Form No. 1

※Revised December 1, 2024

* 2014

<Research Ethics Consultation status>

Do you wish to receive the Consultation?

 [ ]  Yes [ ]  No

|  |  |
| --- | --- |
| RECEIPT No.\*Official Use |  |

**Application for Examination of Research Plan**

**(Research on Human Subjects)**

Submission Date:

To:

Chairperson, Sophia University Ethics Committee for Research on Human Subjects

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| Dean(Gakubucho or Kenkyuka iincho) | Name: Signature:  |
| Chairperson(Gakkacho or Senko syunin) | Name: Signature:  |
| Applicant (NB 1)\* If the applicant is a student, state the grade. | Affiliation and title:  |
| Name: Signature:  |
| Tel: E-mail:  |
| Supervisor\* If the applicant is a student, indicate the supervisor’s name. | Affiliation and title:  |
| Name: Signature:  |

NB 1: Applicants must submit their application forms via the Dean and Chairperson.

I would like to apply for evaluation of my research proposal on the following subject.

Please make sure that you have all the required documents

|  |  |  |
| --- | --- | --- |
| [ ]  | Research Proposal | Document Number:  |
| [ ]  | Request for research cooperation (for research participants) | Document Number:  |
| [ ]  | Request for research cooperation (for institutions) | Document Number:  |
| [ ]  | Description of research contents for participants | Document Number:  |
| [ ]  | Forms to consent / withdraw consent for research participation (for research participants) | Document Number:  |
| [ ]  | Forms to approve / withdraw approval for research implementation (for institutions) | Document Number:  |
| [ ]  | Questionnaire form, Interview guide …etc. | Document Number:  |
| [ ]  | Others:  | Document Number:  |

**\* The University uses the “Forms to consent / withdraw consent for research participation” to confirm the research participants’ intention to participate in the research, and the “Forms to approve / withdraw approval for research implementation” to obtain the consent of the head of the organization or institution where the research participants are recruited.**

**I. Research subject** \* Check the applicable box ☑ or ■

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| --- | --- |
| **①Research title** |  |
| **②Research period** | From After Approval to |
| \* Research starts on approval date, if date approved at committee is later than the starting date applied for. |
| **③Source of research funds** | [ ]  Internal budget | Name of budget ( ) |
| [ ]  External fund | Source of fund ( ) |
| [ ]  Private expenses |  |
| [ ]  Other |  |
| **④Items for Evaluation** | [ ]  New |  |
| [ ]  Reapplication | Reapplication as a result of committee examination.RECEIPT No.  |
| [ ]  Revise | To change the approved research subject.RECEIPT No.  |

**II. Implementation structure**

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| **①Principal Investigator**\* The Principal Investigator carries out the research and supervises the research-related work.\* If the applicant is a student, his/her supervisor will be the principal investigator. |
| Affiliation | Title | Name |
|  |  |  |
| **②Lead Researcher, Co-Researchers**The following individuals are excluded: individuals outside the research institution who only provide experimental samples and information or individuals who do part of research-related work upon request of the researcher.\* Students conducting research as a primary investigator and the advisors of student investigators have distinct responsibilities need to be described below. |
| Affiliation | Title / Grade | Name | Task(state if you are a co- researcher, research collaborator) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **③Collaborative Research Institutions**\* Institutions participating in collaborative research based on Research Proposal, including also institutions collecting new experimental samples and information from research participants, and providing them to other research institutions.\* If a principal investigator is placed at the collaborative research institution, state the name of researcher. |
|  [ ]  No 　　 [ ]  Yes 　\* if “Yes”, fill out the following boxes:　 |
| Collaborative Research Institution | Principal Investigator of the Collaborative Research Institution / Title |
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**III. Proposal for Research on Human Subjects**

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| **①Location of research activity**Give the names of facilities so that we can specify the actual place where your research will be carried out. |
| Groups and organizations that recruit the research participants: The location where the primary investigator will conduct research project, experiments, and analysis:  |
| **②Objectives and significance of the research**Give a brief summary (about 10 lines) of the research background, proposal and objectives, scientific rationality: this is required information.\* If you want to provide detailed explanation on your research, attach your research proposal to this application. |
|  |
| **③Research participants and selection process** (Attach the flyer of a call for participants if there is any) |
| Research participants | [ ]  | 18 years old or over | \* Number of participants 　　 |
| [ ]  | Between 16 and under 18 years old | \* Number of participants 　　 |
| [ ]  | Under 16 years old | \* Number of participants 　　 |
| [ ]  | Socially vulnerable persons | \* Number of participants 　　 |
| [ ]  | Of them, who have been assessed objectively as incapable of giving consent to participate in research | \* Number of participants 　　 |
| Criteria of selecting participants\* Describe exclusion criteria, if you have inclusion and exclusion criteria |  |
| Methods of call and selection |  |
| Whether research participants will be selected or recruited through the institution manager or head of the group, organization, etc. [ ]  Yes [ ]  No\* If “Yes,” complete and attach a “Forms to approve for research implementation (for institutions).” |
| **④Proposal for Research**Give a brief summary: this is required information; do not replace by exhibits. If you are conducting the research as collaborative research with other institutions, state ①concretely describing the division of roles, ②whether this application covers the whole research or only the part of research to be conducted at Sophia, and ③if this application covers only the collaborative part of research to be conducted at Sophia, give also the entire research plan and its application status. If you are applying for a change in your initial research plan, underline the sections you wish to make the changes. |
| ■Research Design (Research Methods) (Explain purpose of this research, research participant, research recruitment methods)■Methods of data collection■Methods of data analysis |
| **⑤Relationship with research approved in the past**\* In case the same research contents have been examined by the Ethics Committee and conducted in the past, check “Yes” and describe the relationship between that research and the research to be examined now. |
| [ ]  No [ ]  Yes \* If “Yes,” fill out the fields below:  |
| [Relationship with the research approved in the past and similarities/differences] | Receipt number: Research subject:  |
| **⑥Request for participant (Research participants' experiences)**\* State the steps to be taken when requesting the participants to take part in the research and how they are expected to cooperate while doing research in chronological order. State the chronological order of your communications with the research participants. Provide a brief narrative to describe the recruitment process. Include in the description how research participants will be informed of the research. |
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**IV. Ethical consideration during the research**

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| **①Process for obtaining an informed consent \*(request for participation, explanation, and how to obtain consent)**\* “Informed consent” refers to the process by which the researcher provides an explanation to the research participants or legal representative (guardian) regarding the research in advance and obtains their understanding of the purpose, meaning, method of the research, burden and predictable profit/loss. Upon understanding the explanation, the research participants may make a voluntary choice to accept involvement in research.\* When writing the research description, please reference the “IC check sheet” and the “Example of Description of research contents for participants” |
| Eligible person | [ ]  | Participant |
|  | [ ]  | Legal representative (parent, guardian, etc.) |
|  | [ ]  | Others ( ) |
| Method | [ ]  | Written (incl. electronic means) |
|  | [ ]  | Oral \*If “Oral”, need to keep the record. |
|  | [ ]  | Both oral and written (incl. electronic means) |
|  | [ ]  | Others ( ) |
| Specific method of explanation (Attach the copies when using a request form and consent form, etc.): |
|  |
| Does the research require deception\*?\* In order to avoid influencing the results by communicating the true research subject and research purpose to the research participants in advance, so-called deception is carried by conducting an experiment or survey by communicating a fictitious subject and purpose ahead of time. When using deception, it is necessary to obtain consent by explaining the true subject and purpose as well as the reason why deception was necessary after the experiment or survey. |
| [ ]  No [ ]  Yes \* If “Yes,” indicate debriefing method below:  |
|  |
| \*Answer if applicable |
| In case of obtaining an informed consent from the legal representative, do you need to obtain an assent (“informed assent”) from the research participants?\* “Informed assent” refers to the process by which the participants who have been assessed as being incapable of giving “informed consent” will receive explanation about the research in words easy to understand so that they may assent to the research. |
| [ ]  No [ ]  Yes \* If “Yes”, state below the steps and methods:  |
| Process for obtaining an “informed assent” (Please attach a sample if you are using a written document.):  |
| Method of confirming participant’s refusal to cooperate or withdrawal from the research; and how to ensure that participants will not be subject to any disadvantages arising from refusal or withdrawal to cooperate in the research.:\* Describe the specific deadline and the instruction for the research participants to cancel or withdraw his/her participation. |
|  |
| Where to contact and how to respond when consultation is requested by the participants:\* Please provide your preferred contact information (NO cell phone number) with your own risk |
|  |
| **②Relationship between a researcher and a participant. Status of conflicts of interest.**  |
| Do you have a special relationship with the participant or participating organizations that a third party may raise concerns over good research execution.(e.g. relationship based on economic interests resulting from the executive post that the researcher may hold concurrently in the participating organizations; teacher-student relationship; friendship among colleagues at work; interfamilial relationship) |
|  [ ]  No [ ]  Yes |
| \* If yes, please describe below such relationship and measures to be taken to make the research appropriate.  |
| Relationship |  |
| Measures |  |
| **③The burden on the research participants and possible risks and benefits. Measures to minimize such burdens and risks.** |
| (i) Burdens and risks (Physical and mental burdens and distress, social discrimination and proprietary disadvantages, etc.):  |
|  |
| (ii) Measures to minimize such burdens and risks: |
|  |
| (iii) Measures to be taken when such burdens and risks actually occur(e.g., if research involves risks, make arrangements to deal with emergency situations during the experiment, to compensate for health damage or take out insurance to cover medical expenses that may arise in the future.): |
|  |
| (iv) Whether there are any direct benefits\* the participant gets by participating and cooperating in the research: |
| [ ]  No\*No direct benefits for the research participants as the research is conducted for academic development and social benefits[ ]  Yes\*If “Yes,” please fill out the concrete contents of those benefits below |
|  |
| (v) Remuneration |
| Payment of remuneration | 　[ ]  No [ ]  Yes\* If “Yes”, state below the contents, amount, calculation basis and adequacy of remuneration (Please refer to “Guidebook for Budget Execution” of the Sophia university, when spending from research expenses.) |
| If “yes”, state the contents of remuneration (amount of money, goods, etc.): |
| If you need to pay the remuneration other than the actual cost of transportation, describe how such remuneration has been set up and why it is applicable. |
| **④Personal information** |
| (i) Contents of personal information etc.\*1 to be collected and collection methods.\*1 Information such as name, birth date, voice and video that can identify a specific individual, or may identify a specific individual by matching with other information, or includes individual identification code\*2\*2 ①Digitalized data of biological information such as genomic or biometric data or ②Codes such as driving license number, passport number or codes attached to use of service, purchase of goods, or documents given to identify individual person.\*3When handling especially sensitive personal information (personal information that includes medical history, disability, social status, race, creed, criminal history, record of crime victimization, or other descriptions that require special consideration to prevent unfair discrimination, prejudice, or other disadvantages to the individual), please give careful consideration to the methods of obtaining, storing, and disposing of that personal information and describe them here. |
|  |
| (ii) Anonymous/pseudonymous processing\* of personal information etc.\* Total or partial elimination of description (includes individual identification code) that identify a specific individual. (Includes cases in which code or number is given that does not identify a specific individual) |
| [ ]  | No |
| Describe the reason: |
| [ ]  | Yes |
| Describe in detail the method of anonymous/pseudonymous processing: |
| [ ]  | Using information which has already been anonymous/pseudonymous processed. |
| Detailed description: |
| [ ]  | Others (ex. Personal information etc. will not be collected) |
| Detailed description: |
| (iii) Storage and disposal of samples, materials and information (includes personal information etc.) |
| Storage methods: | [ ]  The media will be stored in a locked locker in the principal investigator’s laboratory, and the electronic data will be stored with a password on a computer in the principal investigator’s laboratory. (If creating a comparison table: The comparison table is stored in a separate locked locker in the same laboratory.)[ ]  Other than the above\* If “Other than the above,” please indicate concrete storage methods below |
|  |  |
| Storage manager |  |
| Disposal period: | [ ]  Dispose of research results after 10 years have passed since publication\* The “7. Points to consider for proper conduct of research activities” in Sophia University Guidelines for Prevention of Misconduct in Research Activities stipulates that “(i) Research materials such as experimental data that are the basis of research results announced in papers or other presentation form shall in principle be preserved for ten years from the date of announcement.”[ ]  Other than the above\* If “Other than the above,” please indicate concrete disposal timing below |
|  |  |
| Disposal methods: | [ ]  Paper media is shredded and disposed of, while for electronic media, the data are completely deleted and physically destroyed, so that the data cannot be recovered.[ ]  Other than the above\* If “Other than the above,” please indicate concrete disposal methods below |
|  |  |
| Research involving future use and sharing of collected research data must be described |
| May be used in future research[ ]  No [ ]  Yes | May be supplied to other research institutions[ ]  No [ ]  Yes |
| \* If yes, you must describe the plans to use obtained data in future research (plans to supply data to other research institutions) and the process to obtain the informed consent from the research participants. \* In order to share the especially sensitive personal information to a third party, you will need to obtain the informed consent from the research participants. |
| Plans to use obtained data in future research / plans to supply data to other research institutions |
|  |
| The process to obtain the informed consent from the research participants |
|  |
| **⑤Outsourcing** |
| Are you planning to outsource the research-related work? (Data collection, analysis, etc.) |
| [ ]  No [ ]  Yes |
| \* If “Yes”, describe below the outsourced work, the name of the contractor and the supervision scope and method |
| Outsourced work:Contractors:Supervision methods (When you outsource the research-related work, how to ensure the handling of personal information etc. during or after the research.): |

**V. Information release and disclosure (Availability and method of research-related information disclosure, registration, release, publishing to research participants or to the outside)**

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| **①Information disclosure to research participants** |
| Availability of information disclosure to participants |
| [ ]  No [ ]  Yes \* If “Yes”, describe below the target, method and content of information disclosure. |
| Disclosure target | [ ]  Research participant |
| [ ]  Legal representative of research participant(parent, guardian) |
| [ ]  Affiliated group of research participant (institution director, head of group, organization etc.) |
| [ ]  Other target:  |
| Disclosure method and content, if applicable |  |
| **②Information disclosure to the outside (academic societies, scientific communities, the general public)** |
| Availability of information disclosure to the outside |
| [ ]  No [ ]  Yes\* If “Yes”, describe below the method and content of information disclosure and the name of academic meeting at which research results will be presented. |
| Disclosure method and content, if applicable(Describe in terms of ① publishing research results② accountability for research) |  |
| Name of academic meeting or academic journal at or in which research results will be presented and the presentation period. |  |

**VI. Appling to ethics committee of other institution**

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| Have you applied to ethics committee of other institution? |
| [ ]  No [ ]  Yes \* If “Yes”, state below the progress of ethical examination |
| [ ]  | Under examination / To be scheduled |
| [ ]  | Examined (\* If examination is completed, state the examination result and attach a copy of the result) |
| Name of institution: |

**VII. Others**

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| Please state if there are additional items that you think would be important. |