

* The Japanese version is the authoritative version, and this English translation is intended for reference purposes only. Should any discrepancies or doubts arise between the two versions, the Japanese version will prevail.

Regulations Concerning Ethics Review of Research Involving Human Subjects at Tokyo University of Foreign Studies

(March 20, 2018
Regulation No. 6)

Amended March 19, 2019: Regulation No. 35

July 23, 2019: Regulation No. 92

Article 1 Purposes

The purpose of these Regulations is to ensure proper implementation of research which has gained the understanding of society in the research concerned by providing for necessary matters concerning research involving human subjects at Tokyo University of Foreign Studies (hereinafter referred to as the "University").

Article 2 Definition

- 1 The term "Research Involving Human Subjects" as used in these Regulations shall mean research activities conducted by collecting and gathering personal information and information and data, etc. relating to individual activities, environment, mind, body, etc.
- 2 The term "Researchers" as used in these Regulations shall mean those who are engaged in research at the University, such as faculty members and researchers belonging to the University, as well as undergraduate students and graduate students who participate in research at the University.
- 3 The term "Research Subjects" as used in these Regulations shall mean those who have given consent to provide cooperation as a research subject (including those who have declined cooperation for research after such consent is given).
- 4 The term "Research Representative" as used in these Regulations shall mean a person who is engaged in the implementation of research and also supervises the business related to such research.

Article 3 Subject of Review

The subject of the review under these Regulations shall be the plans for the Research Involving Human Subjects to be performed by Researchers which requires the ethics review conducted by the University in advance of implementation of research.

Article 4 Ethics Committee

- 1 An Ethics Committee (hereinafter referred to as the "Committee") shall be established at the University to conduct the review prescribed in the preceding article.
- 2 The President shall refer the review to the Committee upon application by the Researchers for review of any Research Involving Human Subjects in accordance with the prescribed procedure.

Article 5 Tasks of the Committee

The Committee, upon referral by the President, shall conduct review, etc. on the following items:

- (1) Matters concerning the ethics of the research plan for the Research Involving Human Subjects;

- (2) Matters concerning the establishment and revision of rules, guidelines, etc. relating to the Research Involving Human Subjects; or
- (3) Any other matters relating to the matters referred by the President in connection with the Research Involving Human Subjects.

Article 6 Organization of the Committee

- 1 The Committee shall consist of the following members:
 - (1) Director (in charge of research) or Vice President (in charge of research): 1 person
 - (2) Faculty member of the Institute of Global Studies who is appointed by the President: 2 persons
 - (3) Faculty member of the Institute of Japan Studies and the Research Institute for Languages and Cultures of Asia and Africa who is appointed by the President: 1 person each
 - (4) Other persons who are deemed necessary by the President: several persons
- 2 The term of office of the Committee members listed in Items (2) to (4) of the preceding paragraph shall be two (2) years, and they may be reappointed. However, any vacancy shall be filled, and the member appointed shall serve only the unexpired term of his/her predecessor.
- 3 The Committee shall have a Chairperson and a Vice-Chairperson.
 - (1) The member prescribed in Item 1 of paragraph 1 hereof shall serve as the Chairperson of the Committee; and
 - (2) The Vice-Chairperson shall be elected by mutual vote from among the members in Items 2 and 3 of paragraph 1 hereof.
- 4 If the Chairperson is unable to act as such, the Vice-Chairperson shall act on behalf of the Chairperson.
- 5 The Chairperson shall convene a Committee meeting and shall serve as the chairperson thereof.
- 6 The Committee may not open a meeting without the attendance of at least half of the members thereof.
- 7 If the Chairperson deems it necessary, the Committee may require persons other than the Committee members to attend a meeting and offer opinions.
- 8 Committee members shall keep strictly secret and confidential any secret learned by them in the course of their duties during and after their terms of office.

Article 7 Standards of Review

The Committee shall conduct a review with due regard to the matters listed in the items below:

- (1) Protection of human rights of the Research Subjects
- (2) Prediction of disadvantages of the Research Subjects and benefits or contributions of research activities, etc.
- (3) Understanding and consent of the Research Subjects
- (4) Assurance of safety of the Researchers and the Research Subjects
- (5) Measures for protection of personal information
- (6) Other consideration for social impact and ethical issues

Article 8 Application for Review

The Research Representative who intends to apply for review shall submit to the President the following documents:

- (1) Ethics Review Application (Attached Form 1)

- (2) Explanatory documents for the Research Subjects, consent documents of the Research Subjects, and other documents necessary for ethics review

Article 9 Method of Review

- 1 At the time of examination, the Committee may require the Research Representative or his/her representative to attend the review, explain the details of the application, and offer opinions.
- 2 The judgment in the review shall be, in principle, agreed upon by all the Committee members present. However, if the Chairperson deems it necessary, such judgment may be made with the consent of a majority of the members present by a secret ballot.
- 3 If the Research Representative is a Committee member, he/she may not participate in the discussion or judgment in the review.

Article 10 Results of Review

- 1 The result of the review shall be either of Approved, Conditionally Approved, Disapproved, or Not Applicable.
- 2 The Chairperson shall report the results of the review to the President promptly after the review.
- 3 The President shall notify the Research Representative of the results of the review by sending the Notice of Review Results (Attached Form 2).
- 4 If the result of the review is either of Conditionally Approved, Disapproved, or Not Applicable, the reasons therefor shall be stated in the notice under the preceding paragraph.
- 5 If the result of the review is Conditionally Approved, the Research Representative shall make necessary amendments, etc. and submit the Ethics Review Application (Attached Form 1) again to the President.
- 6 If the application for review under the preceding paragraph is filed, the Committee shall, upon referral by the President, confirm whether or not the conditions imposed have been satisfied.
- 7 Upon confirmation that the conditions imposed have been satisfied, the President shall approve the conduct of the research. If the conditions imposed are not satisfied, the Research Representative shall not conduct the research.
- 8 If the result of the review is Disapproved, the Research Representative shall not conduct such research.
- 9 If the result of the review is Disapproved, the Research Representative may apply for a re-review only once per research theme. In this case, the Research Representative shall make necessary amendments, etc. and reapply by submitting the Ethics Review Application (Attached Form 1) again.
- 10 If the application for review under the preceding paragraph is filed, the Committee shall conduct the review through the review procedures prescribed in the preceding article upon referral by the President.
- 11 The process and result of the review may be made public if deemed necessary by the President.
- 12 The Chairman shall record the process and result of the review and retain them for the period prescribed in the Regulations for Management of Corporate Documents of Tokyo University of Foreign Studies.

Article 11 Change of Research Plan

In the event of any change in the research plan approved by the Committee, the Research Representative shall promptly apply for review of the change of plan based on the content of the changed research plan by submitting the Application for Change of Research Plan (Appended Form 3).

Article 12 Announcement of Research Results

In publishing the results of research approved by the Committee, the publication shall be made

appropriately, considering the social impact that such announcement is expected to have, after making clear that such research has been reviewed and approved as prescribed in these Regulations and taking necessary measures to protect personal information, intellectual property rights, etc.

Article 13 Completion or Discontinuation of Research

When the research approved by the Committee is completed or discontinued, the Research Representative shall submit the Research Completion (Discontinuation) Report (Attached Form 4) to the President.

Article 14 Other Matters

General affairs relating to ethics review shall be handled by the Research Promotion Division of the General Affairs and Planning Department.

Article 15 Any matters not set forth in these Regulations shall be prescribed by the Committee separately.

5) Place of implementation

3. About Research Subjects

1) Number of persons, etc.

Adult (18 and older)

Student (TUFS Other educational institution Name of educational institution: _____)

Other (_____) Number of persons: _____

Minors (under 18)

Student (High School Student Junior High School Student

Elementary School Student Name of School: _____)

Child (age: _____)

Other (_____) Number of persons: _____

2) Reward (or equivalent) to the Research Subjects

Yes (_____) No

4. Ethical Considerations in Research Activities, etc.

1) Consideration for protection of human rights of Research Subjects

2) Prediction of disadvantages of the Research Subjects and benefits or contributions of research activities, etc.

(i) Disadvantages to Research Subjects arising from Research Activities, etc.

(ii) Benefits or contributions brought by research activities

3) Method of seeking understanding and consent of Research Subjects

(i) Recruitment of and explanation to Research Subjects

Writing Oral Others (_____)

(*Please attach a sample of the Explanation Sheet, if any.)

(ii) Method of obtaining informed consent

Writing Oral Others (_____)

(*Please attach a sample of the Consent Form, if any.)

(iii) Method of guaranteeing the right of the Research Subjects to withdraw their cooperation in the research after giving consent

Written offer Oral offer Others (_____)

(*Please attach a sample of the Consent Withdrawal Form, if any.)

4) Handling of personal information (acquisition, anonymization, storage, disposal, etc.)

(i) Acquisition of personal information Yes No

Yes: Name Address Date of birth Telephone number, E-mail address, etc.

Other matters ()

(ii) Purpose of use of personal information

(iii) Method of anonymizing personal information

Linkable anonymization (Removing any personally identifiable information, anonymizing it with a new code or number, and creating a chart.)

Unlikable anonymization (Removing any personally identifiable information, anonymizing it with a new code or number, and creating no chart.)

Anonymization by a third party (*If applicable, please attach materials which show the outline and information management policy of the outside organization to be outsourced.)

No anonymization

(Reason(s):)

(iv) Method of storing collected data, personal information, etc.

Storage management manager (Affiliation/Title/Name):

Place of storage and management:

Specific measures:

(v) Method of disposing of collected data, personal information, etc.

5. Schedule for Publication of Results of Research Activities, etc.

[Reasons for Application]

*Please describe the reason and circumstances leading to your application for ethics review.

Notice of Review Results

Date:

Research Representative

To:

President of Tokyo University of Foreign Studies Seal

Receipt No. _____

Theme _____

We hereby notify as follows the result of the review of the implementation plan for the theme indicated above for which application has been filed.

Review Date				
Judgement	Approved	Conditionally Approved	Disapproved	Not applicable
Reasons or Conditions				

Application for Change of Research Plan

Date of submission:

To: President of Tokyo University of Foreign Studies

Research Representative's Affiliation/Title

Research Representative's Name

We hereby file an application for changes as follows to the research plan that is already approved.

Please check the applicable box below.

- Extension/change of research period only
- Expansion/change of range of Research Subjects
- Change of the topic/procedures of research
- Changes in informed consent and ethical procedures
- Other Matters ()

1. Research Theme	
	Approval date: Receipt No.:
2. State of Implementation	Whether or not any ethical problem has occurred:
3. Details of Changes	
4. Reasons and Grounds for Changes	
5. Anticipated Ethical Consequences Caused by Changes	
6. Attachments	Review Application

1. If there are multiple changes, itemize or otherwise list one by one and explain the reason for such change.
2. The changes in the application form for which approval was given previously shall be clearly identified with underline or shade.

Attached Form 4 (Related to Article 13)

To: President of Tokyo University of Foreign Studies

Date of submission:

Research Representative's Affiliation/Title

Research Representative's Name

Research Completion (Discontinuation) Report

Receipt No.	
Research Theme	
Research Period	From to
Research Results (Attachments)	In the case of published papers, the name of the magazine and volume, and in the case of a academic conference presentation, the name of the academic conference, the date of presentation, etc.
In case of Discontinuation, the Reasons therefor	

*The space below is for use by the Administration Office.

Date of Receipt by Administration Office	
Date of Report to the Committee	
Date of Report to President	
Retention Period for Review Materials	