# 「Research Involving Human Subjects」

## ～Application Procedures after December 1, 2023～

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Ethics Review Committee for Research Involving Human Subjects

Chair of the committee　Hiroshi Ichinose

(School of Life Science and Technology)

# Differences in ethics review targets for research involving human subjects

- Tokyo Medical and Dental University
  - Medical and biological research involving human subjects (stipulated in the Ethical Guidelines*)
  - Other research for which ethical considerations are deemed necessary (optional application)
- Tokyo Institute of Technology (until November 2023)
  - Medical and biological research involving human subjects
  - Experimental research studies involving human subjects (all applications)

- Tokyo Institute of Technology (from December 2023)
  - Medical and biological research involving human subjects
  - Experimental research studies involving human subjects that require particular ethical consideration for research targets (All cases will be checked using the "Checklist for Ethics Review Requirement" and only applicable cases will be subject to review.)

*Ethical Guidelines for Medical and Biological Research Involving Human Subjects (Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labor and Welfare, and Ministry of Economy, Trade and Industry)

# Changes in Ethics Review Committee for Research Involving Human Subjects

Effective from December 1, 2023

1. New procedure with requirement checklist

Create new checklist to determine whether an ethics review is required. Only studies with applicable items in the checklist are subject to review.

2. Limiting applicants to faculty members

System entry is limited to faculty members (full-time faculty and specially appointed faculty).

3. Expansion of expedited review targets

If certain requirements are met, expedited review will be applied to research that handles personal information or equipment which is a target for ethics review.

4. Simplified procedure for collective review (of collaborative research projects) approved by other institutions

Projects approved via collective review by other institutions may now be exempted from review at Tokyo Tech upon request. The president's approval will be issued upon consent by the Ethics Review Committee Chair.

# 1. New procedure with requirement checklist

From December 1

**Key points of judgement in Checklist for Ethics Review Requirement**

- Applicability to the government's "Ethical Guidelines for Medical and Biological Research"
  - Research to obtain knowledge contributing to maintaining and promoting people's good health or recovery from injury and disease and improving the quality of life for patients
  - Research to obtain knowledge on the structure or function of the human genome and genes, as well as on gene mutation or expression, using human-origin specimens and information
- Potential burden and risk to human subjects
  - Invasive research (including minor cases), interventions
  - Experiments and analysis using specimens (blood, body fluids, etc.) or biological information (brain wave, heartbeat, visual information, etc.) obtained from human research subjects
  - Experiments using equipment created by the researcher themselves or using equipment in a different way from approved usages
- Necessity of "special consideration for human research subjects"
  - Whether voluntariness of participation is secured
  - Whether appropriate handling of sensitive personal information (race, creed, medical history, etc.) is needed
- Other considerations for necessity of ethics review for individual cases
  - Guidelines of academic societies, etc.

# Flow of requirement checks from Dec. 1 (1/2)

1. All individuals who conduct "research involving human subjects" must undergo ethics training by watching the video (Seminar on Ethics of Research Involving Human Subjects) available on Tokyo Tech's Human Subject Research website before the principal investigator applies for an ethics review (the training must be completed once a year).
2. The principal investigator downloads a Word file of the Checklist for Ethics Review Requirement from the website and checks the following items.

- Ethics Review Requirement Checks
- Confirmation of responsibilities of researchers, etc. and their fulfillment of ethical requirements

Important: All principal investigators follow the application procedure (step 3 below) even when they have not checked "Yes" to any of the items in the Ethics Review Requirement Checks.

3. The principal investigator uploads the Checklist for Ethics Review Requirement to the "Other documents attached" section on the system and completes the ethics review application procedure online.

# Flow of requirement checks from Dec. 1 (2/2)

- If you check "Yes" to any of the items in the "Ethics Review Requirement Checks"
  - The research is subject to ethics review by the committee (no change from the current procedure).
  - If the committee determines that the checked items are inconsistent with the descriptions in the research plan on the system, the committee will notify the principal investigator and ask them to revise the checklist and re-apply by submitting a "Request for Exemption from Review."
- If you check "No" to all of the items in the "Ethics Review Requirement Checks"
  - The research is not subject to ethics review, but you must still submit a "Request for Exemption from Review" for the relevant research plan on the system.
  - For the relevant research plan, fill in sections 1) research subject (add "(Request for Exemption from Review)" before the research title), 2) names of researchers involved in the research, 3) research period (up to three fiscal years), and 4) honorarium-related items (if required). For other sections, you can just enter "Not applicable."
  - You will receive a Notification of Exemption from Review on the system.

Note: The Notification of Exemption from Review will be needed when submitting an application for honorarium payment for research not subject to ethics review.

# Checklist for Ethics Review Requirement

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| 1 | The research falls under medical and biological research involving human subjects to be carried out for the purpose of<br><br>a. obtaining knowledge contributing to maintaining and promoting people's good health or recovery from injury and disease and improving the quality of life for patients, through (i) understanding the cause of diseases (including the frequency and distribution of various health-related incidents and factors affecting them) and their pathology, and (ii) improving measures to prevent injury and disease as well as diagnostic and treatment measures in medical care, or verifying the validity of those measures, and<br>b. obtaining knowledge of the structure or function of the human genome and genes, as well as of gene mutation or expression, using human-origin specimens and information. | ☐ Yes<br>☑ No |

# Checklist for Ethics Review Requirement

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| 2 | Important: Items 2 through 9 need to be checked regardless of whether or not item 1 is checked "Yes."<br><br>The research may be invasive (causing injuries or distress to the individual's body and/or mind by conducting procedures such as puncture, incision, administration of drugs, irradiation, or questions related to the individual's mental trauma, etc., including those of a minor nature, for research purposes) to those participating as human subjects.<br>Example:<br>• Possible increase in respiration and heart rate, sweating, etc. beyond the range of normal homeostasis due to lack of appropriate rest, etc. in response to the exercise load<br>• Asking of questions about painful experiences such as disasters, accidents, abuse, bereavement of close relatives, etc. that the individual does not want to be reminded of<br>• Behaviors that disturb the individual's mental homeostasis, such as intentionally causing nervousness and anxiety | ☐ Yes<br>☑ No |
| 3 | The research may involve intervention (practices to control the presence or absence of, or the degree of, factors that can affect a variety of events occurring in relation to human health, including activities to maintain and promote good health, as well as medical practices such as medication and examinations to prevent, diagnose, and treat injuries and diseases) for research purposes. Intervention as defined above also includes medical practices beyond usual treatment that are conducted for research purposes.<br>Example:<br>• Changing brain activity, state of mind, etc. by providing sensory stimulation such as visual, auditory, or other stimuli (including cognitive and sensory functions in virtual space)<br>• Implementing new methods such as smoking cessation guidance and dietary therapy and verifying differences from conventional methods | ☐ Yes<br>☑ No |

# Checklist for Ethics Review Requirement

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| **4** | The research involves analysis or experiments using specimens extracted from human subjects (blood, body fluids, tissues, excreta, and DNA extracted from these, etc.) or biological information obtained from the results of examinations (pulse, brain wave, blood pressure, heartbeat, electromyogram, body temperature, sweat, visual information, etc.). | ☐ Yes<br>☑ No |
| **5** | In your experiment, you may use self-made equipment of a type that has not been approved by a Tokyo Tech ethics review, or use commercially available equipment in a way that differs from normal usage or from cases previously approved by a Tokyo Tech ethics review. | ☐ Yes<br>☑ No |
| **6** | Human subjects for the research include individuals with impaired judgment and those who are disadvantaged for economic or medical reasons, such as those whose voluntary decision-making may be unduly influenced by the anticipated benefits of participation in the research or disadvantages of refusing to participate.<br>Example:<br>• Minors under 16 years of age<br>• Students and employees whose voluntariness is not secured | ☐ Yes<br>☑ No |
| **7** | In the course of research, personal information is obtained that requires special consideration (race, creed, social status, medical history, criminal record, the fact of having suffered damage by a crime, or other identifiers requiring special care so as not to cause unjust discrimination, prejudice, or other disadvantages to the individual). | ☐ Yes<br>☑ No |

# Checklist for Ethics Review Requirement

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| **8** | You are requested to undergo an ethics review according to the guidelines of an academic society or for a paper you plan to submit<br>(Name of conference/journal in which the presentation will be made:<br>) | ☐ Yes<br>☑ No |
| **9** | You are requested to undergo an ethics review by your partner institution(s) for collaborative research, etc.<br>(Institution name:<br>) | ☐ Yes<br>☑ No |
| **10** | Although items 1 to 9 above do not apply, you wish to apply for an ethics review due to special circumstances and reasons that require investigation and deliberation from ethical and scientific viewpoints as described below.<br>(Special circumstances and reasons:<br>) | ☐ Yes<br>☑ No |

# 2. Limiting online system application to faculty members

From December 1

- Faculty members must make the decision on whether or not an ethics review is required
  - Students cannot be held responsible for deciding whether or not a review is required.
- The faculty member must also apply for an ethics review
  - The faculty member responsible for the research plan and research content will apply for an ethics review.
  - This will eliminate one factor that makes the review process time-consuming, as unclear application details by students can cause delays.

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- Decision on the necessity of and application for an ethics review on the system is limited to faculty members (including specially appointed faculty members)
  - Applications from students, etc. will not be accepted even if there is approval from the principal investigator, and will be returned to the student, etc.
  - To assist faculty members entering application information into the system, a Word file with the same items on the system is provided as a draft for students and others to use.

*Students can also download the Word file from the "Research on Human Subjects" website.

# 3. Expansion of expedited review targets

From December 1

- Until now, expedited review has been limited to research that does not involve personal information or equipment.

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- Research that is both non-invasive (or minimally invasive) and non-interventional will be newly included in the scope for expedited review even when personal information or equipment is handled.
- The committee will determine whether the application falls under any of the following categories 1-4 and is eligible for expedited review.

1. In the case of collaborative research projects involving external institutions, the entire research has already been reviewed by the Ethics Review Committee of the partner institution, and opinion has been obtained that expedited review is appropriate.
2. Minor changes to the research plan that do not affect the implementation of research involving human subjects and that are not likely to increase the burden or risk to the research subjects, such as changes or additions to the principal investigator/co-investigator and extensions of the research period that do not involve changes to the research content
3. Non-invasive research involving human subjects that does not involve intervention
4. Research involving human subjects with minor invasive procedures that does not involve intervention

# 4. Simplified procedure for collective reviews

From December 1

- Collaborative research projects involving external institutions currently require an ethics review (expedited review) at Tokyo Tech regardless of approval by the collaborating institution.

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- Collaborative research projects with approval from the collaborating institution may be exempted from review at Tokyo Tech upon submission of a request for exemption through the system; president's approval to be issued upon consent by the Ethics Review Committee Chair.

  Note:
  - Approval by the responsible institution is mandatory.
  - To request exemption, insert "Collective review completed" before the project title. Submit with documents verifying approval via collective review including certification, documentation reviewed, and those for recruiting research subjects.
  - Input into the system can be done simply by referring to the provided examples.
  - Research may begin only upon receipt of the president's approval.

# Honorariums and accident insurance for research not subject to an ethics review

From December 1

- For projects subject to an ethics review, payments of honorariums and purchases of accident insurance will follow the current procedures.

- For projects not subject to an ethics review, honorarium payment must be requested via the system.
  - Fill in the required information by referring to the example, and add the phrase "Request for Exemption from Review" before the project title.
  - Submit the research plan and Notification of Exemption from Review to the Accounting Division.

- Projects that request exemption from review are not covered by the accident insurance contracted by the Committee.
  - Apply individually when necessary
  - Based on assumption that research requiring accident insurance would not be exempt from review

# Seminar on Ethics of Research Involving Human Subjects

Tokyo Tech

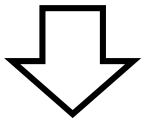
## Seminar video on fundamentals: mandatory for all concerned (once a year)

- How to obtain informed consent
  - Consent Form, Revocation of Consent Form, Opt-Out
- Method for handling specimens from humans
  - Addressing risk of infection
- Analysis of the human genome
- Types and management of personal information
  - Definition of "personal information"
    - Personal information requiring consideration
  - Restrictions on the transfer of personal information
- Privacy considerations and copyright protection
- Cautionary measures for research conducted abroad

# Cloud storage of data containing personal information

Immediately applied

- Data containing personal information (information that can identify a specific individual, such as name, photograph, voice, and gait)
  - Stored on a device disconnected from the internet and kept by the principal investigator in a securely locked location



- Storage in personal area of the Tokyo Tech Cloud Box accepted (commercial cloud services not allowed)
  - Reason: risk of leakage is minimal as accounts are restricted by the authentication infrastructure of the Tokyo Tech Portal.