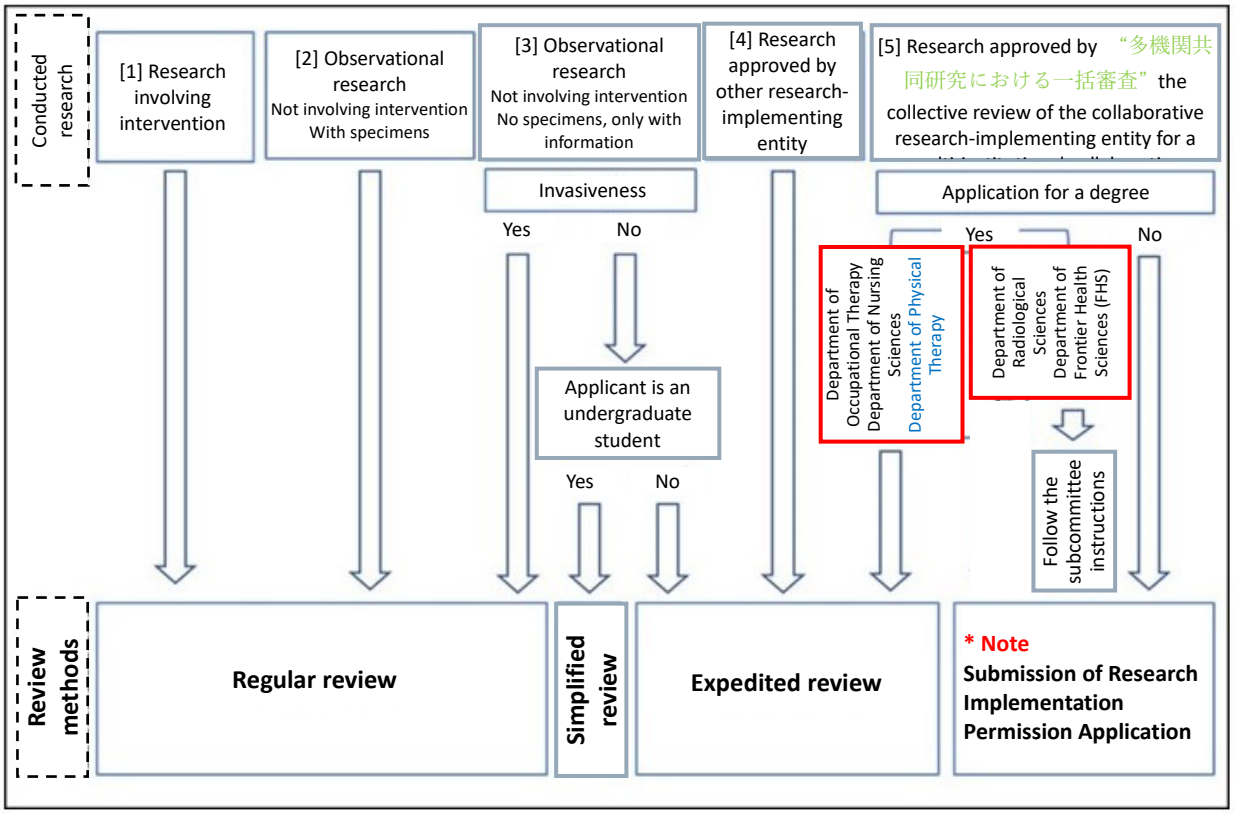
* If an investigator takes a leave of absence from the University, the approval of the ethics review will be suspended during the period of absence, even if it is during the approval period.
(Research cannot be conducted during the period of absence)

You cannot apply retroactively to do research that has already started or ended. Be sure to apply before you start your research.

Chapter 3 Types of Review

The committee conducts regular reviews, expedited reviews, and simplified reviews and the review methods differ depending on the extent of the burden on research subjects. Refer to the following figure to determine which review to apply for.

However, the review method may differ depending on the content of the research. For any inquiries, consult with the subcommittee of the applicant's affiliated department.



Chapter 4 Common items

1. All submitted documents must be copies. The original copies of such documents as written approvals and certificates should be kept in a safe place by the applicant.

2. Submit the application documents electronically.

- All submitted documents should be integrated into one file.

If any additions or revisions are made, the submission should always be in the form of a complete set of revised documents rather than just the revised pages.

- Write consecutive numbers at the bottom right of each page.
- Write document numbers of the attachments at the upper right of each page.
- The submission date is the date of the sending of a file by e-mail.
- When any additions or revisions are made, write relevant parts in red.

* If any deficiency is found in the documents regarding the above-mentioned points, the submitted documents will be returned to the applicant.

Since the documents are accepted for review on the re-submission date, it may be subject to review in the next and subsequent reviews.

3. The submitted file name should include corresponding “document type,” “affiliation” and “name" of the applicant.

- Six document types: [Regular], [Expedite], [Simplified], [Change], [Implementation Permit], [Completion Report]
- Affiliated department: Ns, PT, OT, R, FHS

(Example) [Regular] Ns, Name XXXX

4. The e-mail subject is as follows in accordance with the content of the application.

State in the following order: [Document type], [Affiliated department (Ns, PT, OT, R, FHS)], [Name].

- Seven document types: [Regular], [Expedite], [Simplified], [Change], [Implementation Permit], [Completion Report],

[Other]; use for inquiries, not for submission of documents

(Example) [Regular] Ns, Name XXXX

* Add application number after notification of approval number. [Regular] 20XXXX, Ns, Name XXXX

5. Deadline and destination for submission

- Submission after the time of deadline will be regarded as acceptance of the next application.
- If the application cannot be accepted due to incomplete documents, the documents will be returned to the applicant.
- Refer to the Research Ethics Review on the websites of the Faculty of Health Sciences and Graduate School of Human Health Sciences (hereinafter the “website”) for the application schedule for this

academic year.

- The schedule for the simplified review varies depending on the faculty, so please confirm with the applicant's affiliated subcommittee.

Subcommittee: 5PM on the closing date

The submission destinations may vary depending on the subcommittee, so please confirm with your supervisors for details.

Committee: 12PM on the closing date

Submission address: a-rinri@jmj.tmu.ac.jp

If the applicant is other than a full-time faculty member, include supervisors or host faculty members in the cc field.

(For graduate students, research students, researchers, etc.)

Chapter 5 Main Flow from Preparation of New Application Documents, Submission, Approval, and Start to End of Research

1. Download documents required for the application process
   - The website of the Ethics Committee is updated in April and October every year (and as needed). Therefore, when preparing application documents, be sure to check the updated contents and use the latest forms.

2. Submission for the subcommittee review
   - Check the submission destination and deadline for the Subcommittee Review, as they may vary depending on the department.
   - List the matters pointed out by the Subcommittee review in the "Revision and Change Histories" (briefly describe the contents pointed out and the contents after revision), and add or revise the documents in red text (deleted portions should be crossed out).

3. Submission to the committee (secretariat)
   - List the matters pointed out by the Committee in the "Revision and Change Histories" of the application form in an addendum to the matters pointed out by the subcommittee review. Then, add or revise the documents in red (the deleted portions should be crossed out).
     * After all additions or revisions pointed out by the subcommittee review are changed to black, only those corrections that were pointed out by the Committee should be noted in red text.

4. Approval (Receipt of Notification of Approval (and Notification of Research Implementation Permission))
   - When conducting research involving intervention, register the necessary information to the public database of the Ministry of Health, Labour and Welfare (MHLW), etc., which is to be registered after receiving the notice of approval and before starting the research.

5. Submission of documents for storage by the secretariat (a complete set of approved documents)

- Change all portions written in red to black and fill in items that were blank or planned at the time of application because they had not been determined yet.

[1] State the following information in posters, leaflets, request forms, etc.

- Research period: The specific research implementation permission date (or the research start date) and the scheduled date of research completion

- Ethics review approval number, etc.

[2] During research involving intervention: Registration number of registered public database

6. Start of research

7. When the study plan changes (the changed research cannot be conducted until the contents of changes are approved)

- Perform procedures to change the study plan.
- To extend the research period, apply at least 30 days in advance.

8. Completion of research

- Submit a completion report promptly.

(During research involving intervention: Enter the completion information in the registered public database)

Chapter 6 Research Ethics Training

1. Purpose

Prior to conducting the research involving human subjects, be sure to attend the Research Ethics Training for the purpose of studying ethics of research and obtaining the knowledge and skills necessary to conduct it.

2. Training completion certificate

The applicant and other researchers (principal investigators, co-investigators, research collaborators, supervisors, etc.) should complete the training by the time of submission of application documents. The attendance of training is confirmed at the time of submission of application documents. The committee receives the research protocol for review attached to a copy of the training completion certificate showing attendance within the past year.

Be sure to take ethics training at least once a year. When conducting research over multiple years, there is no need to submit a training completion certificate to the secretariat every year. Applicants should attend and renew the training and keep the training completion certificate so that they can submit the certificate promptly if requested by the secretariat.

* When submitting any applications to the secretariat, such as changes in the study plan, submit the revised research protocol with a replacement copy of the training completion certificate showing attendance within the past year.

3. Eligible participants

Those involved in the study plan for the research ethics review application (principal investigators, co-investigators, research collaborators, supervisors, etc.).

3-1 Persons affiliated with the Tokyo Metropolitan University

(1) Persons affiliated with the Arakawa Campus

Persons affiliated with the Arakawa Campus are those who fall under the following [1] through [4].
(For details, refer to "4. Courses, units, and effective periods for persons affiliated with the Arakawa Campus")

[1] Students enrolled at the Arakawa Campus (graduate students, undergraduate students)

[2] Full-time faculty members affiliated with the Arakawa Campus

[3] Specially appointed faculty members (not including part-time lecturers) among the part-time faculty members affiliated with the Arakawa Campus

[4] Research students or visiting researchers approved by the Arakawa Campus

* Persons affiliated with the Arakawa Campus must newly take the "Research Compliance Training (including research involving human subjects)" course and units specified by the committee, even if they have already taken the same training at other institutions (workplace, etc.).

(2) Persons affiliated with the Minami-Osawa Campus or Hino Campus

If those affiliated with the University other than the Arakawa Campus are involved in the research (as co-investigators, etc.) applying for the Arakawa Campus Research Ethics Committee, they must take the same "Research Compliance Training (including research involving human subjects)" course as those affiliated with the Arakawa Campus.

3-2 Persons not affiliated with the Tokyo Metropolitan University

(1) Persons who have already taken the ethics training at their affiliated institution

In the case of those not affiliated with the Tokyo Metropolitan University who have already taken the ethics training at their affiliated institution, a copy of the ethics training certificate should be attached to the research protocol (even if the certificate is valid within the effective period stated on it, the effective period stipulated by the University is within one year from the date of training). If one year has passed since the date of training as of the application date, the following (2) - 2) should be deemed to apply.

* If the certificate is not issued and the "status of training completion, name of the attendee, and date of the training" are displayed on the PC screen, attach a copy of the screen capture.

(2) Persons who can take ethics training in Japanese or English and who meet any of the following criteria:

1) Those who have difficulty in taking ethics training at their affiliated institution
2) Those who have already taken ethics training, but one year has passed since the date of the training and it is difficult to retake the training.
3) Those who have already taken the ethics training within the past year, but do not have any documentation to prove the completion.

Those who fall under the above should take the e-learning course from the website of the Japan Society for the Promotion of Science individually and attach a certificate of training completion, showing attendance within the past year, to the research protocol.

* Japan Society for the Promotion of Science (Free tuition and individual registration required)
e-Learning Course on Research Ethics [eL CoRE]
https://elcore.jsps.go.jp/top.aspx

Training course: Select either of the following two courses
[For researchers] "Learning/Thinking" Research Ethics by Case Study - Tips for Honest Scientists -

[For graduate students] "Learning/Thinking" Research Ethics by Case Study - Tips for Honest

Scientists -

* Those who do not plan on being involved in research funding are advised to take the course for graduate students.

(3) Persons who have difficulty in taking the training course in Japanese or English

For those who fall under (2) above and have difficulty in taking the training course in Japanese or English, the principal investigator is responsible for providing ethics guidance to such co-investigators, etc. A certificate of ethics guidance attendance stating the content, date of guidance, and the instructor's name should be attached (and any forms other than the specified form are acceptable if the same contents are stated). When conducting research over multiple years, the principal investigator should provide the same guidance at least once a year and ask for attendance.

The certificate of ethics guidance attendance can be substituted for the certificate of research ethics training completion (Effective period: one year from the date of attendance).

If taking the training course in Japanese or English is possible, the ethics guidance conducted by the principal investigator is not permitted.

4. Courses, Units, and Effective Periods for Persons Affiliated with The Arakawa Campus

Those affiliated with the Arakawa Campus should take training through the APRIN e-learning program.

(1) Course to be taken: Research compliance training (including research involving human subjects) Effective period: one year from the date of attendance

Unit: [1] "Digest of research involving human subjects"
[2] "Digest of Responsible Conduct of Research"
[3] "Handling of Public Research Expenses"

* For undergraduate and graduate students, units [1] and [2] are required. For other persons, unit [3] is also required in addition to units [1] and [2].

(2) Granting of Course IDs

1) Persons who can take classes according to the guidance e-mail

[1] Full-time faculty members of Tokyo Metropolitan University

[2] First year graduate students (master's and doctor's courses) and junior (third year of undergraduate) students

From the end of July to the beginning of August, the guidance email from the department in charge is sent to the address provided by the University regarding the ID and password. After receiving the notification, follow instructions and take the course by the designated date.

If the course is not taken by the designated date, reminder emails are sent until the course is taken.

(For students who entered in Autumn, the guidance email is sent in late October)

* Those who want to take the course before receiving the guidance email from the department in charge (after April), refer to (3) below and apply for ID registration to the secretariat (responding individually).

2) Graduate students other than above (2nd year of master's and 2nd and 3rd year of doctor's courses) and senior (4th year of undergraduate) students

Basically, the course can be taken at any time (except during the academic year renewal).

* State the required information and contact the secretariat.

* Logging in or taking courses is not possible during the leave of absence period.

Apply for ID registration after returning to the University.

3) Other than full-time faculty members or regular students (research students, visiting researchers, specially appointed faculty members)

Since individual registration is required, write the following required information and apply for ID registration by e-mail to the secretariat.

* The registration is only for one year and the registered information is deleted at the end of the academic year.

Even if you continue to belong to the same affiliation from the previous year, apply for ID registration again after confirming the affiliation (after April 1st).

(3) Required information for issuance of ID and password

- Name
-Title at the University (e.g. research students, visiting researchers, specially appointed faculty members, etc.; for students, department and year)
- Individual number (e.g. research student number, student number, employee number)

If no individual number is provided, state so.

- E-mail address provided by the University

Persons other than students without an e-mail address provided by the University, state so.

* Address for ID issuance application

Secretariat: a-rinri@jmj.tmu.ac.jp

Subject: ID Issuance for Research Ethics Training System

* ID cannot be issued immediately; apply well in advance (allow 1 week to 10 days).

(4) How to take the course

1) Log in individually using the username (ID) and default password.

Login URL: https://edu.aprin.or.jp/

2) After completing the research ethics course, take the comprehension measurement test.

3) The training is completed with a test score of 80% or higher. The training completion certificate is issued and should be kept.

* For details on how to operate the e-learning system, refer to the eAPRIN User's Manual.
https://www.aprin.or.jp/e-learning/usersmanual

*** Notes for all attendees**

After downloading the certificate of attendance, keep the certificate in a safe place.

[1] Information is deleted at the end of the academic year.

After a new academic year has started, the certificate from the previous year cannot be downloaded.

[2] The effective period stated on the certificate and the effective period permitted by the Ethics Committee (one year from the date of attendance) are different.

Chapter 7 Regular Review

At the Arakawa Campus, the Research Ethics Committee conducts a regular review once a month. The following is the overview of the review. Subcommittee meetings are held in each department.

1. The study plan subject to regular reviews
   - Research involving intervention
   - Research using specimens without involving intervention
   - Research involving invasiveness

2. Documents for submission

   A complete set of application documents
   - Items [1], [2], **[19], and ②, ③** are mandatory.
   - Add documents of other items as necessary.
   - The order of documents for submission is as follows:

[1] Ethics Review Application Form (appended form No. 1)
[2] Research Protocol (Designated form)
[3] Explanation Form for research subjects
[4] Consent Form for research subjects
[5] Consent Withdrawal Form for research subjects
[6] Request Form for collaborative research-implementing entity
[7] Consent Form for collaborative research-implementing entity
[8] Posters, leaflets, and other publicity materials for recruiting research subjects
[9] Survey materials for obtaining information (questionnaire forms, etc.)
[10] Interview guide
[11] Explanation materials for MRI, NIRS, and ultrasonic imaging
[12] Written Approval for MRI, NIRS, and ultrasonic imaging
[13] Report on Provision of Specimens and Information
[14] Application / Report on Provision of Specimens and Information
[15] Agreement (In case of outsourcing, the attachment of the quotation is unnecessary.)
[16] Copy of the Certificate of Approval from the Ethics Review Committee of another institution
[17] The documents that the attendance of the ethic committee was written in the committee mentioned above
[18] Application documentation package (study plans etc.) approved with another institution
[19] Japanese manual of research ethics review
[20] Copy of Notification of Review Results (for an application after a recommendation for change)
[21] References and materials related to the research

[22] Other (add as appropriate)

< Documents to attach in the last of application documents>

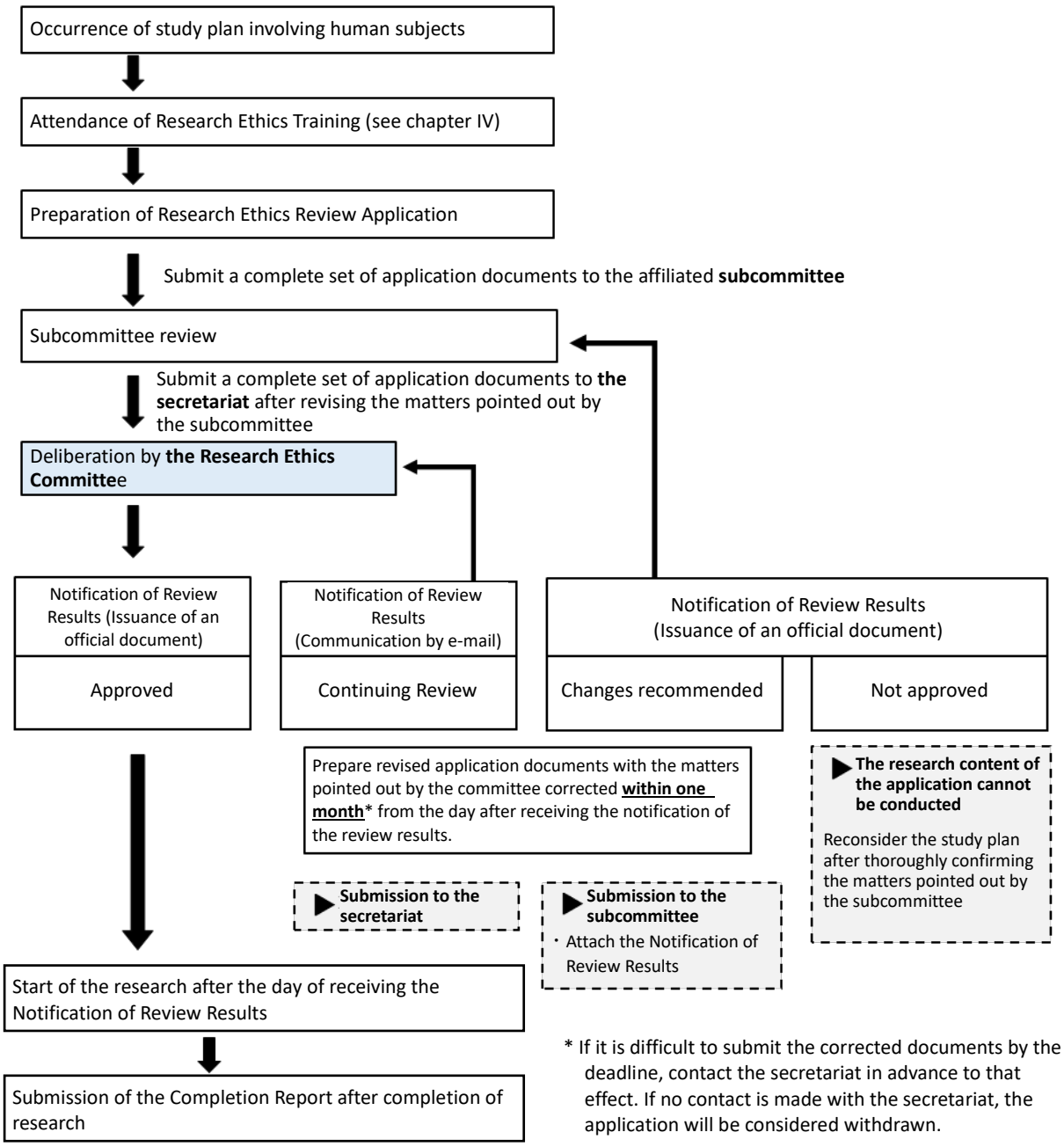
※document number unnecessary

① Copy of Consent Form for Co-investigators or Share-investigators, etc.

② Copy of the Certificate of Research Ethics Training (e.g. APRIN) Attendance, for all members

③ Checklist

◆Flow from Regular Review Application to Completion of Research



* If it is difficult to submit the corrected documents by the deadline, contact the secretariat in advance to that effect. If no contact is made with the secretariat, the application will be considered withdrawn.

Chapter 8 Expedited Review

At the Arakawa Campus, the Research Ethics Committee conducts an expedited review twice a month and the subcommittee is held in each department.

1. The study plan eligible for expedited review

Categories of "Ethics Review Application"

(1) Review of multi-institutional collaborative research and its entire research has already been reviewed and approved by the Ethics Review Committee.

(2) Review of research in which the entire project has already been reviewed and approved by the Ethics Review Committee in a research-implementing entity other than the University.

(3) Review of research not involving invasiveness, and research not involving intervention

(4) Review of research involving minor invasiveness, and research not involving intervention

(5) Review of research involving changes in the study plan that are not considered a minor change

(6) Review of research receiving recommendations for change in the regular review

(7) Review of research, other than the above, that is subject to the Expedited Review by the consent of all members present at the Committee meeting

* If (5) applies, refer to "Chapter 12 Changes to the Study Plan, etc." separately.

2. Documents for submission

A complete set of application documents

- Items [1], [3], [**20**], and ②, ③ are mandatory.
- Attach documents of other items as necessary.

[1] Ethics Review Application Form (appended form No. 1)

[2] Revision Application Form (for making changes in the study plan that are not considered minor)

[3] Research Protocol (Designated form)

[4] Explanation Form for research subjects

[5] Consent Form for research subjects

[6] Consent Withdrawal Form for research subjects

[7] Request Form for collaborative research-implementing entity

[8] Consent Form for collaborative research-implementing entity

[9] Posters, leaflets, and other publicity materials for recruiting research subjects

[10] Survey materials for obtaining information (questionnaire forms, etc.)

[11] Interview guide

[12] Explanation materials for MRI, NIRS, and ultrasonic imaging

[13] Written Approval for MRI, NIRS, and ultrasonic imaging

[14] Report on Provision of Specimens and Information

[15] Application / Report on Provision of Specimens and Information

[16] Agreement (In case of outsourcing, the attachment of the quotation is unnecessary.)

[17] Copy of the Certificate of Approval from the Ethics Review Committee of another institution

[18] The documents that the attendance of the ethic committee was written in the committee mentioned above

[19] Application documentation package (study plans etc.) approved with another institution

[20] Japanese manual of research ethics review

[**21**] Copy of Notification of Review Results (for an application after a recommendation for change)

[**21**] References and materials related to the research

[**22**] Other (add as appropriate)

< Documents to attach in the last of application documents>

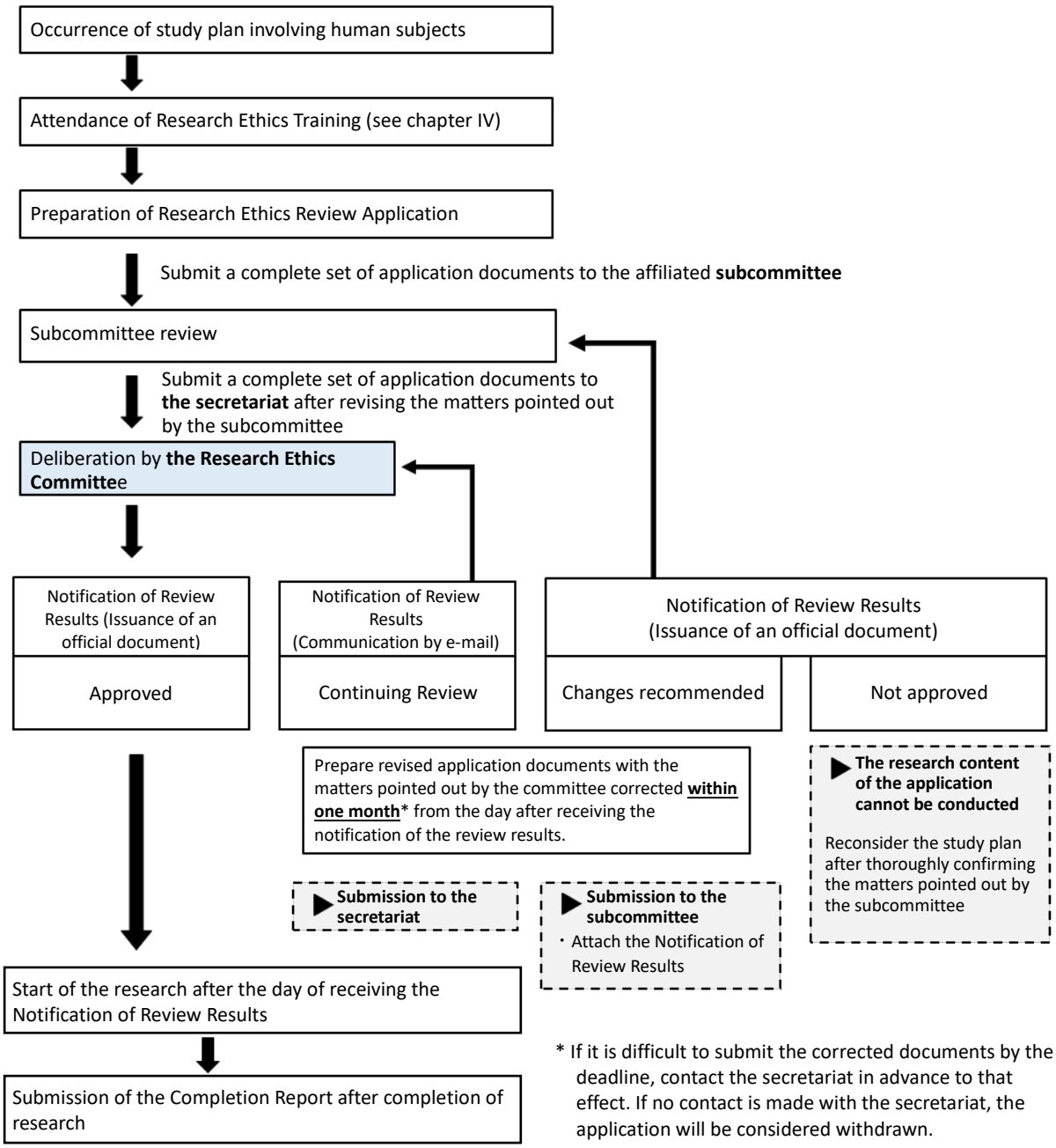
※document number unnecessary

① Copy of Consent Form for Co-investigators or Share-investigators, etc.

② Copy of the Certificate of Research Ethics Training (e.g. APRIN) Attendance, for all members

③ Checklist

◆Flow from Expedited Review Application to End of Research



* If it is difficult to submit the corrected documents by the deadline, contact the secretariat in advance to that effect. If no contact is made with the secretariat, the application will be considered withdrawn.

Chapter 9 Simplified review (research conducted mainly by undergraduate students)

Apart from the regular and expedited reviews, there is a simplified review conducted only by the subcommittee. The simplified review can be applied only to research conducted mainly by undergraduate students in their graduation research, etc.

1. The study plan that can be considered for an expedited review

If the research conducted mainly by undergraduate students falls under any of the following, the research may be subject to an expedited review by the subcommittee.

- Observational research with little impact on research subjects
- Research not involving invasiveness
- Research that causes little physical or mental injury or burden to the research subjects (minor invasiveness)

* For research involving intervention or invasiveness and using specimens, the supervisor should be an applicant and the research must undergo a regular or expedited review.

2. Subcommittee review

The applicant should prepare the necessary documents and submit them electronically in accordance with the method specified by the applicant's affiliated subcommittee.

Documents for submission

- Items [1], [2], [6], and [7] are mandatory.
- Attach documents of other items as necessary.

[1] Application Form (appended form No. 1)
[2] Research Protocol (designated form)
[3] Survey materials for obtaining information (questionnaire forms, etc.)
[4] Interview guide
[5] Consent Form to Participate in the Research (Consent Forms of all co-investigators, research collaborators, etc., are required)
[6] Copy of the Certificate of Completion of Ethics Training within the valid period (copy) (Certificates of all principal investigators, supervisors, co-investigators, research collaborators, etc., are required)
[7] Checklist

3. After receiving the approval from the subcommittee, a complete set of approved documents is submitted to the secretariat attached to e-mail.

Documents for submission: Documents in which all red revisions pointed out during the

subcommittee review have been changed to black

* If the documents are incomplete and the application cannot be accepted, the documents will be returned to the applicant.

Deadline for submission: Anytime (once approved by the subcommittee review)

Flow from Expedited Review Application to Start of Research

Applicant (undergraduate student)	Subcommittee	Committee (secretariat)
[1] Submit a complete set of application documents to the affiliated subcommittee	[2] Determine whether the application is eligible for simplified review -> In the case of "Incomplete documents," application not approved *1 In the case of "Review not required," the application will be returned [3] Start review [4] Give notification of the review results	
[5] Receive the review results **A. Approved** => Submit a complete set of application documents to the secretariat -> Proceed to step [10] **B. Revision required** => Submit a complete set of revised documents to the subcommittee -> Proceed to step [6]	[6] Accept revised documents Start second review [7] Notify the second review results	
[8] Approved*2 => Submit a complete set of approved application documents to the secretariat -> Proceed to step [10]	[9] Submit Approval List of Simplified Reviews to the secretariat (twice a month, on the 1st and 15th)	[10] Accept a complete set of approved application documents => Start procedures to issue the Notification [11] Issue Notification of Review Results
[12] Receive Notification of Review Results *3 [13] Start research *4 [12] Complete research [13] Submit Completion Report to the secretariat		[12] Receive Completion Report

*1 If the application is not approved, perform procedures for an expedited or regular review.

*2 Revise documents until the approval is obtained.

After the approval, submit a complete set of documents, with all text changed to black, to the secretariat.

The procedure for issuing a notification will not take place until the documents are submitted.

*3 Receive the Notification of Review Results from the supervisor.

*4 The research cannot be started until receiving the Notification of Review Results.

Chapter 10 Notification of Review Results

The official document of the final review results ("Approved," "Changes recommended," or "Not approved") decided through the committee is issued by the chief executive of the research-implementing entity.

The secretariat will notify you of the results of the review about two weeks after the date of the committee meeting. In cases other than "Approved," the research cannot be conducted until the notice of "Approved" is received.

1. Types of Review Results

(1) Approval
(2) Continuing Review
(3) Changes recommended
(4) Not approved

2. How to receive the Notification of Review Results (for graduate students, research students, etc.)

For non-undergraduate students, select how to receive the notification from the following and state in the application form.

(1) Receipt from the supervisor
(2) By mail: Send the application to the secretariat in advance, using a letter pack or other similar package with the recipient's name written on it and which allows for tracking of the delivery status.

3. Commencement of research

Note that the research cannot be started until the principal investigator receives a notification of "Approved."

Chapter 11 Response to the Review Results

1. “Approved”

The application is “Approved” when there are no findings at all on the submitted set of application documents following deliberation by the committee. The Secretariat applies to the Dean of the Graduate School for permission to conduct research (application by proxy), and then a notification of approval (notification of research implementation permission) is issued based on the approval results of the Committee.

The research can be started after the principal investigator receives a notification of "Approved.”

2. "Continuing Review"

The application is considered a “continuing review” when there are any revisions, changes, or matters to be confirmed in the study plan or the attached application documents.

The applicant should correct the matters pointed out by the Committee of which the applicant was notified by the secretariat, in the "Ethics Review Application Form" (appended form No. 1) in red, in addition to the matters pointed out by the subcommittee, and prepare a complete set of application documents. The revised application documents should be sent to the secretariat within one month from the day after receiving the notice.

If it is difficult to submit the corrected documents within one month, contact the secretariat to notify them in advance to that effect or to withdraw the application. If no contact is made with the secretariat after the deadline, the application will be considered withdrawn.

The committee confirms the matters pointed out have been properly corrected, and then categorizes the application as "Approved."

3. “Changes recommended”

The application is categorized as “Changes recommended” by the committee when the content of the study plan is found to be significantly ethically inappropriate or it is judged that the entire study plan needs to be revised.

The applicant should write a summary of correction responding to the matters pointed out in the notification in the "Ethics Review Application Form" (appended form No. 1), make corrections in red, and prepare a complete set of application documents within one month from the day following the notification issuance date (the date stated on the upper right of the notification). The revised application document, with a copy of the Notification of “Changes recommended” attached to the last page, should be submitted to the subcommittee and undergo subcommittee review.

If it is difficult to submit the corrected documents within one month, contact the secretariat to notify them in advance to that effect or to withdraw the application. If no contact is made with the secretariat after the deadline, the application will be considered withdrawn.

After the subcommittee review, add or correct the matters pointed out by the subcommittee in red, prepare a complete set of application documents, and send it to the secretariat.

4 "Not approved"

The committee, in principle, only reviews the ethical aspects of the study plan.

However, if the research methods violate other provisions, or if a part of the research is clearly inappropriate due to safety issues for the research subjects, and it is judged that the research cannot be carried out as the part relates to the entire study plan, the application is categorized as “Not approved.”

The applicant should reconsider the study plan and submit a new application.

5. Objections to the review result

The applicant may request a second review if there is an objection to the review results of the committee (including the contents of the matters pointed out). A request for a second review should be made by the applicant himself/herself by submitting the "Request for Second Review of Research Ethics" (appended form No. 3) to the secretariat.

A request for a second review should be made within two weeks from the day after the notification issuance date (the date stated on the upper right of the notification) (or the date of the contact from the secretariat in the case of “continuing review”). The request can be made only once for one study plan (one receipt number).

Chapter 12 Changes in the Study Plan

If the applicant intends to conduct research that differs from the contents of the research protocol after receiving the "Approved" notification, the research protocol must be changed in advance.

Note that the research on the changed part cannot be conducted until the application is approved, regardless of the contents of changes.

1. Conditions for review of study plan revision

(1) This only applies when the contents of changes **constitute "minor changes."**

Minor changes are defined as the following items.

Minor changes

[1] Change in the title of research topic (Changes are possible only if they do not affect the content of the research)

[2] Change of the supervisor

[3] Change in the researcher's name, job title, and the affiliation, etc., that do not fall under the interests of the research

[4] Addition or deletion of a co-investigator, etc., who is not an interested party in the research

[5] Change in research funds that do not fall under the interests of the research

[6] Change in the research location

[7] Change in the research period (within 5 years from the initial research start date)
(Approval of the subcommittee is required if the research period exceeds five years from the initial research start date)

[8] Change in the number of research subjects

[9] Change in the location and method of storing specimens and information, and a change of person responsible for their management

[10] Changes other than the above items (approved as minor changes by the affiliated subcommittee)

[11] Change after the approval of research implementation permission (change approved by the approved research-implementing entity)

~~[12] Changes in the study plan that are not considered a minor change (application for a revision due to expedited review)~~

* If [1] through [9] do not apply, consult with the applicant's affiliated subcommittee in advance and apply for changes after obtaining approval (applicable to [10]).

If the affiliated subcommittee determines that "Deliberation in the committee is appropriate, " the committee will deliberate whether the changes are minor or not. If the changes are minor, the committee will also decide whether to approve the changes.

(2) When the content of the changes does **not constitute "minor changes"**

If the Subcommittee or the Committee determines that the change does not fall under "minor changes," the applicant should prepare the Revision Application Form "[12] Change in the study plan that is not considered a minor change (application for a revision due to expedited review)" for taking expedited review.

2. The following cases do not constitute "minor changes."

[1] Contents concerning the protection of human rights of research subjects

[2] Contents in the method for obtaining the understanding and consent of research subjects

[3] Contents of disadvantages, burdens, and risks of research subjects

*** Changes in the method and content of data acquisition do not constitute minor changes.**

Documents for submission

(1) Study Plan Revision Application Form (appended form No. 6)

List changes briefly by item.

(2) Application Form (appended form No. 1) (Revised in red based on the contents of changes in the study plan)

* Do not delete items of the Revisions and Changes Histories in the past Ethics Review Application Form.

(3) Research Protocol

In the current study plan (written all in black), make additions or revisions in red only to the sections that are changed according to the study plan to be applied.

(4) Attached documents (Revised in red based on the changes in the study plan and renewed documents)

[1] Letter of Request and Consent Form addressed to the Research-Implementing Entity

=> If a new research-implementing entity is added, add a request form as necessary.

[2] Copy of Consent Form to Participate in Research

=> If co-investigator, etc., is added, add the Consent Form of the person concerned.

[3] Copy of the Certificate of Research Ethics Training Attendance within the effective period

=> If co-investigator, etc., is added, add the Certificate of Attendance of the person concerned.

For other persons, replace with documents within the effective period

(Certificates of all principal investigators, supervisors, co-investigators, research collaborators, etc., are required)

(5) Checklist (**Replace with the latest version**)

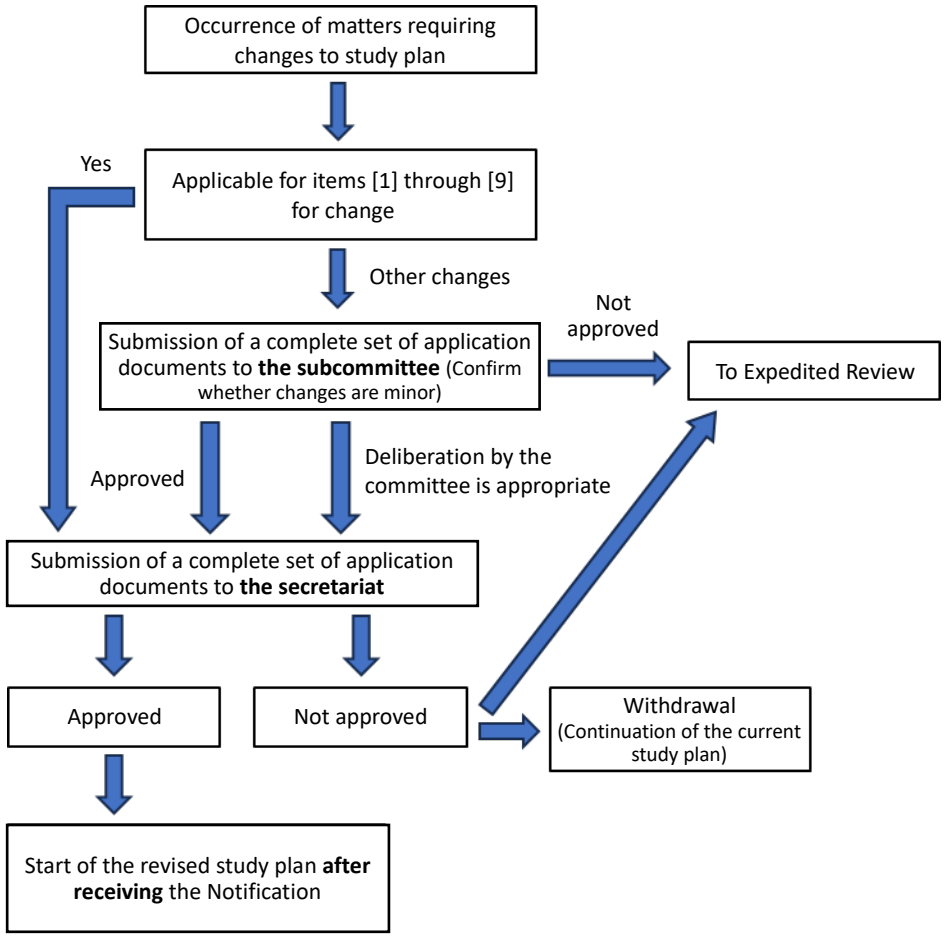
Informed consent when changing the study plan

When conducting research with changes in research protocol, the procedures for informed consent should be performed again, in principle, for the changed parts. The principal investigator should describe the application of the principle in the research protocol after considering the contents of the research and the burden on research subjects, etc., related to informed consent procedures, etc.

As a result of the review, it is possible to omit the explanation of the changes approved by the Dean of the Graduate School in response to the opinion of the committee (provided that it is made clear that the

explanation has been omitted for any parts where this is the case, and the research protocol should be made available for disclosure upon request of the research subjects, etc., at a later date).

◆ Flow of Procedures for Changes in Study ◆



* Until the new study plan is approved, conduct the research according to the current contents.

After the application for changes in the study plan is approved and the notification is received, it is possible to conduct the research with the changed contents. Therefore, take sufficient time to apply.

*** Cases involving a change in an applicant's status do not constitute a change in the study plan.**

- Change from master's course to the doctor's course due to advancement
- Change status from graduate student to research student, etc.

* If the affiliation (graduate school course, etc.) of the principal investigator changes during the research period, a new ethics application should be submitted. The maximum research period will be the period of enrollment in the new status (up to a maximum of five years if the student plans to use the long-term enrollment system and the enrollment period is scheduled to exceed five years).

After the status change is confirmed (after the new academic year): Reapply under the new status and obtain a new approval number.

=> Submit a completion report for the study plan with the approval number before the change of status.

Chapter 13 Research Period

There is no time limit set on the validity of approval for research ethics review; however, the applicant should consult with the committee chairperson if the research extends for more than five years.

In addition, if the principal investigator conducts the research beyond the research period specified in the research protocol, he/she must apply for a change of the study plan according to the procedure “X. Changes of The Study Plan” at least 30 days before the period completion.

1. Effective period of the Research Ethics Committee review

The review by the Research Ethics Committee is valid only while the principal investigator is enrolled in the University and conducting approved research. If the principal investigator wishes to continue the research after leaving the University, perform necessary procedures after confirming with the subcommittee chair of the affiliated department.

2. Timing of research period completion

Undergraduate and graduate students	Faculty members and Researchers
- Leaving the University (Graduation, Completion, Withdrawal, etc.) - When the research is discontinued - When a thesis is submitted (In the case of research mainly involving the submission of a thesis)	- Leaving the University - When the research is discontinued - When the presentation at the academic conference is completed (In the case of research mainly focusing on conference presentations) - Publication of books (In the case of research mainly involving the publication of books) - Submission of a paper (In the case of research mainly involving the submission of a paper) - Submission of reports on funded research, etc. - Completion of data acquisition

3. Actions after the completion of research

Able	Unable
- Confirmation of the information source - Submission or re-composition of a paper However, addition of methods and data by revising are not allowed.	- Addition or change of research targets and methods - Data analysis

* If visiting researchers, research students, etc., continue to conduct research

After the new academic year (after the status is confirmed), conduct procedures to apply for changes to the approved study plan (maximum enrollment period of one year) to extend the research period.

Chapter 14 Submission of Completion Report

After the termination or completion of the research, the principal investigator shall prepare a "Research Completion Report" (appended form No. 4) within 60 days of the completion of the research or while the principal investigator is in the University, and make sure to submit it to the secretariat electronically.

If the principal investigator has to leave the University due to withdrawal, etc., the report shall be submitted even if the research has not been completed, and the relevant report must be submitted again after the research is completed.

Chapter 15 Storage of Specimens and Information

When storing specimens and information, etc., the principal investigator shall provide guidance and control to researchers, etc., so that the information, etc., can be accurate, and shall perform necessary management to prevent leakage, mixing, theft, loss, disposal, etc., of specimens and information, etc. In addition, necessary measures shall be taken to make them available for submission upon request.

When managing research data, the storage method specified by laws and regulations and company regulations must be observed, and in addition, it must be appropriately stored in a manner and in the place(s) specified by each department as follows.

Refer to "東京都立大学 情報セキュリティ実施手順"

Retention period (common to all departments)

- At least until the day on which 5 years have passed from the date of submission of the "Research Completion Report" (appended form No. 4) or the day on which 3 years have passed from the date of reporting the final publication of the results of the research, whichever is later

Department of Nursing Sciences

- While in the University: In principle, the principal investigator will keep the materials in the graduate student's room or laboratory (however, since there are not enough desks and lockers to keep them in the graduate student's room, a lockable desk at home is also acceptable.)
- After completion: The principal investigator shall specify the new storage location in the "Research Ethics Report" (appended form No. 4) and manage it at that location

Department of Physical Therapy

- While in the University: If the research is conducted in the University, store research materials in a lockable shelf in the laboratory (in the case of a student, store it in the supervisor's room).
- After completion: Same as while in the University

Department of Occupational Therapy

- While in the University: In principle, keep the materials in the graduate students' room
- After completion: Keep the materials in supervisor's laboratory

Department of Radiological Sciences

- While in the University: In principle, keep the materials at each laboratory
- After completion: The principal investigator shall retain them

Department of Frontier Health Sciences

- Keep the documents in accordance with the instructions of the supervisor

Chapter 16 Ethic Review Application for Visiting Researchers

1. Period of Acceptance and Research for Visiting Researcher

In accordance with the rules for visiting researchers from corporations, "the period of acceptance for visiting researchers shall be within one year," the period that they are accepted as a "person affiliated with the University" shall be the same as the period of acceptance under the Guidelines for Arakawa Campus as well.

2. Ethics Review Application

1) Research period

The research period for the study plan submitted to the Ethics Committee shall be set within the period of acceptance for visiting researchers.

2) If the visiting researcher wishes to continue the research beyond the period initially set for the research

If the acceptance of the visiting researcher is approved for the following year, proceed with changing the research plan (extending the research period) and apply to the Ethics Committee to obtain approval.

When a change occurs in the research protocol other than the research period, the necessary application shall be made in accordance with the content of the change.

* "Prospect of renewal" is not available for visiting researchers.
  - After the new academic year starts and your status is confirmed (after receiving an official document approving you as a visiting researcher), proceed with the change application process.
  - The APRIN course history will be deleted at the end of the fiscal year, so download the certificate after taking the course and keep it in a safe place (the certificate issued within one year needs to be attached when applying for changes).

Chapter 17　　Glossary of Terms

The definitions of terms used in the Ethical Guidelines of the Arakawa Campus Research Ethics Committee are compliant with the "人を対象とする生命科学・医学系研究に関する倫理指針ガイダンス "（"Guidance on Ethical Guidelines for Medical and Biological Research Involving Human Subjects (Partial Revision on April 17, 2023)."）

The terms in this section are excerpted and summarized for the University, for the purpose of confirming the minimum requirements before preparing a research protocol, so please refer to the above mentioned guidance for details. These are reference English translations.

(1) Medical and Biological Research Involving Human Subjects

Activities conducted for the purposes (a) or (b) below, targeting human participants:

(a) Through the following [1], [2], [3] or [4], to obtain knowledge that contributes to the maintenance and promotion of the health of citizens, or the recovery from disease or improvement in the quality of life of patients

[1] Understanding of the causes of diseases (including the frequency and distribution of various health-related events and factors affecting the events)

[2] Understanding of the disease state

[3] Validation of improvement and efficacy of disease prevention methods

[4] Validation of improvement and efficacy of diagnostic and treatment methods for medical treatment

(b) To obtain knowledge concerning the structure or function of the human genome and genes, and mutation or expression of genes, by using human-derived specimens and information

(2) Invasion

An injury or burden to the body or mind of a research subject caused by puncture, incision, drug administration, irradiation, or questions that may touch on psychological trauma, etc., conducted for the purpose of research.

Among the invasions, those that cause only minor physical or mental damage to research subjects are called "minor invasions."

Whether or not applying a certain type of exercise load to a research subject for the purpose of research is considered "invasive," and when it is considered "invasive," whether or not the invasion is regarded as a "minor invasion," the judgment requires comprehensive consideration on the inclusion criteria for research subjects, the environment where the exercise load is applied, etc., in addition to the content of the exercise load.

The degree of injury and burden that may occur to the mental state of research subjects may be judged based on the mental distress, etc., that is generally assumed in the research subject population.

1) Cases considered to be invasive

[1] Irradiation conducted under certain conditions for research purposes

[2] When asking questions (questions that touch on trauma) about a painful experience that the person

does not want to recall (for example, disaster, accident, abuse, past serious illness, etc.)

[3] When a mental burden is applied to the research subjects by acting in a manner that intentionally disturbs their mental homeostasis, such as causing tension, anxiety, etc., for the purpose of research

2) Cases that may be judged as minor invasion

[1] When MRI imaging without contrast agent is performed for research purposes, and when there is no physical or mental burden on the research subjects due to behavioral restrictions for a prolonged time, etc.

[2] When sufficient consideration has been given, such as a questionnaire survey with a clear notation that there are contents which may cause psychological distress, etc., to the research subjects, and with options for the research subjects to answer anonymously or to refuse to answer, etc.

[3] When conducting research using NIRS, when there is no physical or mental burden on the research subjects due to behavioral restrictions for a prolonged time, etc.

3) Cases judged to be non-invasive

[1] Collecting naturally excreted urine, feces, sputum, saliva, sweat, or shed hair/body hair for research purposes

[2] When there is no physical and mental burden on the research subjects caused by behavioral restrictions for a prolonged time, etc., while performing measurements of surface electromyogram or electrocardiogram, or capturing ultrasound images for research purposes

[3] When changes in physical homeostasis (increased respiration, heart rate, sweating, etc.) caused by exercise load are resolved in a short time with appropriate rest or hydration

(3) Intervention

Research activities that control the presence, absence, or the degree of factors that affect various human health events (including activities that lead to the maintenance and improvement of health, and medications, tests, etc., for prevention, diagnosis, or treatment of diseases in medical treatment) (including medical activities that exceed ordinary medical care and are conducted for research purposes).

"Various human health events" refers to the state of injury or disease in individual patients, as well as trends in health status and in occurrence of certain diseases in a group of individuals with common attributes (cohort).

In addition to "activities that lead to the maintenance and improvement of health" and "medications, tests, etc., for prevention, diagnosis, or treatment of diseases in medical treatment," factors that affect human health events and can control the presence, absence, or degree of the events include, for example, nursing care, lifestyle guidance, nutrition guidance, diet therapy, and occupational therapy.

Possible behaviors in daily life, such as moderate exercise, sleep, balanced diet, and smoking cessation, are considered "activities that lead to the maintenance and improvement of health."

"Medical activities" includes not only the treatments for patients, but also the treatments for healthy people and activities not intended for prevention, diagnosis, or treatment of diseases and injuries.

"Control" means to intentionally cause or prevent changes. One example of an intentional change is to change the brain activity or the psychological state by giving a sensory stimulus, such as visual or auditory stimulation.

1) Research involving "interventions"

[1] To conduct assignment or random assignment (including cases where blinding or masking is performed) based on a research protocol with regard to methods of treatment, diagnosis, and prevention for injury or disease, and other factors that may affect the health of research subjects.)

[2] Conduct assignment or random assignment according to the research protocol, even if it does not involve medical activities beyond the usual medical care.

2) Research not involving "interventions" (observational research)

When medical information, such as an outcome and prognosis of a patient suffering from a disease or injury, is obtained for research purposes without controlling the presence, absence, and the degree of medication, test, etc., for diagnosis and treatment.

3) Research not involving "invasions" but involving "interventions"

When different types of care are provided prospectively in order to compare and verify the effects of different types of care. For example, when providing new methods, such as guidance for quitting smoking and diet therapy, and allocating subjects to investigate the differences from the conventional methods.

(4) Specimens

Blood, body fluid, tissue, cell, excrement, and DNA extracted from these acquired from human bodies and used for research (including that related to the deceased).

(5) Information used in research

Any information on human health and others used in research (including information on the deceased), including the name of disease, details of medication, results of tests or measurements, etc., acquired through diagnosis and treatment of a research subject (including those recorded in nursing records, etc., in addition to those recorded in medical records).

Information used in research is not dependent on whether or not a particular individual can be identified by such information. Information accompanying the "specimens" in (4) and information acquired by analyzing the "specimens" are also included.

In addition to information acquired from research subjects, information on human health-related events published in, for example, the Vital Statistics, the National Health and Nutrition Surveys, and the National Epidemiological Surveillance of Infectious Diseases, etc., is also included.

(6) Specimens and Information

Specimens and Information used for research.

(7) Existing specimens and information

Any specimens and information that falls under any of the following:

[1] Specimens and information that already exist by the time the research protocol is prepared

It applies to the specimens/information acquired from the research subjects before the preparation of the research protocol. The background of the acquisition of the specimens/information from research subjects (e.g., the institution where the specimens/information was acquired, or the purpose for which the specimens/information were acquired) does not matter.

[2] specimens/information acquired after the preparation of the research protocol, which were not intended to be used for the research of said research protocol at the time of acquisition.

It applies to the specimens and information acquired from the research subjects after the preparation of the research protocol for the research concerned, excluding those newly acquired from the research subjects for the purpose of use in said research.

- Specimens and information acquired from the research subjects for a purpose different from that of said research (provision of medical care, use in research other than that stated, etc.) at the research institution.

- Specimens and information acquired from the research subjects for a purpose other than said research at the institution other than said research institution, and provided to said research institution for use in said research

It shall be noted that the "existing specimens/information" in these Guidelines may include specimens/information acquired from the research subjects after the preparation of the research protocol. For example, samples (so-called residual samples) or information (medical information recorded in medical records, test data acquired in the course of medical care, etc.) acquired from patients (research subjects) for medical care that is not intended for research purposes fall under [1] if the time of obtainment from patients (research subjects) is before the preparation of the research protocol, and fall under [2] if the time is after the preparation of the research protocol. In either case, they fall under "existing specimens/information" specified in these Guidelines.

<Reference: Classification of "specimens/information" in this Guideline>

Existing specimens and information:

- Residual specimens, medical records
- Specimens and information acquired from research subjects in the conduct of research different from the research concerned

Newly acquiring specimens/information (specimens/information other than those listed above):

- Specimens and information to be acquired from research subjects for use in the research
- Specimens and information to be acquired from patients (research subjects) for the purpose of

research in advance, in addition to medical care outside the research purposes

(8) Genetic information

Information that can be passed on to offspring, which is available to acquire through the process of research using the specimens/information or which is already accompanying the samples/information, and that indicates the genetic characteristics and constitution of an individual.

(9) Research institutions

A corporation or governmental agency where research is conducted, or a sole proprietor who conducts research.

However, this shall exclude institutions where only a part of the work related to research is commissioned, such as storage of specimens/information, statistical processing, and other tasks.

When a researcher, etc., participating in the concerned research belongs to a corporation as well as a voluntary organization, and the research is conducted using information which is retained by the corporation and the voluntary organization for the research, the two organizations will become "research institutions" and the research will be regarded as multi-institutional collaborative research conducted collaboratively by the two organizations.

(10) Collaborative research-implementing entities

Research institutions at which research is conducted based on a research protocol in collaboration (including research institutions that newly acquire specimens/information from research subjects for the purpose of the research and provide them to other research institutions).

When a company participates in research held by a medical institution or university, etc., in order to collaboratively conduct the research, the company may be regarded as a "collaborative research-implementing entity."

Institutions to which the "person providing existing specimens/information" belongs or institutions that acquire new specimens/information from research subjects and provide them to other research institutions based on a research protocol, do not necessarily need to become collaborative research implementing entities.

(11) Research cooperating entities

Institutions other than a research institution at which research is conducted based on a research protocol, which acquires new specimens/information from research subjects for the purpose of the research (excluding the acquisition of specimens that involve invasions other than minor invasions) and whose role is only providing them to the research institution.

(12) Institutions that collect and provide specimens and information

Research institutions that collect specimens/information from research subjects or receive and store specimens/information provided by other institutions, and repeatedly and continuously providing them to

other research institutions (hereinafter referred to as "collection/provision").

(13) Academic research institutions, etc.

"Academic research institutions, etc." refers to universities and other institutions or organizations for academic research, or persons belonging to those institutions or organizations.

University hospitals: Regarded as "academic research institutions, etc."

Hospitals, clinics, etc.: Not regarded as "academic research institutions, etc."

(14) Researchers, etc.

The term refers to principal investigators and others engaged in the conduct of research (including performing tasks at an institution that conducts collection/provision of specimens and information). However, such persons, other than those belonging to research institutions, who fall under any of the following are excluded:

[1] A person who newly acquires specimens/information and only provides them to a research institution

[2] A person who only provides existing specimens/information

When a doctor belonging to a medical institution or a person belonging to a public health center only provides a part of the medical information held by that medical institution or a part of the health information of residents held by that public health center, respectively, upon request from a researcher, etc., who intends to conduct research using that information.

When providing existing specimens/information to collaborative research-implementing entities in a research institution as a "provider of existing specimens/information," or when being engaged in the preparation of a research protocol or the writing of a research paper in addition to the provision of existing samples/information, it is considered to fall under "researchers, etc." An institution to which "a person who only provides existing specimens/information" belongs is not considered a research institution.

[3] A person who is commissioned to engage in only a part of the tasks related to a research project

(15) Director of research institution

A representative person of a corporation or head of an administrative organ where a research project is conducted, or the sole proprietor who conducts a research project.

(16) Ethics review committee

A council established to investigate and deliberate on the appropriateness of conducting or continuing a research project and other necessary matters relating to the project from ethical and scientific viewpoints.

(17) Informed consent

The consent is of a research subject, etc., concerning the conduct or continuation of the research (including handling of specimens/information), which is made out of their own will after receiving and understanding a sufficient explanation from researchers, etc., or those who only provide existing specimens/information, about the purpose, significance, methods, burden to be borne by the research

subject, expected results (including risks and benefits), etc., of the research project.

The difference between "informed consent" and "appropriate consent"

When receiving "informed consent," it is necessary to receive consent for the conduct or continuation of a research project after giving sufficient explanation on the matters to be explained, as stipulated in Article 8-5 of the Guidelines.

Receiving "appropriate consent" is different because the consent is received after clearly indicating the matters necessary for a research subject to make a decision on consent (purpose of use of the specimens/information, the fact that the consent can be withdrawn, etc.) in a reasonable and appropriate manner in accordance with the purport of the Act on the Protection of Personal Information and ordinances.

(18) Appropriate consent

The consent is of a research subject, etc., concerning the acquisition and use (including provision) of specimens/information, in which matters necessary for the research subject, etc., to make decisions on consent are clearly indicated in a reasonable and appropriate manner (in the case of personal information, etc., the consent shall satisfy the criteria for the consent of the identifiable person under the Act on the Protection of Personal Information).

Way to "receive appropriate consent"

- Receive an oral expression of consent
- Receive written documents (including electromagnetic records) or emails indicating consent
- Have the confirmation column for consent checked
- Have the button on the website for consent clicked

* In the case of a research project using a questionnaire form that only describes the outline of the research and does not provide a column for confirmation of consent, it cannot be said that "appropriate consent" was received only by the fact that the questionnaire form was collected.

* The term "appropriate consent" in the Guidelines refers only to explicit consent and does not include implied consent.

(19) Proxy consenter

A person who is considered to be able to represent the will and interests of a living research subject and who can give informed consent or appropriate consent to the researchers, etc., or persons who only provide existing specimens/information in lieu of that research subject, in the case where it is objectively judged that the research subject lacks the ability to give informed consent or appropriate consent.

(20) Proxy consenter, etc.

A person, in addition to a proxy consenter, who can give informed consent or appropriate consent to a person who only provides existing samples/information when the research subject is a deceased person.

(21) Informed assent

The term means that a research subject who is objectively judged to lack the ability to give informed consent understands a research project is conducted or continued on the subject and expresses the approval, after receiving an explanation of the research using easy-to-understand terms fitted for the subject's ability to understand.

In foreign countries, "assent" or "informed assent" is often used when a child is a research subject. However, this guideline stipulates that informed assent should be received when research subjects who are objectively judged to lack the ability to give informed consent, not only children, can express their intention to engage in research, depending on their degree of ability to express their intention and the circumstances.

(22) Personal information

"Personal Information" shall mean "information relating to a living individual" which "can identify a specific individual by name, date of birth, or other description contained in said information (including information that can be easily collated with other information and thereby identify a specific individual)" (Article 2, Paragraph 1, Item 1 of the Act on the Protection of Personal Information) or "information containing an individual identification code" (Item 2 of the same paragraph).

The term "information relating to an individual" is not limited to information that identifies an individual, such as name, address, gender, date of birth, and facial images, but includes all information that represents facts, judgments, and evaluations regarding attributes of an individual, such as the body, property, occupation, job title, etc. Evaluation information, information made public through publications, and information in the form of images and sounds are also included, regardless of whether they are kept secret through encryption, etc.

[Examples that fall under personal information]

- Name of an identifiable person
- Information combining the name of an identifiable person with information on the person's date of birth, contact information (address, residence, phone number, email address), and the position or affiliation in the company
- Voice recording information that can identify a specific individual by reason of the inclusion of the individual's name, etc.
- Email address that can identify a specific individual
  (Even if the data is only an email address, such as "kojin_ichiro@example.com," it is possible to recognize that the email address is of Ichiro Kojin who belongs to the Example company.)
- Information related to an individual that is added to personal information after the information was acquired (even if a specific living individual cannot be identified at the time of acquisition, if the specific living individual can be identified as a result of the addition of new information or collation after the acquisition, the information falls under personal information at that time.)
- Information that can identify a specific individual that is made public on websites, social media, etc.

<Classification of MRI/CT Images>

MRI/CT images fall under personal information when a specific individual can be identified from solely the content of the image; when a specific individual can be identified by easily collating the image with other information, such as a name, the whole set of the image together with that information falls under personal information.

On the other hand, when it does not fall under personal information, it is regarded as information related to personal information.

(23) Individual identification code

The term means an individual identification code prescribed in Article 2, Paragraph 2, of the Act on the Protection of Personal Information.

For a detailed definition of the individual identification code, see the Guidelines for the Act on the Protection of Personal Information (General Rules).

(24) Sensitive personal information

The term "sensitive personal information" means personal information that includes descriptions prescribed by Cabinet Order, such as an identifiable person's race, creed, social status, medical history, criminal record, the fact of having suffered harm as a result of a crime, or other information requiring special care so as not to cause unjust discrimination, prejudice, or other disadvantages to that person.

[1] Medical history

It refers to a history of diseases from which a person has suffered, and the part which describes that person's history with a specific disease (e.g., a specific individual has cancer, schizophrenia, etc.).

[2] The person has a physical disability, intellectual disability, mental disability (including developmental disability) or other mental or physical disability as stipulated in the Order of the Personal Information Protection Commission.

[3] Results of examinations that reveal the health status of the identifiable person, and that were conducted for the purpose of prevention and early detection of diseases, such as health examinations, medical examinations, specific health checkups, stress checks, genetic tests (excluding those conducted in the course of medical treatment) and comprehensive medical examinations, etc. The fact that the patient had a medical examination is not applicable.

[4] The fact that the identifiable person has been provided with guidance, medical treatment, or a prescription for improvement of the person's mental or physical conditions by a doctor, etc., or the content of health guidance, etc., provided by a public health nurse, based on the results of medical examinations, etc., or for the reason of illness, injury, or other mental or physical changes. This includes medical records, dispensing records, drug administration history and information recorded in medication notebooks. The fact that the person visited a hospital, etc., and received a prescription at a pharmacy, etc., is also applicable.

This does not apply to cases where information on personal health, such as height, weight, blood pressure, pulse rate, and body temperature, is acquired by a method unrelated to the operations of medical examinations and medical treatment, etc., or tasks related to them.

(25) Adverse events

All unfavorable or unintended diseases or signs (including abnormal laboratory test values) found in the research subjects, regardless of the presence or absence of causal relationships with the research conducted.

If a minor deviation from baseline is found and it can occur under normal conditions, it is not necessarily considered "abnormal," but may be a sign of an adverse event.

(26) Serious adverse events

Refer to adverse events that fall under any of the following:

[1] Results in death

[2] Life-threatening

[3] Requires hospitalization for treatment or prolongation of the hospitalization period

[4] Results in permanent or significant disability/incapacity

[5] Those that cause congenital abnormalities in their offspring

In addition to the measures listed in [1] through [5], in the case of a serious event that does not immediately threaten the life of the research subject or result in hospitalization but may endanger the research subject or require measures to prevent the outcomes listed in [1] through [5], necessary measures shall be taken in accordance with written procedures, etc.

(27) Unexpected serious adverse events

Serious adverse events that are not described in the research protocol or documents for informed consent, or that are described but their nature or severity is not consistent with the description.

(28) Monitoring

Examination, conducted by a person designated by the principal investigator, on the progress of a research project and whether the research is conducted in accordance with the "Guidance on Ethical Guidelines for Medical and Biological Research Involving Human Subjects" and the research protocol, in order to ensure that the research is conducted properly.

(29) Audit

Examination, conducted by a person designated by the principal investigator, on whether a research project is conducted in accordance with the "Guidance on Ethical Guidelines for Medical and Biological Research Involving Human Subjects" and the research protocol, in order to ensure the reliability of the research.

(30) Genetic counseling

Support or assist research subjects, etc., or relatives of research subjects to make their own choices and take actions for their future lives, aiming to eliminate or alleviate medical or psychological problems that may arise around genetic diseases, while repeatedly holding dialogues and providing information to research subjects, etc., or relatives of research subjects, using knowledge of medical genetics and counseling techniques.