Form No. 1

Please mark with an ☑ the relevant sections regarding your request for a “research ethics consultation.”

**A research ethics consultation is voluntary**.

<Research Ethics Consultation status>

Do you wish to receive the Consultation?

Yes  No

※Revised XXXX 1, 2024

* 2014

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

**(1) Research ethics consultation**

\*See “Notes for filling out the form” at the end

**Application for Examination of Research Plan**

**(Research on Human Subjects)**

Submission Date:

To:

Chairperson, Sophia University Ethics Committee for Research on Human Subjects

**(2) If the applicant is a JSPS Research Fellow (DC/SPD/PD/RPD) Japan**

\*See “Notes for filling out the form” at the end

Please mark “□” with an ☑ and write the document number, also including the document number in attachments

|  |  |
| --- | --- |
| 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: Graduate School of ■■, Department of ■■, ■■■■ Program Year 2 |
| Name: Taro Sophia Signature: |
| Tel: 090-＊＊＊＊-＊＊＊＊ E-mail: abc123＠eagle.sophia.ac.jp |
| Supervisor  \* If the applicant is a student, indicate the supervisor’s name. | Affiliation and title: Professor, Department of ■■, Faculty of ■■ |
| Name: Ichiro Kioi 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: ● |
|  | Instruction of research contents for participants  (for the institute head)  Instruction of research contents for participants  (for research participants) | Document Number: ●-◆  Document Number: ●-▲ |
|  | Forms to consent / withdraw consent for research participation (for research participants) | Document Number: ●-◆  Document Number: ●-▲ |
|  | Forms to approve / withdraw approval for research implementation (for institutions)  Please submit an institutional request or withdrawal form if needed according to the application method. | 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 ■

To determine whether it is necessary to match the title of the research project in the application form with the research title at the time of publication of the results, please check the regulations of academic societies and journals by yourself.

**(4) When applying for a change in the research plan, etc.**

\*See “Notes for filling out the form”

|  |  |  |
| --- | --- | --- |
| **①Research title** | An Examination of Factors of ・・・・・ Concerning ・・・・:  Focusing on ・・・・・・・・・・・  **(3) Beginning and end of the research period**  \*See “Notes for filling out the form” at the end | |
| **②Research period** | From After Approval to March 31, 2025 | |
| \* Research starts on approval date, if date approved at committee is later than the starting date applied for.  In addition to marking ☑, please also include the specific budgets and research funds. | |
| **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**

**(2) When the applicant is a JSPS Research Fellow (DC/SPD/PD/RPD) Japan**

\*See “Notes for filling out the form”

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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 | |
| Department of ■■,  Faculty of ■■ | | Professor | | | Ichiro Kioi | |
| **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) |
| Department of ■■, Graduate School of ■■ | ■■■■ Program, Year 2 | | | Taro Sophia | | Research implementer |
| Department of ■■, Graduate School of ■■ | ■■■■ Program, Year 1 | | | Hanako Yotsuya | | Information gathering (research assistant) |
| **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 | | | |
|  | | |  | | | |
|  | | |  | | | |

**(5) When there is a joint research institute**

\*See “Notes for filling out the form”

**III. Proposal for Research on Human Subjects**

Please indicate the location of the research activity. When doing so, if you are recruiting research participants or collecting data through an institute or organization, please include the official name of the institute. In addition to the locations of data collection, the locations of research activities also include data analysis and paper writing, so please include the university’s laboratories as well.

What has already been clarified and what has not yet been clarified by previous research, etc.?

Please describe in **about 10 lines** why this research is necessary (= background / question), what you are trying to clarify (= purpose), whether the methodology (= plan) for that purpose is reasonable, and whether it is well-devised (= originality).

Moreover, please briefly describe the academic and social significance of this research.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **①Location of research activity**  Give the names of facilities so that we can specify the actual place where your research will be carried out. | | | | | |
| **✍Example**  Groups and organizations that recruit the research participants: ■■■ Hospital, ■■■■ Institute  The location where the primary investigator will conduct research project, experiments, and analysis:  Location preferred by the applicant,  ■■■ Laboratory, Building No. ■■■, Yotsuya Campus, Sophia University | | | | | |
| **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. | | | | | |
| 【Purpose of the Research】  The purpose of this research is to clarify factors related to ・・・・・ in ・・・・  ・・・・・・・・.  【Significance of the Research】  This study can provide suggestions for ・・・・・ in the field of ・・・・・・  It is expected that this research will lead to ・・・ in ・・・　　etc. | | | | | |
| **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  △ persons (questionnaire survey)  ◇ persons (interviews) | |
|  | Between 16 and under 18 years old | | \* Number of participants  The number of participants should be calculated and stated in consideration of scientific validity and feasibility. | |
|  | 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 | Please specify the institution, facility, group name, region, etc. to which the research participants belong, and also indicate the physical, mental, and social attributes of the research participants, clarifying the selection criteria.  E.g. residents of ■■ Home, students of the ■ Course, ■ University  Moreover, if there are specialized criteria, the criteria must be described, and depending on the attributes of the research participants, exclusion criteria (criteria for not being a research participant) may be required.  **✍Example**  Those who have more than ● years of experience of ・・・ with ・・・ qualification, working at ■■■ institute, etc. at ・・・ in Tokyo. | | | | |
| Methods of call and selection | **\*This item will scrutinized as part of the ethics review.**  **Please describe the procedures for the relevant persons to decide whether or not to cooperate with the research based on their free will, concretely, and chronologically, and in an easy-to-understand manner.**  **(1)** When, where, by whom, and by what method (e.g., recruitment leaflet, research cooperation request form, research description, e-mail, telephone, face-to-face verbal recruitment) will research candidates be recruited, requested to participated, or receive explanations?  (2) How do potential research subjects who intend to participate in the research express this intention to the researcher?  (3) Describe by whom, where, and how the research will be explained to the research candidates and the research participants will be determined.  **✍Example**  **(1) Request for research cooperation**  ・・・・・・・・・・・・・・・ will make the request.  **(2) Explanation of research contents**  ・・・・・・・・・・・・・・ will explain.  **(3) Obtaining consent to conduct the research**  Consent to conduct the study will be obtained by ・・・・・・・.  **(4) ・・・・・・・・・**  ・・・・・・・・・・・・・・・・・・・・・・・・・, | | | | |
| 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 “Form for research implementation acceptance.” | | | | |
| **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.  **\* The ethics review will also consider the applicant's ability to carry out the research and the appropriateness and feasibility of the research methods.** | | | | | |
| ■Research Design (Research Methods) (Explain purpose of this research, research participant, research recruitment methods)  There is a wide variety of types and designs of research. Please describe the research you are applying for. Moreover, please describe the research methods for experiments, interventions, studies, etc.  **✍Example**  Intervention study (randomized controlled trial), case study, grounded theory, etc.  ■Methods of data collection  Concretely describe the data collection methods and procedures.  Data collection method examples: Anonymous self-administered questionnaire survey, semi-structured interviews, experimental study, online survey, etc.  **✍Example**  ○ When conducting a questionnaire survey  (1) Recruit research collaborators according to the procedure described in the “Selection and Recruitment Methods” described above.  (2) Distribute a questionnaire to research collaborators in ・・・・・.  (3) The main questions are as follows (see Appendix ● for details), and the time required is expected to be about XX minutes.  [Question items]  1. Attributes of research participants (age, gender, years worked)  2.・・・・・・・・・・・・・・・・・・・・  3.・・・・・・・・・・・・・・・・・・・・  (4) Completed questionnaires will be collected by ・・・・・.  --------------------------------------------------------------------------------------------  ○ When conducting semi-structured interviews  (1) Recruit research collaborators according to the procedure described in the “Selection and Recruitment Methods” described above.  (2) On the day of the interview, the contents of the research, etc. will be explained again to the research collaborator by ・・・・.  Describe specific data collection procedures, such as whether or not the interviews will be filmed or recorded and how questions will be asked with consideration for the research participant and their personal information  Interviews will be conducted based on the “Interview Guide” (Appendix ●), but the main contents are as follows, and the time required is about XX minutes per interview.  [Interview contents]  Ask ・・・・・・・・・・・・・・・・・ about ・・・・.  1. About explanation at the beginning of the interview  2. About ・・・・・・  3. About ・・・・・・  ■Methods of data analysis  Please explain the data analysis methods as concretely as possible based on what you currently anticipate.  **✍Example**  ○ Questionnaire survey  The data collected from the questionnaires will be analyzed using ・・・・・・・・・・・・・・・・・・・・・・・・・・・・.  ○ Semi-structured interviews  The interview contents will be analyzed ・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・. | | | | | |
| **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]  **✍Example**  Regarding the research purpose and survey methods of a research plan on the same research subject as this application, approved by the Ethics Committee in MM 202Y, major changes have been made in the plan with regard to □□□□, and after consideration, I would like it to be examined as a new application. | | | | | Receipt number: 2022－〇〇〇  Research subject: 〇〇〇・・・ |
| **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. | | | | | |
| Assuming that the applicant themselves has become a participant of the research project, please describe in chronological how the principal investigator or the research implementer will request cooperation and what will actually be done from the perspective of the research participant. If there are discrepancies when writing this, there may be a problem with the research plan. If so, please review the entire research plan.  **✍Example**  (1) Research participant candidates will be asked to participate in the research by ・・・  (2) If they intend to participate in the research, they indicate consent by ・・・  (3) After receiving an explanation of ・・ from the researcher, ・・・・・・・・・・・.  (4) ・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・.  ・・・・・・. | | | | | |

**IV. Ethical consideration during the research**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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 Instruction 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.  Unless there is a special reason with regard to this research, “both written and verbal” is recommended. | |
|  | | |  | | | Both oral and written (incl. electronic means) | |
|  | | |  | | | Others ( ) | |
| Specific method of explanation (Attach the copies when using a request form and consent form, etc.):  Even if you have attached a separate “Research Cooperation Request Form,” “Research Contents Explanation,” “Research Implementation Consent Form,” etc., please describe the methods concretely in the relevant fields. | | | | | | | |
| **✍Example of description**  It is ・・・・・ if “Research Contents Explanation” (Appendix ●) is used to explain, request, and obtain agreement for research participation, verbally and in writing. | | | | | | | |
| 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.):  If you have received informed assent, please indicate this so as to keep a record. | | | | | | | |
| 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. | | | | | | | |
| Please describe concretely how consent can be withdrawn. Please describe regarding the withdrawal of consent,  (1) How can it be done and up to what point in time?  (2) How is the acquired data handled?  (3) How the research participant will receive an explanation that they will not be disadvantaged.  **✍Example**  Since it is an anonymous survey, consent cannot be withdrawn after responding. Participants can withdraw their consent until /・・・・.  They can withdraw their consent by ・・・・・・.  If they withdraw your consent to participate in the research, the data obtained from them will ・・・・・・・・.  They will face no disadvantage by not participating in the research or stopping in the middle of the research.  These matters will be explained verbally in advance and are written in the “Research Contents Explanation [To Institute Heads]” (Appendix ●) and “Research Contents Explanation [To Research Participants]” (Appendix ●). | | | | | | | |
| 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  Please describe how (telephone, e-mail, direct laboratory visit, etc.) the principal investigator, the research implementer, etc. will receive inquiries and by what method information will be shared (described in the “Research Contents Explanation” and communicated verbally, etc.). | | | | | | | |
| **✍Example**  [Inquiries] Principal investigator: Ichiro Kioi; Research implementer: Taro Sophia  [Inquiry method]・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・  [Information method] Explanations in the “Research Contents Explanation [To Institute Heads]” (Attachment ●) and “Research Contents Explanation [To Research Participants]” (Attachment ●) as well as verbal explanations. | | | | | | | |
| **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)  If there are benefits from the joint research institute or potential bias that affects the research results, it is necessary to self-report that there is a conflict of interest. If such is the case, please describe measures to ensure that participants will cooperate with the research out of their own free will. Moreover, if there is no conflict of interest, please state (declare) that there are no such relationships. | | | | | | | |
| No  Yes | | | | | | | |
| \* If yes, please describe below such relationship and measures to be taken to make the research appropriate. | | | | | | | |
| Relationship | | **(6) When there is a conflict of interest with research participants**  \*See “Notes for filling out the form” at the end | | | | | |
| 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.):  **Do not leave this field blank as it is required**  Please also describe what will happen definitively and what may happen. Moreover, even if relevant risks are similar to those of daily life, you need to describe them. | | | | | | | |
|  | | | | | | | |
| (ii) Measures to minimize such burdens and risks:  **Do not leave this field blank as it is required** | | | | | | | |
| **✍Example**  Potential physical and mental burdens are ・・・・・・・・・・, so measures such as ・・・・・・・ are taken to minimize such burdens. | | | | | | | |
| (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.):  **Do not leave this field blank as it is required** | | | | | | | |
| **✍Example**  If a burden actually occurs during the research, ・・・・・・・・・・・・・・・・・・・・.  **(7) Medical expenses in the event of unforeseen circumstances**  \*See “Notes for filling out the form” at the end | | | | | | | |
| (iv) Whether there are any direct benefits\* the participant gets by participating and cooperating in the research: | | | | | | | |
| Please describe it if it is assumed that there will be direct benefits to the research participants, rather than to the research implementer.  If there are no direct benefits, please state that there are none.  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 | | | | | | | |
| **✍Example**  By conducting this research, it is expected that ・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・  ・・・・・・・・・・・・. | | | | | | | |
| (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.):  **✍Example**  QUO card worth 500 yen (interview survey ● minutes / one time) | | | | | | | |
| 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.  It is also possible to base this on regulations such as the University’s “Budget Execution Guidebook.”  **✍Example**  As the interviews for this research were ・・・・・・・・・・・・・, an honorarium equivalent to ・・・・・・・・・ yen is offered on the basis of・・・・・・・・・・. | | | | | | | |
| **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. | | | | | | | |
| Even if it does not fall under “personal information” as defined by the Act on the Protection of Personal Information, please describe information that can be used to identify or pertain to individuals.  (Reference) Act on the Protection of Personal Information -Personal Information Protection Commission Japan-  https://www.ppc.go.jp/en/legal/  **✍Example**  ○ Personal information, etc. collected for the purpose of research  Age, gender, years worked, voice data ・・・・・, etc.  ○ Personal information collected in order to contact participants  Name, e-mail address・・・・・, etc. | | | | | | | |
| (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)  〇 Alphabetic processing: Creating a comparison table or other processing so that a specific individual cannot be identified unless checked against a comparison table.  〇 Anonymous processing: Processing so that a specific individual cannot be identified. | | | | | | | |
|  | No | | | | | | |
| Describe the reason: | | | | | | | |
|  | Yes | | | | | | |
| Describe in detail the method of anonymous/pseudonymous processing:  **✍Example**  No information that can be used to identify individuals will be collected.  Information that can be used to identify individuals is removed from the original data, after which they are managed with numbers and codes unrelated to the participants.  A comparison table that can be matched against the original data will be created/not created.  　　　　　　　　　　　　　　　　　　　　　　　　　　　　etc. | | | | | | | |
|  | 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: | | | | | All materials collected in the course of the research, such as “laboratory notebooks,” “forms for consent and withdrawing consent to conduct the research,” “questionnaires,” and "comparison tables,” should be treated as research samples, materials, information, etc. (including personal information).  Please describe the storage methods (specific locations and methods of storage, including safety management) of research materials collected as “paper media” and “electronic media.”  ◆ If creating a comparison table: Please store the comparison table and the information collected in the research in separate places so that they cannot be easily collated.  ◆ If collecting research materials outside the university: Please describe the safety management when transporting such research materials.  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 | | |
|  | | | | | According to the “Sophia University Guidelines for the Prevention of Misconduct in Research Activities, 7: Points to consider for proper conduct of research activities,” storage of research data is regulated as follows: “(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. Specimens and other tangible research materials shall in principle be preserved for five years. These research materials shall be disclosed as necessary.” Please describe your storage in accordance with the relevant standards. | | |
| 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.  **(8) When there is a possibility that the research materials will be used for future research or provided to other research institutes**  \*See “Notes for filling out the form” at the end  \* 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 | | | | | | | |
| **✍Example**  The data obtained for this research may be used in future research developed based on this research. | | | | | | | |
| The process to obtain the informed consent from the research participants | | | | | | | |
| **✍Example**  The plan is to contact candidates individually to ask if they would agree to participate in the research. | | | | | | | |
| **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.): | | | | | | | |

If outsourcing to a third party, please attach a copy of the business consignment agreement with them.

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

|  |  |
| --- | --- |
| **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 | **✍Example**  If requested by the research participant or the institution to which the research participant belongs, a summary of the study results will be sent. When doing so, we will not disclose any personal information pertaining to the research participants. |
| **②Information disclosure to the outside (academic societies, scientific communities, the general public)**  There is an ethical obligation to publish research results in the absence of a special reason not to do so. Please publish them at the relevant academic conference or in an academic journal, a university bulleting, a department website, etc. | |
| 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) | Please also state that you will take care not to allow identification of research participants’ personal information.  **✍Example**  The research results will be presented at ○● academic conference/presented as a ●● paper/submitted to the ●○ journal. In doing so, we will not disclose any personal information of the research participants. |
| Name of academic meeting or academic journal at or in which research results will be presented and the presentation period. | If you are already planning to submit to a journal or present at an academic conference, please indicate this.  **✍Example**  ○● academic conference (・・ academic year), etc. |

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

|  |  |
| --- | --- |
| 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:  If you wish to have the participation of persons who belong to another institution or facility (including hospitalized patients and outpatients), please be sure to obtain the consent of the institution concerned. When obtaining consent, if an ethics committee has been established, please obtain consent in accordance with the provisions of the institution.  **✍Example**  ■■■ Ethics Committee  Furthermore, for the ■■■■ institution, we will ask the research participants if an ethics committee exists, and if it does, an application shall be made in accordance with that committee. After their examination, a copy of the examination results will be submitted to the Ethics Committee of the Sophia University, so that the research will begin after receiving confirmation. If no committee exists, a copy of the institution’s consent form will be submitted to the Ethics Committee of Sophia University, so research will begin after receiving confirmation. | |

**VII. Others**

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

**Notes for filling out the form**

**\* The Ethics Committee will review the “Application for Examination of Research Plan” and the attached documents submitted (e.g., requests and explanations submitted to the facility requested to cooperate with the research).**

It is assumed that the research contents are properly understood and easy to understand for participants who will cooperate with the research. Please take care so as to write in a way that considers the position of the research participants.

E.g.) Definitions and notes should be included for technical terms and abbreviations.

Moreover, when asking research participants to participate in research, please plan and conduct the research with an awareness that there is always some risk and burden.

**(1) Research ethics consultations**

A research ethics consultation refers to the discovery and analysis of ethical issues and advice to research implementers from the research planning stage to the end of the research, with the Ethics Committee providing such support to ensure a smoother start of research projects prior to discussion.

If you would like to have a research ethics consultation, please contact the Research Promotion Center.

(1) Prior consultation

(1) Before submitting the application documents to the Ethics Committee, make an appointment with a research ethics consultant and receive a consultation (interview, e-mail, telephone, etc.). Application documents reflecting the contents of the application must be submitted to the Center for Research Promotion and Support by the submission deadline.

(2) Discussed at the following month’s Ethics Committee meeting

(2) Consultation at the time of application

(1) Submit the application documents to the Center for Research Promotion and Support by the submission deadline.

(2) The Center for Research Promotion and Support will request a consultation with a research ethics consultant if you would like this.

(3) Receive a consultation from the research ethics consultant (response form attached to the e-mail) and resubmit revised application documents reflecting the research contents to the Center for Research Promotion and Support.

(4) Discussed at that month’s Ethics Committee meeting

\* The procedure under (1) is recommended because the schedule for (2) is very tight from the consultation response to the submission of the revised application documents.

**(2) If the applicant is a JSPS Research Fellow (DC/SPD/PD/RPD) Japan**

**<Applicant’s affiliation and job title>**

**In the case of a Research Fellow (DC) of the Japan Society for the Promotion of Science**

Please state your affiliation, job title, and employment status at the Japan Society for the Promotion of Science, obtaining approval from your academic advisor.

**✍Example**

■■■ Program Year 2, Department of ■■, Graduate School of ■■ / JSPS Research Fellow (DC2)

**In the case of a Research Fellow (SPD/PD/RPD) of the Japan Society for the Promotion of Science**

Please state your employment status at the Japan Society for the Promotion of Science as well as host affiliation at Sophia University, indicating the name of the host faculty member at Sophia University in the “Supervisor” column for approval.

**✍Example**

Research Fellow (PD), Japan Society for the Promotion of Science / Department of ■■

**<About the principal investigator>**

**In the case of a Research Fellow (DC) of the Japan Society for the Promotion of Science**

The principal investigator should be your supervisor.

**In the case of a Research Fellow (SPD/PD/RPD) of the Japan Society for the Promotion of Science**

The principal investigator should be the host faculty member at Sophia University.

**(3) Beginning and end of the research period**

The research period begins at the time of planning and drafting the research plan, but when applying to the Ethics Committee, please write “After Approval”

The end of the research period is **when the results of the research are published**, so please indicate the relevant end.

**If the research is externally funded**

It is recommended that the research period be until the end of the research project’s adopted period.

**If the applicant is a student**

It is recommended that you use the term of your current status.

If you decide to continue your research, please apply for a change to extend the research period.

**(4) When applying for a change in the research plan, etc.**

In the case of “Change”

Please include the receipt number listed from previous “Notification of Examination Results.”

**✍Example**

Receipt number: 2023-★, 2023- ★★

会付議に先立ち、研究をよりスムーズに開始していただくために、

**(5) When there is a collaborative research institute**

Regarding the implementation system for the research as a whole, please describe the roles of the applicant, the collaborative research institute, and the collaborators of this research separately under “3. Research Summary (4) Research Plan.”

Moreover, if a joint research agreement is concluded, please attach a copy of the relevant document.

**(6) When there is a conflict of interest with research participants**

A conflict of interest is a relationship where a third party may be concerned that the fair and appropriate judgment required for research is impaired or may be impaired primarily due to economic interests with external parties.

Additionally, this item requests you to indicate whether there are any relationships that may raise concerns about whether the research will be fair and appropriate, such as power relationships between teacher and student via grading and personal relationships between researcher and research participants, including being friends or parent and child.

The existence of such relationships is not a problem in and of itself, but please indicate under this item the relevant relationships and countermeasures since the issue is what measures are taken to dispel concerns about the integrity of research, etc.

**◆ When recruiting research participants using classes at the university**

If you use class time to explain your recruitment or research, please make an effort to use **the time before and after the class** so as not to interfere with the class. When doing so, ask the faculty member in charge to cooperate with the research and indicate that here. However, this does not apply if the class itself is part of the research.

Moreover, please explain to the candidates that they will not be disadvantaged even if they do not cooperate with the research, affecting neither the class nor the evaluation of the faculty member in charge, and ensure that they are able to decide whether to participate in the research of their own will.

**◆ When the research subject is a friend, acquaintance, colleague, student, etc.**

When such candidates are selected as research participants, it is easy to have doubts about their autonomy and the research’s objectivity, fairness, and validity if there are personal relationships with the researchers.

In order to dispel such doubts, please state if there is a valid reason why it would be difficult to carry out the research or why the academic value would be impaired if these people were not included as research participants.

Moreover, if a research participant belongs to one of the abovementioned categories, it is important to ensure their free will to participate in the research, so please take the utmost care not to force them to participate in the research.

**(7) Medical expenses in the event of unforeseen circumstances**

In the event of an unforeseen event, it may be necessary to receive some kind of medical care, so if you are conducting research that is considered to features such a risk, please describe the plan and the costs in the event of medical expenses. If the researcher does not pay the costs but uses the insurance of the individual research participants, please state this, also indicating this in the “Instruction of research contents for participants” and obtaining consent as this should be explained to the research participants in advance.

**When conducting interviews with research participants**

When conducting interviews, depending on the contents of the research, the interviewer’s professional experience and interviewing skills also need to be taken into account. If the researcher has qualifications and experience as a clinical psychologist, etc., or has already received some training, please include such information. Moreover, if the researcher has no interview experience, learning some interview techniques is also a way to minimize risks.

**(8) When there is a possibility that research materials will be used for future research or provided to other research institutes**

Since that would differ from the original purpose of use, **it is necessary to explain this to the research participants in advance and obtain their consent, even if it is only within the scope of what is currently known. Furthermore, it should be noted that even if the research participants’ consent is obtained at this time, it does not mean that no ethical review of any new research plan will be necessary.**

The contents of what should be explained are: **(1) the name of the organization supplied, (2) the other organization’s purpose of using the data, (3) the person at the other organization responsible for the use, (4) the scope of the user by the other organization, and (5) the type of data to be provided (items, contents, etc.)**. Based on this, if you wish to use the data for another purpose in the future (other research, etc.), you will need to make a research plan and obtain informed consent again, or if this proves difficult, notify or publish and obtain consent from the research participants. Please apply to the Ethics Committee as you will need to consider and decided on one of these approaches.

For more details, please refer to the “Act on the Protection of Personal Information” or the “Ethical Guidelines for Medical and Biological Research Involving Human Subjects.”

Reference: Act on the Protection of Personal Information -Personal Information Protection Commission-

<https://www.ppc.go.jp/personalinfo/>

Reference: Ethical Guidelines for Medical and Biological Research Involving Human Subjects -Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry-

<https://www.lifescience.mext.go.jp/files/pdf/n2262_01.pdf>