Form No. 1

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| RECEIPT No.  \*Official Use |  |

※Revised July 1, 2021

* 2014

**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　（NB1)  \*If applicant is a student, state Grade | Affiliation and title: |
| Name: Signature: |
| Tel: E-mail: |
| Instructor  \*If the applicant is a student,  please indicate the instructor’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

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|  | Research Proposal | Document Number : |
|  | Request form for research participants to cooperate in research | Document Number : |
|  | Instruction of research contents for participants | Document Number : |
|  | Consent form  Withdrawal of consent for research participation | Document Number : |
|  | Questionnaire form …etc. | Document Number : |
|  | Others: | Document Number : |

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

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

《Research Ethics Consultation status》

Do you wish to receive the Consultation?

Yes  No

**II. Implementation structure**

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| **①** Principal Investigator  \* The Principal Investigator carries out the research and supervises the research-related work.  \* If the applicant is a student, his/her instructor will be the principal investigator. | | | | | | |
| Affiliation | Title | | | Name | | |
|  |  | | |  | | |
| **②** Lead 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) |
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| **③** Collaborative 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. | | | | | | |
| Yes  No ＊ 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 |  | 20 years old or over | \*Number of participants |
|  | Between 16 and under 20 years old | \*Number of participants |
|  | Under 16 years old | \*Number of participants |
|  | Socially disadvantaged individuals or individuals 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 |  | | |
| **④** Proposal 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 ①whether this application covers the whole research or only the part of research to be conducted at Sophia, and ②if 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 | | | |
| ⑤Request 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. \*At this university, the form for confirming the intention to participate in the research to the research subjects is "Consent Form" and "Consent Withdrawal Form". " Signed acknowledgement" is the format used to obtain consent for recruiting research subjects from the heads of organizations and facilities that recruit subjects. | | | | | | |
| Eligible person | | |  | | | Participant |
|  | | | Legal representative (parent, guardian, etc.) |
|  | | | Institution (Responsible person, Head of organization, etc.) |
|  | | | Others（ ） |
| Method | | |  | | | Written |
|  | | | Oral＊If “Oral”, need to keep the record : |
|  | | | Both oral and written |
|  | | | Others（ ） |
| Specific method of explanation (Attach the copies when using a request form and consent form, etc.): | | | | | | |
| \*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. | | | | | | |
| Yes　　　　　 No ＊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. | | | | | | |
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| 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 | | | | | | |
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| 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) | | | | | | |
| Yes　　　　　 No | | | | | | |
| ＊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 or eliminate 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) Prospective benefits\* the participant may get by participating and cooperating in the research:  \* “Benefits” refer to what are objectionably assessed as new findings or ideas discovered by the participants as a result of taking part in the research. (Except for the Remuneration.) | | | | | | |
| (v) Remuneration | | | | | | |
| Payment of remuneration | | | | Yes　　　　　 No  ＊ 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**※1** to be collected and collection methods.  **※1**Information such as name, birth date, voice and video that can identify a particular individual, or may identify a particular individual by matching with other information, or includes personal identification code※2  ※2①digitalized data of biological information such as genomic or biometric data 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. | | | | | | |
| (ii) Anonymization※of personal information  ※Total or partial elimination of description (includes personal identification code) that identifies a particular individual. (Includes cases in which code or number is given that does not identify the particular individual) | | | | | | |
|  | No | | | | | |
| Please describe the reason: | | | | | | |
|  | Yes | | | | | |
| Describe in detail the method of anonymization: | | | | | | |
|  | Using information which has already been anonymized. | | | | | |
| Detailed description: | | | | | | |
|  | Others (ex. Personal information will not be collected) | | | | | |
| Detailed description: | | | | | | |
| (iii) Storage and disposal of samples, materials and information (includes personal information) | | | | | | |
| Storage methods: | | | | |  | |
| Storage manager | | | | |  | |
| Disposal period: | | | | |  | |
| Disposal methods: | | | | |  | |
| Research involving future use and sharing of collected research data must be described | | | | | | |
| Yes　　　　 No  ※If yes, you must describe the process to obtain the informed consent from the research participants.  ※Regarding the personal information of the research participants, in order to share the collected personal information and data (race, belief, medical history and others that could yield a risk of unfair discrimination, prejudice, and other disadvantages against the research participants with the third party, you will need to obtain the informed consent from the research participants. | | | | | | |
| 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.) | | | | | | |
| Yes　　　　 No | | | | | | |
| ＊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 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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| **① Information disclosure to research participants** | |
| Availability of information disclosure to participants | |
| Yes　 　　　 No ＊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 | |
| Yes　 　　　 No ＊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 results  ② 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? | |
| Yes　　　　 No ＊ 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 is additional items that you think would be important. |