

「Research Involving Human Subjects」

～Application Procedures after December 1, 2023～

Ethics Review Committee for Research Involving Human Subjects

Chair of the committee **Hiroshi Ichinose**

Since the explanatory video is in Japanese only, we have translated the audio recording (slides 2-6, 11-16).

Please read it together with the explanatory documents (English).

(2)

I am Hiroshi Ichinose, chairperson of the Ethics Review Committee for Research Involving Human Subjects and professor at the School of Life Science and Technology.

At the meeting of the Education and Research Council held on October 6, the revision of Tokyo Tech's "Regulations on Research on Human Subjects" and "Regulations on Ethics Review Committee for Research on Human Subjects" was approved. The revised regulations will go into effect on December 1. Since there are several major changes, we have prepared a video explaining the changes so as not to hinder the research of everyone involved. Please also visit the website for more information on research involving human subjects.

First, let me explain the background of the revision. There is a big difference in "research involving human subjects" that requires an ethics review between TMDU and Tokyo Tech, which are scheduled to merge in the next fiscal year. At Tokyo Medical and Dental University, research subject to the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" formulated by the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labor and Welfare; and the Ministry of Economy, Trade and Industry is subject to ethics review. However, for research not subject to the guidelines, whether or not an ethics review is required is left to the researcher's own judgement. Conversely, Tokyo Tech has required that all experimental research studies involving human subjects, as well as research that is subject to the guidelines, be reviewed by an ethics committee. Therefore, even when conducting research that does not require particular ethical consideration for research subjects, the researcher is asked to first prepare an application form for review by the committee, which has caused inconvenience as it may delay the start of the

research or affect the research content itself. On the other hand, since a wide variety of research is conducted at Tokyo Tech, we were concerned that some research requiring ethical considerations might be omitted from the scope of the ethics review if we apply the same practice used at TMDU, which only requires a review for research subject to the guidelines. Therefore, we have created a checklist to identify whether or not research requires special ethical consideration for its subjects, and have decided to selectively review research that should or needs to undergo ethics review rather than reviewing all cases.

(3)

This slide summarizes the changes to the ethics review process for research involving human subjects effective from December 1.

First, there is a new procedure with a requirement checklist as I just explained.

Second, we decided to limit applicants for an ethics review to faculty members. This will be discussed in more detail in later slides.

Third, the scope of expedited review targets has been expanded.

Fourth, we have decided to simplify Tokyo Tech's review process for research that has been collectively reviewed by other institutions. I will explain each point in due course.

(4)

Now, let's start looking at the checklist. You can download the "Checklist for Ethics Review Requirement" as a Word file from the Tokyo Tech website. Here, key points are listed to determine if an ethics review is required.

The first point is whether or not the research is subject to the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" issued by the government. Please make sure that if your research falls under the research specified in the guidelines, or is considered to fall under such research, you must apply for an ethics review. However, I assume that few faculty and students at Tokyo Tech know the contents of the guidelines in any detail. Therefore, the checklist is designed to provide useful judgement points such as examples of research subject to an ethics review and relevant excerpts from the guidelines.

For example, there is research with a potential burden and risk to those participating as human subjects. Research that is invasive or involves interventions falls into this category, but it is important to understand that invasions can not only be physical but also psychological — involving questions that could remind an individual of past painful experiences, or intentionally causing nervousness or anxiety. More details are provided in our training video. Other research that falls under this category may include that which uses human-origin specimens or biological information obtained from research subjects, including brain wave

and heartbeat information. At Tokyo Tech, researchers also use self-made or special equipment, which will also be subject to an ethics review.

Another point you must pay attention to regarding experiments is research that requires special consideration for those participating as human subjects. Whether voluntariness of participation is secured, or whether personal information is handled appropriately, especially sensitive information such as race, creed, or medical history, are critical issues in ethics reviews. In addition, some academic societies and journals may require your research to undergo an ethics review.

Faculty members who will act as the principal investigator are expected to check these items and confirm whether or not a review is required. Due to time constraints, I can explain only briefly about each item today, but further details are provided in the training video. An updated version of the video will be available on the website by the end of November.

(5)

Next, I will explain the steps you must follow to apply for an ethics review. Faculty members who plan to conduct "research involving human subjects" and students who are to be involved in such research must first undergo an ethics training session by watching a video provided on our website. We are now updating the content of the training session and the new version will be ready for viewing by the end of November. Please make the most of the training content when drawing up the details of your research plan.

After completion of the training, please go to our Human Subject Research website, download the Checklist for Ethics Review Requirement, and go through the Checklist to confirm the fulfillment of ethical requirements for conducting research involving human subjects and the responsibilities of researchers. The completed checklist must be uploaded to the "Other documents attached" section when entering research details on the Life-Science Research Management System.

(6)

If you check at least one of the items as "Yes" in the checklist, you must apply for an ethics review. Please enter the required information into the system and submit an application in the same manner as before, then the review will be conducted as per the current procedure.

If you check none of the items as applicable on the checklist, please submit a "Request for Exemption from Review" through the system. When applying, please state "Request for Exemption from Review" before the research title, and also fill in the researchers section with the names of students to be involved, and the research period section with the relevant period, which is up to three fiscal years. In other sections, you can just enter "Not applicable," and do

not state any specific information. Please refer to our website for an example of how to fill in the non-applicable items.

After the submitted request for exemption is reviewed, a Notification of Exemption from Review will be issued in cases where the committee confirms that an ethics review is not required. Please remember that for research not subject to an ethics review, this Notification of Exemption from Review will be needed for processing honorarium payments.

(11)

Another major change is that we have decided to limit applications from the system to faculty members.

There are two main reasons. One is that the decision of whether or not an ethics review is required cannot be left to students. The other reason is that many of the research applications submitted by students have been vague or incomplete, and the ethics review process has been difficult to conduct as certain details of the research were not clear from the application form. On the other hand, we believe it is necessary from an educational perspective to have students write their research plans first and then have faculty members correct and guide them. Therefore, we have prepared a Word file containing items to enter into the system and points to note for filling out the form. Students can also download the file from the website. We ask that faculty members use the Word file to correct and guide students on their applications before entering them into the system.

(12)

In order to make the ethics review process fast and efficient, we have expanded the scope of research that is eligible for an expedited review.

Until now, expedited reviews have been limited to research that does not involve personal information or equipment.

From December 1, regardless of whether it involves personal information or equipment, research that is non-invasive, minimally invasive, or non-interventional will be eligible for expedited review.

Research that falls under one of the four categories listed here may be subject to expedited review, to be determined by the Ethics Review Committee.

(13)

Let me move on to the change to the review process for collaborative research projects.

In cases where a collaborating institution has conducted an ethics review of a collaborative

project and approved it, the review procedure at Tokyo Tech will be simplified.

Currently, a Tokyo Tech review is mandatory regardless of whether the project has been approved by another institution. From December 1, however, the president's approval can be issued upon consent by the Ethics Review Committee Chair without going through the review process.

When entering the information into the system, please insert "Collective review completed" before the project title if it has already been reviewed and approved by other institutions. Please also submit a set of documents verifying approval made via collective review.

We will prepare examples to help you enter your data into the system easily.

The planned change will simplify the review process in this way. However, please do not start the research until you receive the president's approval.

(14)

The next section explains the payment procedures for honorariums and accident insurance for projects that do not require an ethics review.

For projects subject to an ethics review, there will be no change in the current procedures.

However, regarding projects for which a Request for Exemption from Review has been made, honorarium payments are possible only when the related information is provided.

We will also prepare examples of data entry for this case. Please enter the required information on the system, and then submit a research plan, including a description of the honorarium, and a Notification of Exemption from Review to the Accounting Division.

In addition, projects for which a Request for Exemption from Review has been made are not covered by the personal accident insurance contracted by the Ethics Review Committee. If insurance is necessary, it must be taken out individually. However, we do not anticipate that this will be the case, based on the assumption that research requiring accident insurance would not be exempt from review.

(15)

The video of the Seminar on Ethics of Research Involving Human Subjects will be revised in accordance with the revision of the regulations.

All principal investigators and research participants are required to take the seminar once a year.

It covers matters requiring consideration, such as how to obtain informed consent, the handling of human-origin specimens, notes for human genome analysis, types and

management of personal information, privacy and copyright issues, and points to note for research conducted overseas.

(16)

Finally, I'd like to explain the decision to allow data containing personal information to be stored on the Tokyo Tech Cloud Box.

Data containing information that can identify a specific individual, such as names, photos, audio recordings of interviews, and gait, is subject to the Act on the Protection of Personal Information, and must be strictly managed.

As such, we have asked that such data be stored on a device disconnected from the internet and kept by the principal investigator in a locked location.

Considering that the Tokyo Tech authentication infrastructure restricts accessible accounts and the Cloud Box service has an extremely low risk of data leakage, it has been decided that personal information can be stored in the personal area of the Tokyo Tech Cloud Box.

There are a variety of other cloud services, but as the risk of leakage from them is beyond our control, we do not allow the use of such commercial services.

This change will be effective immediately.

So, that concludes this session. If you have any questions or comments, please send them to me, Ichinose at the School of Life Science and Technology, or the Ethics Review Committee office. Thank you for your attention.