|  |  |
| --- | --- |
| Reception number |  |

 Appendix Form No. 1

**Application for Ethical Review of Research and Experiments Involving Human Subjects**

**(Teachers, Researchers, etc.)**

Date of submission

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　(　　　　　　 )

 (date, month, year)

Dean, Graduate School of International Cultural Studies,

Tohoku University

Principal Investigator (Applicant)

　　　　　　　　　　　　　　　　　　Affiliation

　　　　　　　　　　　　　　　　　　 Name and title

　　　　　　 Signature

Person in charge of implementation

 Affiliation

　　　　　　　　　　　　　　　　　 Name and title

 Signature

Title of Research Project:( )

I would like to apply for ethical review for the implementation of the research and experiments required for the above research project by submitting the research plan and other documents as follows.

**Research plan**

|  |  |
| --- | --- |
| Title of Research |  |
| Research period (after approval by the Ethics Committee) | ( ) ~　(　　 )(date, month, year) (date, month, year) |
| Principal investigator(Applicant) | Affiliation |  | Name and title |  |
| Phone number |  | E-mail |  |
| Person in charge of implementation | Affiliation |  | Name and title |  |
| Phone number |  | E-mail |  |
| Project member | Affiliation |  | Name and title |  |
| Affiliation |  | Name and title |  |
| Affiliation |  | Name and title |  |
| Research funds |  |

|  |  |
| --- | --- |
| Research Summary | Significance and purpose of the research (include background and ethical aspects of the research) |
| Subjects (Describe the approximate number of subjects required for the study, as well as the policy and criteria for selecting subjects) |
| Implementation plan (also describe the handling of personal information (protection methods) and whether or not an honorarium will be paid) |
| Location of the research |
| Ethical considerations | 1)　 Measures to protect the human rights of individuals who will be the subjects of the research(Describe in detail of the methods etc. for ensuring privacy.) |
| 2)　 Methods of seeking understanding and obtaining consent from subjects (circle the appropriate item below)Explain to the subject in writing/orally/written and orally, and　(a) Keep the signed consent form.　(b) Keep the survey form with the consent signature.Specific details of the explanation: (The explanation and consent form for the subject should be attached.) |
| 3)　 Measures to be taken when the subject is a minor, when an adult does not have sufficient judgment, or when consideration of the name of the disease is necessary (circle the relevant item below)A. Minors　　B. Adult without sufficient judgment　　C. Adult who is unconscious　　D. When consideration for the name of the disease is necessary　　E. Other　　F. Does not fall under any of the above (No need to describe the following specific measures)　Specific measures to be taken:(A copy of the consent form should be attached.) |
| 4）Consideration for risks and discomfort that may be caused to subjects by the research, etc.　(Itemize the details of consideration for each.) |
|  |
| Terms of reference (If there is a patent application or other interest, indicate it) |  |

Appendix Form No. 1-1

|  |  |
| --- | --- |
| Reception number |  |

**Application for Ethical Review of Research and Experiments Involving Human Subjects**

**(Graduate school students)**

Date of submission

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　(　　　　　　 )

 (date, month, year)

Dean, Graduate School of International Cultural Studies,

Tohoku University

 Person responsible for implementation (Applicant)

Affiliation

　　　　　　　　　　　　　　　　　　　　　Name and grade

　　　　　　 Signature

 Supervisor

Affiliation

　　　　　　　　　　　　　　　　　　 Name and title

 Signature

Title of Research Project: ( )

I would like to apply for ethical review for the implementation of the research and experiments required for the above research project by submitting the research plan and other documents as follows.

**Research plan**

|  |  |
| --- | --- |
| Title of Research |  |
| Research period (after approval by the Ethics Committee) | ( ) ~　(　　 )(date, month, year) (date, month, year) |
| Person responsible for implementation (Applicant) | Affiliation |  | Name and title |  |
| Phone number |  | E-mail |  |
| Supervisor | Affiliation |  | Name and title |  |
| Phone number |  | E-mail |  |
| Project member | Affiliation |  | Name and title |  |
| Affiliation |  | Name and title |  |
| Affiliation |  | Name and title |  |
| Research funds |  |

|  |  |
| --- | --- |
| Research Summary | Significance and purpose of the research (include background and ethical aspects of the research) |
| Subjects (Describe the approximate number of subjects required for the study, as well as the policy and criteria for selecting subjects) |
| Implementation plan (also describe the handling of personal information (protection methods) and whether or not an honorarium will be paid) |
| Location of the research |
| Ethical considerations | 1)　 Measures to protect the human rights of individuals who will be the subjects of the research(Describe in detail of the methods etc. for ensuring privacy.) |
| 2)　 Methods of seeking understanding and obtaining consent from subjects (circle the appropriate item below)Explain to the subject in writing/orally/written and oral, and　(a) Keep the signed consent form.　(b) Keep the survey form with the consent signature.Specific details of the explanation: (The explanation and consent form for the subject should be attached.) |
| 3)　 Measures to be taken when the subject is a minor, when an adult does not have sufficient judgment, or when consideration of the name of the disease is necessary (circle the relevant item below)A. Minors　　B. Adult without sufficient judgment　　C. Adult who is unconscious　　D. When consideration for the name of the disease is necessary　　E. Other　　F. Does not fall under any of the above (No need to describe the following specific measures)　Specific measures to be taken:(A copy of the consent form should be attached.) |
| 4）Consideration for risks and discomfort that may be caused to subjects by the research, etc.　(Itemize the details of consideration for each.) |
|  |
| Terms of reference(If there is a patent application or other interest, indicate it) |  |

Appendix Form 2

|  |  |
| --- | --- |
| Reception number |  |

**Notification of Judgment Results for Conducting Research**

 **(Teachers, Researchers, etc.)**

 Date of issue:

Principal Investigator (　　　　　　 )

 (date, month, year)

Name: (　 )

 　Dean, Graduate School of International Cultural Studies, Tohoku University

Title of Research Project: ( )

The research project has been reviewed by the committee on (date, month, year), and the following Judgment results have been determined.

|  |  |
| --- | --- |
| Judgment result | □Approval　□Conditional approval　　□Recommendation for change　　□Disapproved　　□Not Applicable |
| Details of reasons for conditions or recommendations for change, etc. |  |

Appendix Form 2-1

|  |  |
| --- | --- |
| Reception number |  |

**Notification of Judgment Results for Conducting Research**

**(Graduate school students)**

 Date of issue:

Person responsible for implementation (　　　　　　 )

Name: (　 ) (date, month, year)

Supervisor

Name: ( )

 Dean, Graduate School of International Cultural Studies, Tohoku University

Title of Research Project: ( )

The research project has been reviewed by the committee on (date, month, year), and the following Judgment results have been determined.

|  |  |
| --- | --- |
| Judgment result | □Approval　□Conditional approval　　□Recommendation for change　　□Disapproved　　□Not Applicable |
| Details of reasons for conditions or recommendations for change, etc. |  |

Appendix Form 2-2

|  |  |
| --- | --- |
| Reception number |  |

**Approval Form for Conducting Research**

 **(Teachers, Researchers, etc.)**

 Date of issue:

Principal Investigator (　　　　　　 )

Name: (　 ) (date, month, year)

　　Dean, Graduate School of International Cultural Studies, Tohoku University

Title of Research Project: ( )

The research plan for the above project has been approved by the Research Ethics Committee, and since there are no ethical problems with the plan, we hereby approve its implementation.

Appendix Form 2-3

|  |  |
| --- | --- |
| Reception number |  |

**Approval Form for Conducting Research**

**(Graduate school students)**

 Date of issue:

Person responsible for implementation ( )

Name: (　　 ) (date, month, year)

Supervisor

Name: ( )

　　Dean, Graduate School of International Cultural Studies, Tohoku University

Title of Research Project: ( )

The research plan for the above project has been approved by the Research Ethics Committee, and since there are no ethical problems with the plan, we hereby approve its implementation.

Appendix Form No. 3

|  |  |
| --- | --- |
| Reception number |  |

**Application for Change of Implementation**

**(Teachers, Researchers, etc.)**

Date of submission

 ( )

 (date, month, year)

Dean, Graduate School of International Cultural Studies,

Tohoku University

Principal Investigator (Applicant)

　　　　　　　　　　　　　　　　　　Affiliation

　　　　　　　　　　　　　　　　　　 Name and title

　　　　　　 Signature

Person in charge of implementation

 Affiliation

　　　　　　　　　　　　　　　　　 Name and title

 Signature

Title of Research Project: ( )

I would like to make changes to the information approved by the committee on (date, month, year), and would like to request a re-evaluation.

|  |
| --- |
| (Outline of the changes)□ Change of research period □ Change of Project member □ Change of research funds(For changes other than the above, please resubmit the research plan.) |
| (Reason) |

Appendix Form No. 3-1

|  |  |
| --- | --- |
| Reception number |  |

**Application for Change of Implementation**

**(Graduate school students)**

Date of submission

 ( )

 (date, month, year)

Dean, Graduate School of International Cultural Studies,

Tohoku University

 Person responsible for implementation (Applicant)

Affiliation

　　　　　　　　　　　　　　　　　　　　　Name and grade

　　　　　　 Signature

 Supervisor

　　　　　　　　　　　　　　　　　　 Affiliation

 Name and title

 Signature

Title of Research Project: ( )

I would like to make changes to the information approved by the committee on (date, month, year), and would like to request a re-evaluation.

|  |
| --- |
| (Outline of the changes)□ Change of research period □ Change of Project member □ Change of research funds(For changes other than the above, please resubmit the research plan.) |
| (Reason) |

Appendix Form No. 4

|  |  |
| --- | --- |
| Reception number |  |

**Statement of objection to the Judgment result**

**and Application for re-examination**

 **(Teachers, Researchers, etc.)**

Date of submission

 ( )

  (date, month, year)

Dean, Graduate School of International Cultural Studies,

Tohoku University

Principal Investigator (Applicant)

　　　　　　　　　　　　　　　　　　Affiliation

　　　　　　　　　　　　　　　　　　 Name and title

　　　　　　 Signature

Person in charge of implementation

 Affiliation

　　　　　　　　　　　　　　　　　 Name and title

 Signature

Title of Research Project: ( )

I have an objection to the Judgement result by the committee dated (date, month, year) and would like to request a re-examination.

|  |
| --- |
| (Objection) |
| (Reason) |

　(Note) 1. Please attach documentation that supports your objection.

Appendix Form No. 4-1

|  |  |
| --- | --- |
| Reception number |  |

**Statement of objection to the Judgement result**

**and Application for re-examination**

**(Graduate school students)**

Date of submission

 ( )

 (date, month, year)

Dean, Graduate School of International Cultural Studies,

Tohoku University

 Person responsible for implementation (Applicant)

Affiliation

　　　　　　　　　　　　　　　　　　　　　Name and grade

　　　　　　 Signature

Supervisor

Affiliation

　　　　　　　　　　　　　　　　　　 Name and title

 Signature

Title of Research Project: ( )

I have an objection to the Judgement result by the committee dated (date, month, year) and would like to request a re-examination.

|  |
| --- |
| (Objection) |
| (Reason) |

　(Note) 1. Please attach documentation that supports your objection.

Appendix Form No. 5

|  |  |
| --- | --- |
| Reception number |  |

**Notification of Results of Re-examination**

 **(Teachers, Researchers, etc.)**

Date of issue:

Principal Investigator ( )

Name:　　 (date, month, year)

 Dean, Graduate School of International Cultural Studies, Tohoku University

Title of Research Project: ( )

I hereby notify you that the Committee has re-examined the research plan for the above proposal, which has been objected to, and has made the following decision.

|  |  |
| --- | --- |
| Judgment result | □Approval　□Conditional approval　　□Recommendation for change　　□Disapproved　　□Not Applicable |
| Reason, etc. |  |

Appendix Form No. 5-1

|  |  |
| --- | --- |
| Reception number |  |

**Notification of Results of Re-examination**

 **(Graduate school students)**

Date of issue:

Person responsible for implementation ( )

Name: ( )　　 (date, month, year)

Supervisor

Name: ( )

 Dean, Graduate School of International Cultural Studies, Tohoku University

Title of Research Project: ( )

I hereby notify you that the Committee has re-examined the research plan for the above proposal, which has been objected to, and has made the following decision.

|  |  |
| --- | --- |
| Judgment result | □Approval　□Conditional approval　　□Recommendation for change　　□Disapproved　　□Not Applicable |
| Reason, etc. |  |

Appendix Form No. 6

|  |  |
| --- | --- |
| Reception number |  |

**Report of adverse events**

 **(Teachers, Researchers, etc.)**

 Date of submission:

 ( )

 (date, month, year)

Dean, Graduate School of International Cultural Studies, Tohoku University

 Principal Investigator (Applicant)

 Affiliation

 Name and title

 Signature

Title of Research Project: ( )

The following is a report on the implementation of the above research proposal, which was approved as of (date, month, year).

\*Status: (You may be asked to provide an explanation at the Ethics Committee)

(1) Institution where the event occurred □My institution □Other collaborative research institution (Institution name: )

(2) Serious adverse event and process

(Briefly, enter the date of occurrence, reason for judging the event as serious, details of the intervention and causal relationship, process, outcome, etc.)

(3) Measures taken for serious adverse events

(Suspension of new enrollment, revision of explanatory consent document, re-consent to other subjects, etc.)

(4) Dissemination of information to collaborating research institutions, etc.

Collaborative research institution　　　　　 □No □Yes

 (Total number of institutions (including own institution) )

The information has been disseminated. □No □Yes

\*Contact information of Principal Investigator (phone, e-mail, etc.):

|  |  |
| --- | --- |
| Reception number |  |

Appendix Form No. 6-1

**Report of adverse events**

**(Graduate school students)**

Date of submission:

 ( )

 (date, month, year)

Dean, Graduate School of International Cultural Studies, Tohoku University

 Person responsible for implementation

  Affiliation

 Name and grade

 Signature

　　　　　　　　　　　　　　Supervisor

 Affiliation

　　　　　　　　　　　　　　Name and title

　　　　　　　　　　　　　　Signature

Title of Research Project: ( )

The following is a report on the implementation of the above research proposal, which was approved as of (date, month, year).

\*Status: (You may be asked to provide an explanation at the Ethics Committee)

(1) Institution where the event occurred □My institution □Other collaborative research institution (Institution name: )

(2) Serious adverse event and process

(Briefly, enter the date of occurrence, reason for judging the event as serious, details of the intervention and causal relationship, process, outcome, etc.)

(3) Measures taken for serious adverse events

(Suspension of new enrollment, revision of explanatory consent document, re-consent to other subjects, etc.)

(4) Dissemination of information to collaborating research institutions, etc.

Collaborative research institution　　　　　 □No □Yes

 (Total number of institutions (including own institution) )

The information has been disseminated. □No □Yes

\*Contact information of Person responsible for implementation (phone, e-mail, etc.):

\*Contact information of Supervisor (phone, e-mail, etc.):

**How to fill out the application form**

This section explains how to fill out the application form.

Since the members of the ethics committee do not necessarily belong to the same field of expertise as the applicant, please be specific, easy to understand, and provide as much detail as possible when describing each item.

In particular, please describe the purpose of the research in an easy-to-understand manner and in as much detail as possible, explaining what specific results can be expected from the research.

1. Explanation of terms

Definitions of terms used in the application form. Please note that the definitions of research subcontractors, etc. do not necessarily correspond to the definitions used in the application for competitive funds.

1. Principal investigator: The principal investigator of human subjects’ research must be a full-time assistant professor or higher, or a researcher who can conduct research independently. (research fellows, visiting lecturers, cross-appointment teachers, visiting researchers, special researchers, etc.).

 Graduate school students are not eligible to be the principal investigator.

1. Person in charge of implementation: If the principal investigator is a faculty member, the researcher must be a researcher affiliated with the Tohoku University (full-time or part-time) or a graduate school student of the Tohoku University.
2. Supervisor: The faculty member who will guide and supervise the graduate school student conducting the human subjects research to ensure that there are no problems with the overall research content and research ethics.
3. Person responsible for implementation: The graduate school student of the Tohoku University who is primarily responsible for the implementation of the human subject’s research.
4. Research subcontractors: Researchers affiliated with the Tohoku University (full-time or part-time) and graduate school students of the Tohoku University who are engaged in human subject’s research.
5. Research collaborators: Researchers outside of Tohoku University who are engaged in human subject’s research.

 (This does not include those who are engaged in human subject’s research at other institutions.)

1. Explanator: If you wish to ask someone who is not a Principal investigator as an explanator, please make sure that he or she plays a central role in the research, is familiar with the plan, and is able to answer questions responsibly and clearly. Explanator must be a full-time assistant professor or above.

 Graduate school students may also attend the committee meeting, but must be

 accompanied by an assistant professor or above.

1. If a Principal investigator is not a professor, associate professor, lecturer, or assistant professor, please attach a letter of approval from the professor in charge of the course or field. However, if the supervisor is a professor or associate professor, it is not necessary to attach a letter of approval from the professor in charge of the course or field.
2. If there is not enough paper space, please write "as per attached sheet" and submit it on a separate sheet of paper.
3. If necessary, please attach reference materials.
4. When a Principal Investigator and a Supervisor become aware of the occurrence of a serious adverse event or malfunction related to human subject’s research, they must immediately report it using Form 6 or Form 6-1

(Sample Consent Form)

Date of submission:

 ( )

 (date, month, year)

Dean, Graduate School of International Cultural Studies, Tohoku University

○○ ○○

Consent Form

I have received a full explanation of the purpose, methods, and anticipated problems of the "○○○○○○○○ research" from the person who explained it to me (○ ○ ○ ○) using the explanatory document, and I understand the following items.

□ The purpose of the research, the methods, and any risks and how to deal with them.

□ I understand that I can stop the experiment at any time of my own free will.

I understand that I will not be disadvantaged in any way if I refuse to participate in the experiment at any point.

□I will not be disadvantaged in any way if I refuse to participate in the experiment at any point in time.

□ The recorded personal information will be strictly controlled so that it will not be leaked to outside parties and will not be used for any purpose other than to contact me in case of re-experiment or accident.

□I understand that I may file a complaint with the Graduate School of International Cultural Studies, Tohoku University, in the event that I suffer any disadvantage.

Therefore, of my own free will, I agree to become an experimental subject in the research of ○○○○○○○○.

Address: 〒

Phone Number:

Name:

Signature:

**Precautions in Preparing Explanatory and Consent Documents**

Please pay attention to the following points when preparing the explanatory consent document and consent document for application.

(1) Explanatory items to be explained to subjects or their substitutes in the explanatory consent document should be prepared based on the Ethical Guidelines for Clinical Research "No.4 Informed Consent".

In addition, when preparing the document, **please examine it carefully to ensure that it is consistent with the contents of the Research plan.**

(Excerpted with modifications from the Ethical Guidelines for Clinical Research "No.4 Informed Consent")

In general, **explanations to subjects or** **their substitutes should be as follows.** However, it may be changed according to the content of the human subject’s research.

1. Participation in this human subject’s research is voluntary.
2. No adverse action will be taken against the subject for not agreeing to participate in the human subject’s research.
3. Subjects or their substitutes may withdraw their informed consent at any time without disadvantage.
4. The reason for the selection of the subject.
5. Significance, purpose, method and duration of the human subject’s research
6. Name and title of the investigators, etc.
7. The anticipated results of the human subject’s research, the expected benefits and possible risks of participating in the human subject’s research, and any unpleasant physical or mental conditions that may inevitably result, and what will be done after the completion of the human subject’s research
8. At the request of the subject or their substitutes, etc., access to materials related to the human subject’s research plan and the methods of the human subject’s research, to the extent that such access does not interfere with the protection of the personal information of other subjects or the preservation of the originality of the human subject’s research.
9. The possibility of providing the results of the human subject’s research to other institutions after the Ethical Review Committee has reviewed the handling of personal information, the name of the institution to which the information will be provided, and the appropriateness of the purpose of use at the institution to which the information will be provided.
10. The possibility that the results of the human subject’s research will result in the creation of patent rights, etc., and if patent rights, etc., are created, to whom such rights, etc., belong.
11. The possibility that the results of the human subject research will be made public in such a way that the subjects cannot be identified.
12. Sources of funding for the human subject’s research, possible conflicts of interest, and involvement of researchers and other related organizations.
13. Method and period of preservation and use of the samples, etc.
14. Information on the contact information for inquiries, complaints, etc., concerning the human subjects research.
15. In the case of observational research, when the collection of samples, etc. is invasive, care should be taken to obtain informed consent with sufficient explanation of the existence of necessary measures such as insurance for compensation.

 【In cases where it is difficult to obtain informed consent from the subject.】

1. The importance of the human subject research and the reasons why the subject's participation in the human subject research is essential for the conduct of the human subject research.

(2) The name of the principal investigator or supervisor, the name of the person giving the explanation, and the contact information (department name, contact information, etc.) should be clearly indicated in the lower column of the explanatory consent document. Graduate school students are not allowed, even if the contact person is not the principal investigator.

(3) The consent form should be addressed to the principal investigator or the head of the department to which the principal investigator belongs. For example, if a professor of the Graduate School of International Cultural Studies is the principal investigator of human subject’s research, the address should be "Dean of the Graduate School of International Cultural Studies, ○○ ○○ (write his/her name specifically).

(4) **Please attach the explanatory consent document and the consent document used by the Tohoku University for multicenter research.**

(5) In the case of minors, please attach the "Assent Document" as necessary.