Filling out the “Application for Examination of Research Plan

(Research on Human Subjects)”

[Points of note]

1. In the text, “research participant” is a general term for those who are subject to research, those who participate in experiments in experimental research, and those who cooperate in field research, etc.

2. Please carefully read Sophia University's “Guidelines for Research on Human Subjects,” “Submission of Application Documents to the Sophia University Ethics Committee for Research on Human Subjects” and “Pre-check sheet for research on human subjects.”

3. In addition to this application form, please be sure to attach the following documents that you plan to use when conducting your research.

・Letter of request to institution asked to participate in the research

・Instructions for participants

・Forms to consent / withdraw consent for research participation for participants

・Survey documents (questionnaires, interview guides, etc.)

・If outsourcing investigation to a third party, contracts, memorandums of understanding, etc.

・Research plan

\* If you have other materials that can help us understand your research plan and its contents, please attach them as appropriate.

Furthermore, the personal information and personal data contained in this application form and attached documents will be used only for the examination of the research plan.

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| [Matters to be explained to research participants and that require consideration]  When conducting research on human subjects, it is necessary to clearly explain the following matters when collecting personal information and data from research participants. It is desirable that you prepare and present a document in advance when providing the explanation. However, what is included in the explanation may vary depending on the research contents.  (1) Overview, purpose, and significance of the research  Describe and explain in an easy-to-understand manner so that people outside of your specialization can understand the reasons for being selected as a research participant, the contents of the data to be collected, and how you will present your research results.  (2) Handling of personal information, etc.  Explain whether and how anonymization is used, how data is stored and managed, how they are handled after the storage period expires, and that personal information is appropriately protected.  (3) Matters related to burdens, anticipated risks, and benefits incurred by research participants  If it is expected that participants will suffer some physical or mental burden or pain during the collection or gathering of information, data, etc., explain this in an easy-to-understand manner.  (4) Respect for the self-determination and free will of research participants  ・Participation in the research is voluntary, and the research subject will not be disadvantaged by not consenting or withdrawing consent.  ・Even after agreeing to participation, consent can be withdrawn at any time without incurring any disadvantages. If so, the data collected so far will be destroyed.  ・Disclosure of data, etc. can be done at the request of the person in question  ・Collected data will not be provided to a third party without the consent of the person in question  (5) Responding to inquiries, etc.  Provide contact information for responding to inquiries, etc.  (6) Other matters  ・Conflicts of interest  ・Payment of remuneration and expenses  ・Possibility of obtaining findings such as health and genetic characteristics of research participants outside the scope of the research purpose as a result of conducting the research and how these are handled |