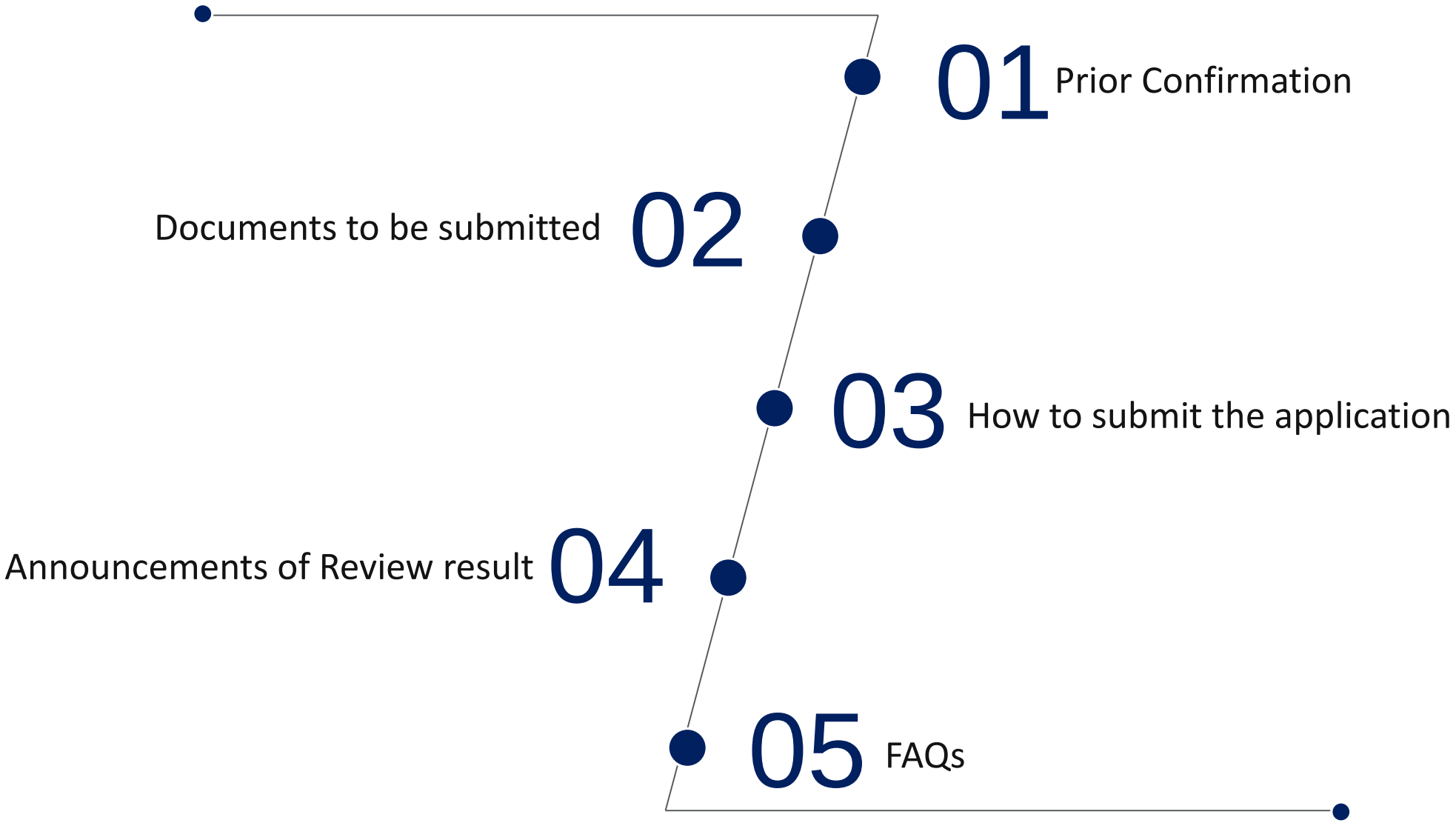
Application Process of SOKA University Institutional Review Board for Human Research

SOKA University IRB Office

AGENDA


01 Prior Confirmation
Documents to be submitted 02
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Prior confirmation

(1)What is the IRB?

(2)Related Regulations

(3)Who are Required to Apply for the Review?

WHAT IS THE "IRB"?

- When conducting research involving human subjects, hereinafter referred to as *human subjects research*, a variety of rules must be observed in order to **protect the rights and dignity of their participants, the human subjects.**
- It investigates and deliberates on studies involving human subjects, **focusing on whether the proposed or ongoing work is ethically and scientifically appropriate.** Its point is **to protect the dignity and human rights of people involved in research (including candidates who do not become subjects) by fair and impartial review from both ethical and scientific angles, including the possibility of a conflict of interest involving the researchers**.
- An IRB is a collegial body organized to deliberate on ethical and scientific sides of a research study, including its fitness for conduct or continuation.

-Quoted by "eAPRIN" : **Review by an Institutional Review Board (IRB)-**

<u>All researchers and graduate students who will conduct human subjects research must file an application to the IRB committee at SOKA University</u>

RELATED REGULATIONS

● **Soka University Code of Ethics for Human Research**

– Preamble –

The word “Soka” in our name “Soka University” means value creation. In essence, to create value means to enhance life. To persevere in the challenge to build a peaceful society which places the highest value on human dignity; to be undaunted by hardship – the mission of Soka University is to nurture such creative humanity.

When taking this mission and responsibility into consideration, any person in the world of academia is naturally required to have the highest ethics; it is obligatory for them to respect fundamental human rights, to commit to intellectual honesty and to fulfill their social responsibility, but moreover, it is essential to contribute to the development of the university and the peace of humankind by fully understanding and implementing the noble mission and goals of the university. This code is set forth as a foundation for realization of this mission and goal and as an ethical code of conduct that every person in Soka University who engages in research activities involving human subjects should observe.

● Soka University Code of Ethics for Human Research
https://www.soka.ac.jp/files/en/20210614_183447.pdf

● Soka University Detailed Rules Regarding Ethics Review Procedure for Human Research
https://www.soka.ac.jp/files/en/20210614_183503.pdf

WHO ARE REQUIRED TO APPLY FOR IRB PROCEDURES ?

- Any Research and Survey involving human subjects inside and outside the University as conducted by instructors and staff and by graduate students at the University
- as well as to any Research and Survey involving members of the University conducted by persons outside the University. (Article 3, The code of Ethics for Human Research)

Faculty and staff members of SOKA University

Graduate students at SOKA University
***Except for professional law school students**

Researchers/Students outside of SOKA University

APPLICATION ELIGIBILITY GUIDE

You can check if you are required to apply for the IRB through the following website (Google form).

https://forms.gle/q76oz8nohXvEA8QUA

創価大学 人を対象とする研究倫理審査申請手続きのご案内　Soka University IRB Application Guide

ここでは、「創価大学 人を対象とする研究倫理委員会」の審査申請手続きについて確認できます。
The application procedure of the Soka University Institutional Review Board for Human Research can be confirmed through the following questionnaire.

以下のリンク先に、関連規程、Q&A、審査申請様式等を掲載していますので、ご参照ください。
Please refer to the following link for the application forms and related regulations.
https://sokauniversity.box.com/v/IRBforms

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How to submit the application

(1)Submission flow

(2)Submission Deadline

SUBMISSION FLOW

1 Complete all required application documents

IRB Check List, F01, F02, F03, F06, Sample survey/interview questions, and etc…
https://sokauniversity.box.com/v/foms-guidelines-EN

2 Submit an Online IRB Application Questionnaire

Fill in the designated items on the IRB Online Application Questionnaire from the link below:
https://forms.gle/6MNW9Uq2opgvH7cs9

3 Submit all required forms and documents to the IRB office electronically via email

Attach the application form and other required documents in a PDF format and send to: soka-irb@soka.ac.jp
*Please submit all electronic files as PDF.
*Attachments file size cannot not exceed 7 MB

4 Submit all hard copy forms and documents with signature by mail or in person.

If you are overseas and cannot submit hard copies, you can submit only data via email. However, please make sure to get the electronic signature of your supervisor in the F01.

IRB WEBSITE

https://www.soka.ac.jp/en/research/humanresearch

Soka University Institutional Review Board for Human Research

SOKA UNIVERSITY INSTITUTIONAL REVIEW BOARD FOR HUMAN RESEARCH

Application Steps

STEP ①: Check the Soka University IRB Application Guide

The application procedure of the Soka University Institutional Review Board for Human Research can be confirmed through the following questionnaire.
Please answer the following questions to determine whether or not an application is required and to confirm the appropriate application method. The necessary procedure will be indicated based on the results.

IRB Application Guide

STEP②: Download latest application forms

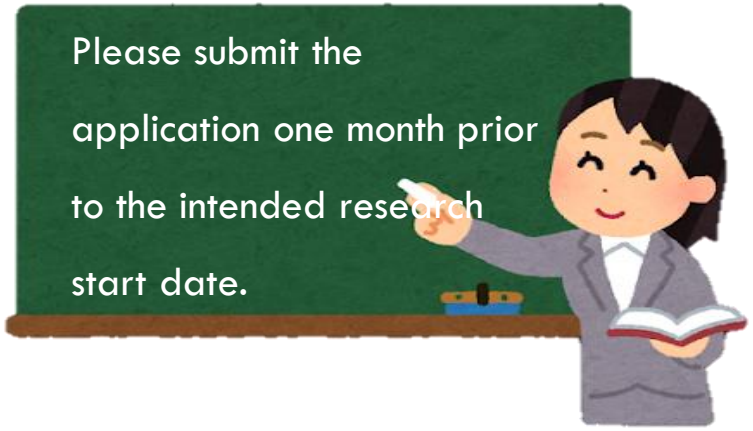
Please refer to the following link for the application forms and related regulations.
Prepare the necessary attachments, such as the documents related to informed consent and the questionnaire. Refer to the samples for documents related to informed consent via the link below.

Latest application forms

SUBMISSION DUE DATE

By 12:00 p.m., the 10th of every month (Except for August)

- If the 10th is on a Sunday or National Holiday in Japan, the due date will be 12:00 p.m. of the latest weekday before the 10th.
- IRB committee will not be held in August.
- Researchers must apply and get approval from the IRB committee before starting their research activities.
- The start date of the research must be on or after the first day of the following month for the submission of the application.
- In case you have started research activities before getting the approval, the relevant application will not be acceptable.
- Please note that applications submitted after the deadline will be reviewed by the IRB committee in the following month.



APPLICATION DUE DATE FOR THE PURPOSE OF WRITING MASTER'S THESIS

Graduate students must apply at least 4 months prior to the submission due date of the academic dissertation

For Graduate students to complete in March

- Paper submission deadline:
  ⇒Early January
- IRB application deadline:
  ⇒July

*Since there is no IRB committee meeting in August

For Graduate students to complete in September

- Paper submission deadline:
  ⇒End of June or Early July
- IRB application deadline:
  ⇒February

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Submission documents

(1) Document to be submitted

(2) Items to be Checked on the Forms

(3) Items to be Checked on the online application

BEFORE FILING AN APPLICATION:

- Discuss and consult with your supervisor/academic advisor extensively about your research plan, research methods, etc.
- If you file an application for the first time, you are advised to submit your application ahead of deadline in order for the IRB staff members to check any parts missing or incomplete.

For Graduate Students,

✓ Please have your application documents reviewed by your supervisor.

✓ Please obtain the signature from your supervisor on F01.

(1) DOCUMENT TO BE SUBMITTED

1. IRB online questionnaire (Google Form)
2. F01 IRB Application Form
3. F02 Explanatory Form
4. F03 Informed Consent Form
5. Sample surveys/Interview questions
6. F06 Permission to conduct a research (if applicable)

   *If you conduct a survey or interview at a school or medical institution, please obtain prior approval for your research from the school principal or facility director, obtain their signature on the consent form, and submit the form to the Institutional Review Board (IRB) office.
7. IRB Application Check List

(2) HOW TO FILL IN “IRB APPLICATION QUESTIONNAIRE” (GOOGLE FORM)

Please access the link below and respond to all required sections.

https://forms.gle/6MNW9Uq2opgvH7cs9

創価大学

Discover your potential
自分力の発見

創価大学 人を対象とする研究倫理審査申請アンケート　Soka University IRB Application Questionnaire

*English announcement follows
●「創価大学 人を対象とする研究倫理委員会」に研究倫理審査を申請する方は、下記に必要事項をご記入の上、回答を送信してください。

●申請様式ならびに関連規程は下記のリンクから取得できます。提出書類を作成の上、下記のオンラインアンケートにご回答ください。

●作成した書類は全てメール添付で事務局までお送りください。送付用のメールアドレスは、アンケート回答後に表示されます。

●署名入りの申請書類原本を事務局までお持ちください（郵送可）

【申請締切】
８月を除く毎月10日・12時まで（日曜・祝日の場合は前の平日・12時まで）※郵送の場合も締切日必着

【お問い合わせ】
人を対象とする研究倫理委員会事務局
住所：〒192-8577 東京都八王子市丹木町1-236　創価大学　学事部学事第２課
Tel: 042-691-6904　（学事第２課・研究管理室）
Email: researchmanagement@soka.ac.jp

●窓口時間：平日9:00～17:00、土9:00～12:00　（学内行事や新型コロナウイルスの感染状況等により変更する場合があります）

●A person who wishes to apply for an ethical review for human research must fill in the following questionnaire and submit the application form to the Institutional Review Board for Human Research with other required documents.

●Application forms can be downloaded from the following link. Prepare necessary documents and fill in the following questionnaire.
<Application forms>
https://sokauniversity.box.com/v/IRBforms

●A person who wishes to apply for an ethical review for human research must fill in the following questionnaire and submit the application form to the Institutional Review Board for Human Research with other required documents.

●Application forms can be downloaded from the following link. Prepare necessary documents and fill in the following questionnaire.
<Application forms>
https://sokauniversity.box.com/v/IRBforms

●Attach the electronic files of the application form and other required documents to an e-mail and send it to the IRB office. The email address for sending the documents will be displayed after you answer this online questionnaire.

●Please submit the original signed application forms (F01) and required documents to the IRB office (The postal mail submission is also acceptable).

[Due date]
By 12:00 p.m., the 10th of every month except August
*If the 10th is on a Sunday or National Holiday in Japan, the deadline will be 12:00 p.m. of the weekday before the 10th.)
*IRB committee will not be held in August.

[CONTACT]
Soka University IRB Office
Address: 1-236, Tangi-machi, Hachioji-City, Tokyo, 192-8577 Soka University, Faculty Affairs Office
Phone: 042-691-6904
Email: researchmanagement@soka.ac.jp

●Office Hours:　Mon.-Fri. 9:00-17:00　Sat. 9:00-12:00　*It can be varied due to the on-campus event/COVID19 situation.

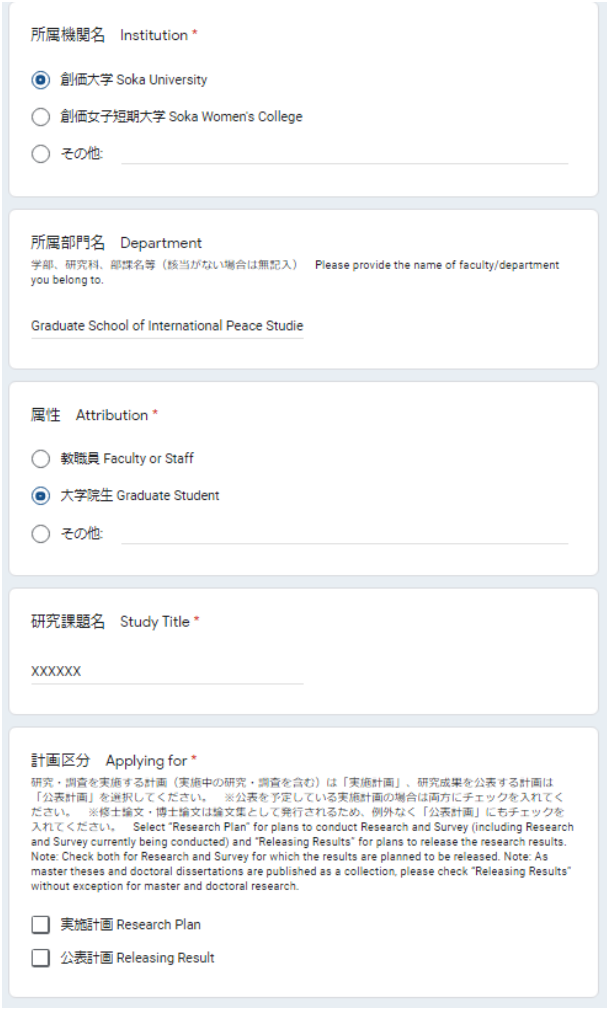
*必須

メールアドレス *

メールアドレス

研究代表者名　Principal Investigator Name *
フルネームでご記入ください。　Please provide your name in full.

回答を入力



所属機関名　Institution *

- (●) 創価大学 Soka University
- ( ) 創価女子短期大学 Soka Women's College
- ( ) その他:

所属部門名　Department
学部、研究科、部課名等（該当がない場合は無記入）　Please provide the name of faculty/department you belong to.

Graduate School of International Peace Studie

属性　Attribution *

- ( ) 教職員 Faculty or Staff
- (●) 大学院生 Graduate Student
- ( ) その他:

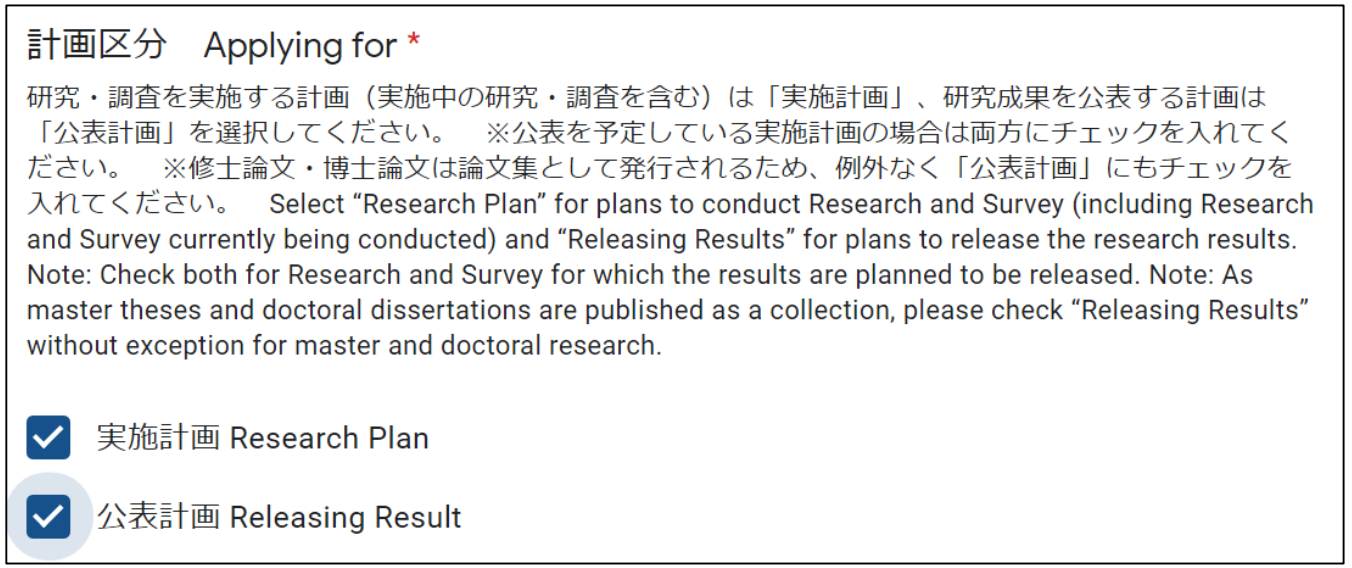
研究課題名　Study Title *

XXXXXX

計画区分　Applying for *
研究・調査を実施する計画（実施中の研究・調査を含む）は「実施計画」、研究成果を公表する計画は「公表計画」を選択してください。　※公表を予定している実施計画の場合は両方にチェックを入れてください。　※修士論文・博士論文は論文集として発行されるため、例外なく「公表計画」にもチェックを入れてください。　Select "Research Plan" for plans to conduct Research and Survey (including Research and Survey currently being conducted) and "Releasing Results" for plans to release the research results. Note: Check both for Research and Survey for which the results are planned to be released. Note: As master theses and doctoral dissertations are published as a collection, please check "Releasing Results" without exception for master and doctoral research.

- [ ] 実施計画 Research Plan
- [ ] 公表計画 Releasing Result

(2) HOW TO FILL IN “IRB APPLICATION QUESTIONNAIRE” (GOOGLE FORM)

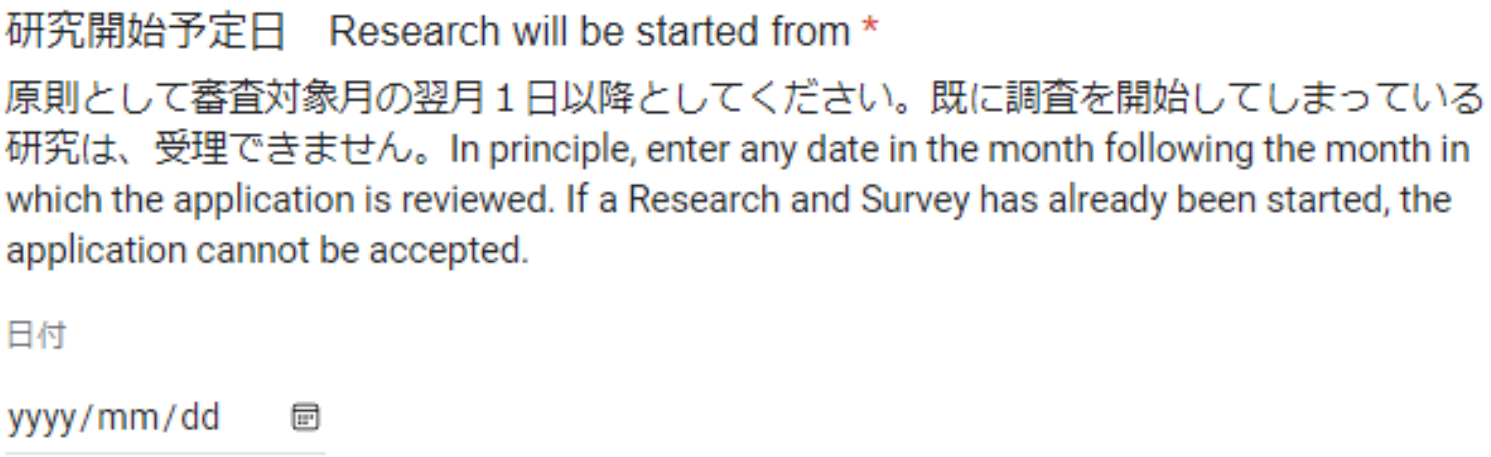


- **“Research Plan Only”:** In case of conducting a survey and having no plans to publish the survey results in a paper or presentation (“Research Change Protocol must be submitted when it needs to be released)

- “**Research Plan” and “Releasing Result”:** In case of conducting a survey as well as releasing results in a paper or presentation (It should be selected for Master's thesis or Doctoral Dissertation)

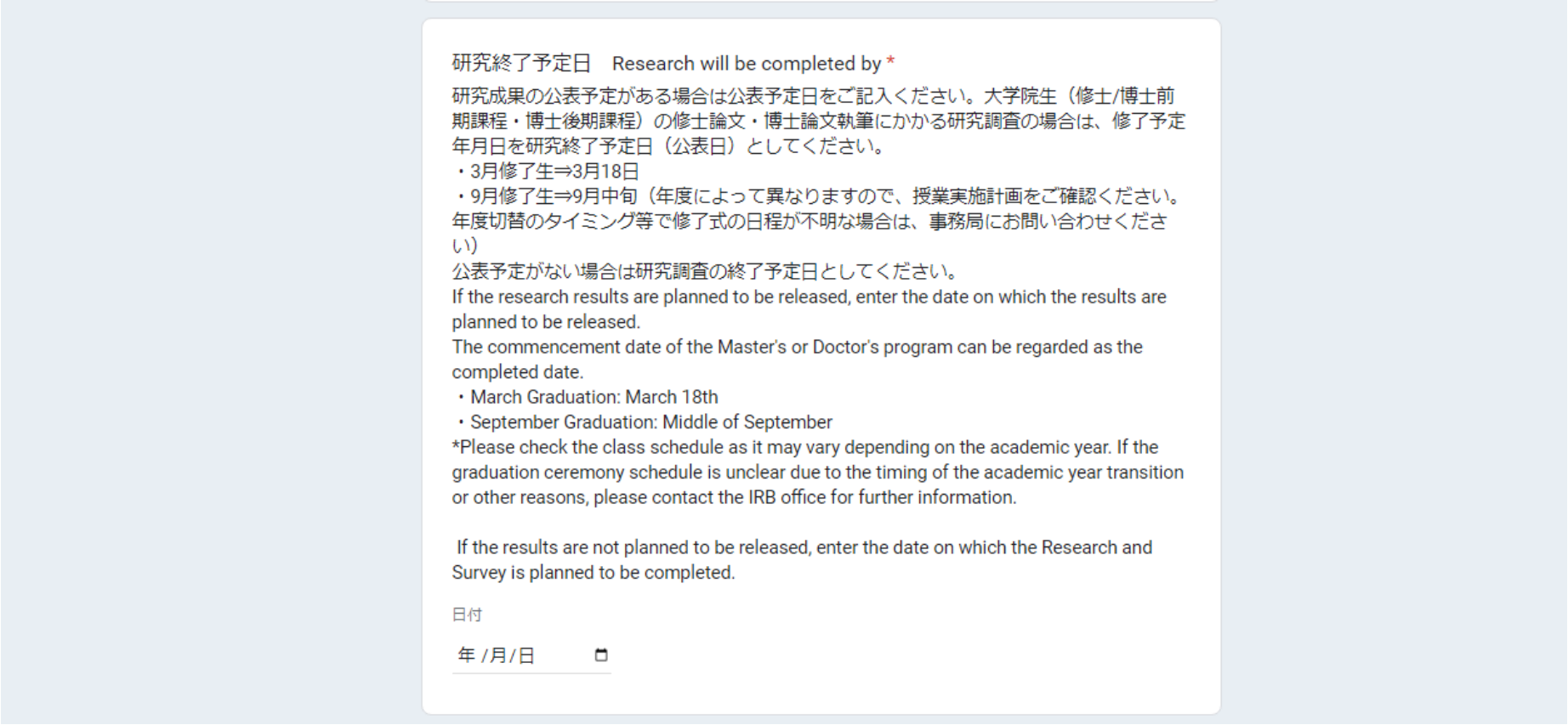
- “**Releasing Result Only”:** In case of using the results of surveys or other investigations conducted for non-research purposes in the past for research purposes (It usually applies for surveys conducted as part of a class, student outputs, etc.)

(2) HOW TO FILL IN “IRB APPLICATION QUESTIONNAIRE” (GOOGLE FORM)



- The earliest possible research start date is the 1st of the following month of your IRB application/review month.
  ⇒If you submit your application on or before June 10, your research start date must be set July 1 or later.
- In case interviews and surveys have already been started, the application cannot be accepted.

(2) HOW TO FILL IN “IRB APPLICATION QUESTIONNAIRE” (GOOGLE FORM)



研究終了予定日　Research will be completed by *

研究成果の公表予定がある場合は公表予定日をご記入ください。大学院生（修士/博士前期課程・博士後期課程）の修士論文・博士論文執筆にかかる研究調査の場合は、修了予定年月日を研究終了予定日（公表日）としてください。
・3月修了生⇒3月18日
・9月修了生⇒9月中旬（年度によって異なりますので、授業実施計画をご確認ください。年度切替のタイミング等で修了式の日程が不明な場合は、事務局にお問い合わせください）
公表予定がない場合は研究調査の終了予定日としてください。
If the research results are planned to be released, enter the date on which the results are planned to be released.
The commencement date of the Master's or Doctor's program can be regarded as the completed date.
・March Graduation: March 18th
・September Graduation: Middle of September
*Please check the class schedule as it may vary depending on the academic year. If the graduation ceremony schedule is unclear due to the timing of the academic year transition or other reasons, please contact the IRB office for further information.

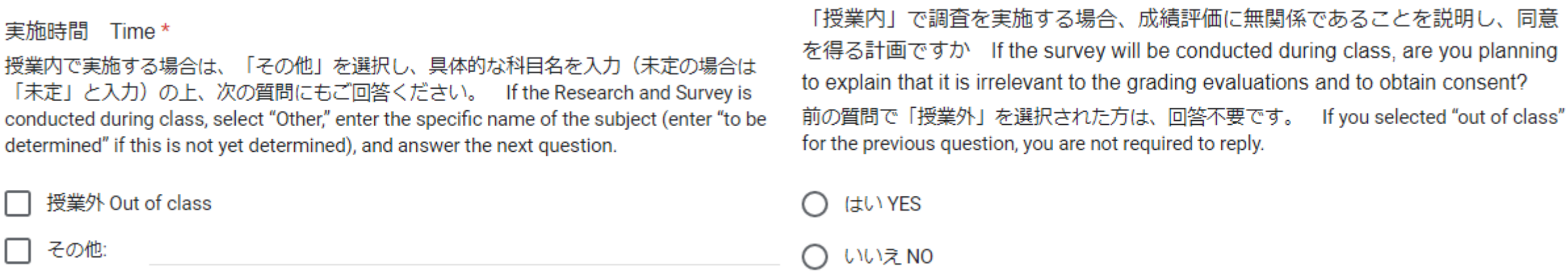
If the results are not planned to be released, enter the date on which the Research and Survey is planned to be completed.

日付

年 /月/日

- If there is a plan for publication, please write the expected date of publication as the expected date of completion of the research.
- For a master's thesis or a doctoral dissertation, please set the following dates (when you complete your program) as your expected research completion date.
- March 18th for those graduating in March
- Middle of September for those graduating in September (Please check the academic calender)

(2) HOW TO FILL IN “IRB APPLICATION QUESTIONNAIRE” (GOOGLE FORM)



- Interview or survey should be conducted outside of the class hours
- In case of conducting research during class hours, give the course name
- Describe the rational reason and considerations for students who refuse to participate on the F01 form.

- If faculty members will use the collected data in the past classes for their research, the Informed consent form must be obtained through a follow-up process.

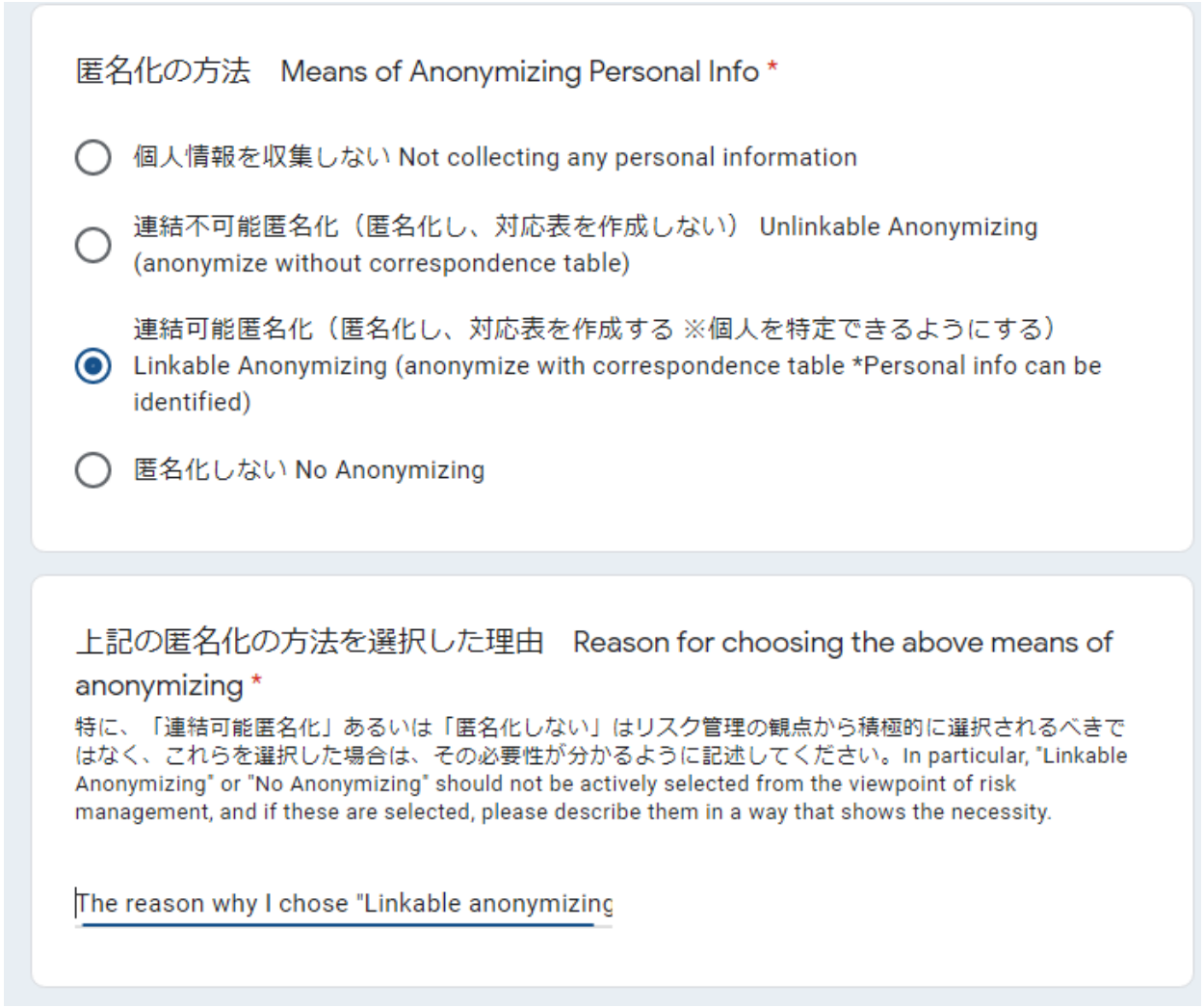
(2) HOW TO FILL IN “IRB APPLICATION QUESTIONNAIRE” (GOOGLE FORM)

- Please select the research methodology and provide detailed information in the application form and explanatory document.
- If conducting interviews via platforms like Zoom and recording them, check the "Audio Recording" or "Video Recording" option and create a consent item in the consent form.

<Caution>

- Pay attention to discrepancies between the checked items here and the information provided in the application form.

(2) HOW TO FILL IN “IRB APPLICATION QUESTIONNAIRE” (GOOGLE FORM)

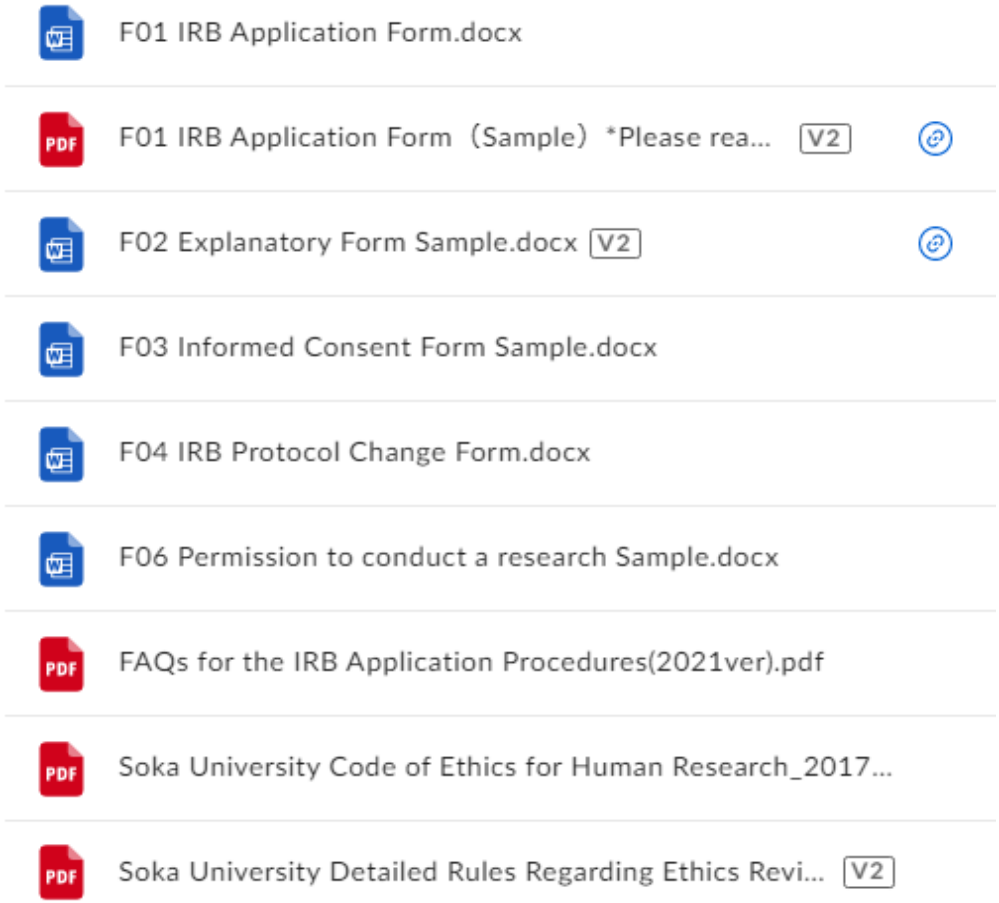


- Please select the means of anonymizing personal information.
- If you will aggregate personal information by anonymizing after conducting an interview or survey, please select "Unlinkable Anonymizing”.
- If you want to create a correspondence table and aggregate personal information in such a way that the personal info can be identified, please select “Linkable anonymizing".

In particular, "Linkable Anonymizing" or "No Anonymizing" should NOT be actively selected from the viewpoint of risk management, and if these are selected, please describe the valid reason in this form and F01.

YOU CAN DOWNLOAD LATEST APPLICATION FORMS FROM THE FOLLOWING URL

https://sokauniversity.box.com/v/foms-guidelines-EN



⇒F04 will only be required in case you will need to change your research protocol once you got an approval.

F01 IRB APPLICATION FORM

Soka University IRB Application Form

Institutional Review Board on Human Research [Form 01]

Date:

Principal Investigator (Applicant)		Supervisor	
Name		Name	
Department		Department	
Phone		Title	
Co-investigator(s)			

Summary of Research Purpose *Please describe purpose of the research succinctly.
*Please be advised that you cannot start your survey/ interviews before getting approval from the Soka University IRB committee.
Summary of Research Design and Procedures *Please describe design and procedures of the research succinctly.
*Please make sure to indicate your detail research conducting plan including when, where, how long, how frequently. *In case you will conduct an interview/survey, please write the expect time to be conducted for the interview/survey and submit the list of questionnaire or the interview questions.
Participants' gender, age, number, and reasons and ways of recruiting
*Please describe the information of your research participants including the participants' gender, age, number, and reasons and ways of recruiting. Especially, if you select the teenagers or the disability person as your research participants, detailed explanation will be required. *Please make sure the points below as for the recruiting methods. -Is the recruiting method appropriate so that the research subject can freely decide to participate in the research?
Potential Risks to the Participants *Please describe potential physical, psychological, and/or social risks to the participants.
*In particular, if your research participants are students, please refrain from conducting research during class hours. If it is unavoidable for you to conduct an investigation during the class period, you must prepare other supplementary study materials for students who will not participate in the survey. *Please describe the detailed reason why you could mention that there are no foreseeable risks to the research participants.
Informed Consent *Please describe how the participants will be informed about their rights to participate or not.
*Please specify how to obtain / where to collect the informed consent. (In the case of collecting at the public facilities, please explain if it is an enough quiet place where you can fully secure the privacy of your research participant.) *Please write the contact information of the academic advisor in the informed consent documents as well. *Please describe that the research participant can withdraw his / her consent at any time during the research period without any disadvantage in the informed consent and the Explanatory Form. *If you will ask for cooperation from other institutions when you are conducting surveys for people outside Soka University, a letter of consent signed by the principal of institution must be submitted to the committee and get approval prior to conducting the survey.

Means of Storing and Disposing of Personal Information	Storage Life yyyy/mm/dd
*The data storage life should be 10 years from the release date of research results according to the guideline implemented on April 1st, 2019. *Research data should be stored in a storage which is not accessible by the internet. (e.g. External HDD) *The cloud storage including Google Drive cannot be accepted.	
Release of Research Results *Please describe the means of releasing the research results if applicable.	

*Frame can be extended depending on the length.

Signature

Principal Investigator		Date:
Supervisor		Date:

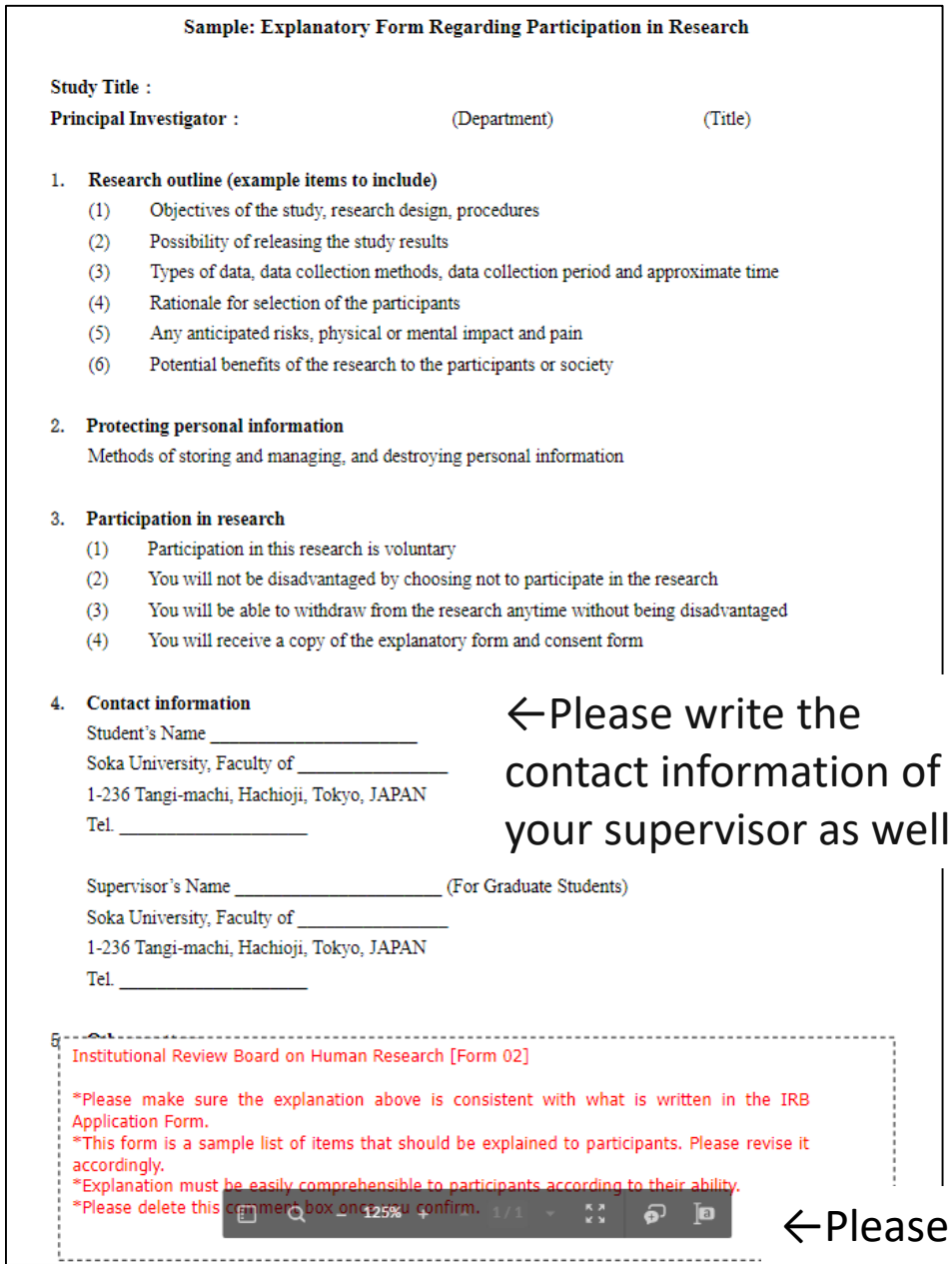
*Please submit an original with the signature(s) and attachments to Faculty Administration Department.

<Means of storing and disposing personal info>
①The data retention period should be 10 years from the date of the release of research results.
②Research data should be stored in an external storage device that is not accessible by the internet and should be secured with a password.

Describe the research purpose, plan, and methods clearly.
Provide a detailed description of the attributes & number of research participants/methods & reasons for selection.

<Potential Risks>
① Harm and discomfort to the participants should be described in detail, assuming all possible risks that may occur.
②In case it is just shown like "None", it is not acceptable.

F02 EXPLANATORY FORM



Sample: Explanatory Form Regarding Participation in Research

Study Title :

Principal Investigator : (Department) (Title)

1. **Research outline (example items to include)**
   - (1) Objectives of the study, research design, procedures
   - (2) Possibility of releasing the study results
   - (3) Types of data, data collection methods, data collection period and approximate time
   - (4) Rationale for selection of the participants
   - (5) Any anticipated risks, physical or mental impact and pain
   - (6) Potential benefits of the research to the participants or society

2. **Protecting personal information**
   Methods of storing and managing, and destroying personal information

3. **Participation in research**
   - (1) Participation in this research is voluntary
   - (2) You will not be disadvantaged by choosing not to participate in the research
   - (3) You will be able to withdraw from the research anytime without being disadvantaged
   - (4) You will receive a copy of the explanatory form and consent form

4. **Contact information**
   Student's Name _____
   Soka University, Faculty of _____
   1-236 Tangi-machi, Hachioji, Tokyo, JAPAN
   Tel. _____

   Supervisor's Name _____ (For Graduate Students)
   Soka University, Faculty of _____
   1-236 Tangi-machi, Hachioji, Tokyo, JAPAN
   Tel. _____

Institutional Review Board on Human Research [Form 02]

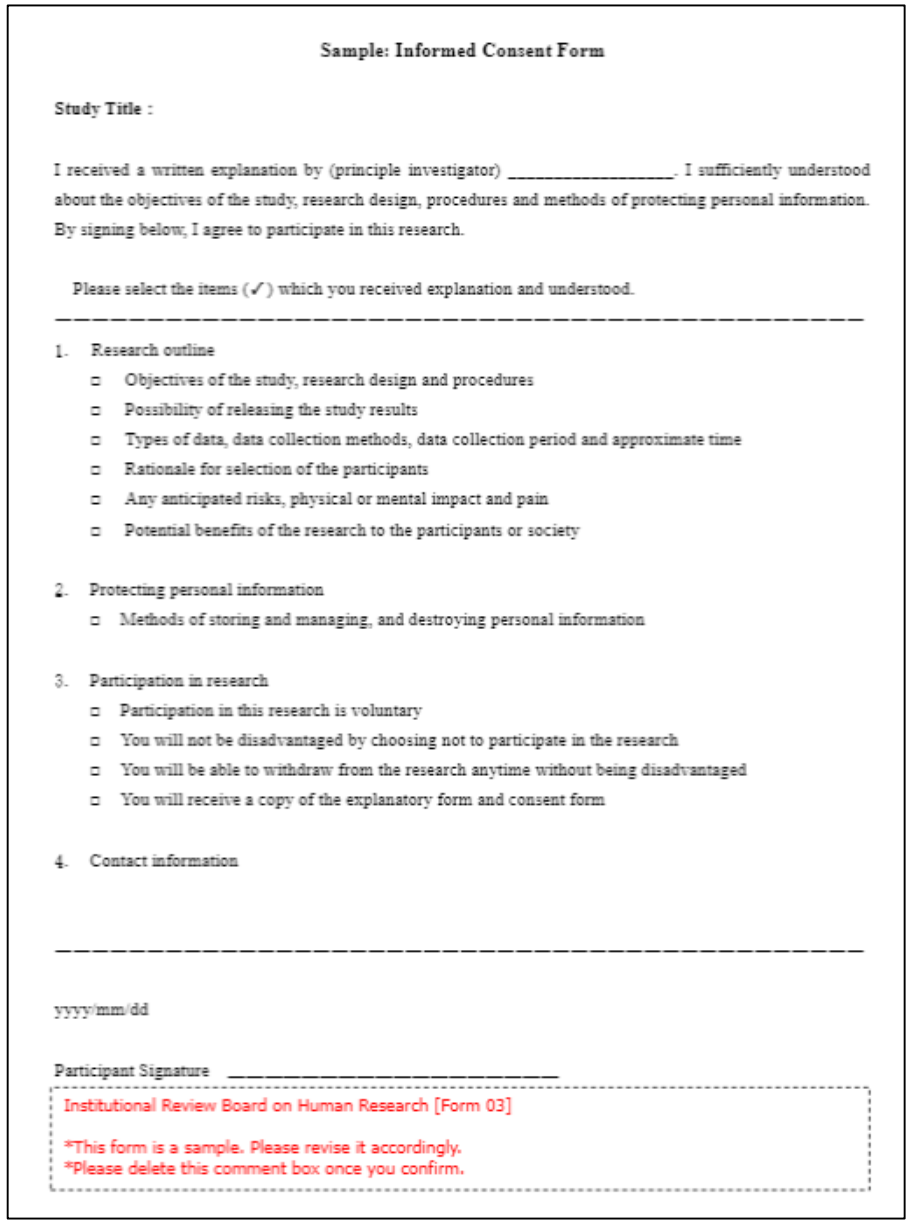
*Please make sure the explanation above is consistent with what is written in the IRB Application Form.
*This form is a sample list of items that should be explained to participants. Please revise it accordingly.
*Explanation must be easily comprehensible to participants according to their ability.
*Please delete this comment box once you confirm.

←Please write the contact information of your supervisor as well.

←Please delete the text boxes in red

- This is an important document to ensure that research participants understand the purpose, outline, potential risks of the research and so on in advance.
- Please fill in the Explanatory Form regarding human subjects according to the items listed on the left.
- Be sure to include the estimated time required for the interview and questionnaire
- If possible, when a non-native Japanese speaker distributes a written document in Japanese to students or others, it is recommended to have the document checked by a native Japanese speaker for accuracy before preparation.

F03 INFORMED CONSENT FORM



Sample: Informed Consent Form

Study Title :

I received a written explanation by (principle investigator) _____. I sufficiently understood about the objectives of the study, research design, procedures and methods of protecting personal information. By signing below, I agree to participate in this research.

Please select the items (✓) which you received explanation and understood.

1. Research outline
   - ☐ Objectives of the study, research design and procedures
   - ☐ Possibility of releasing the study results
   - ☐ Types of data, data collection methods, data collection period and approximate time
   - ☐ Rationale for selection of the participants
   - ☐ Any anticipated risks, physical or mental impact and pain
   - ☐ Potential benefits of the research to the participants or society

2. Protecting personal information
   - ☐ Methods of storing and managing, and destroying personal information

3. Participation in research
   - ☐ Participation in this research is voluntary
   - ☐ You will not be disadvantaged by choosing not to participate in the research
   - ☐ You will be able to withdraw from the research anytime without being disadvantaged
   - ☐ You will receive a copy of the explanatory form and consent form

4. Contact information

yyyy/mm/dd

Participant Signature _____

Institutional Review Board on Human Research [Form 03]

*This form is a sample. Please revise it accordingly.
*Please delete this comment box once you confirm.

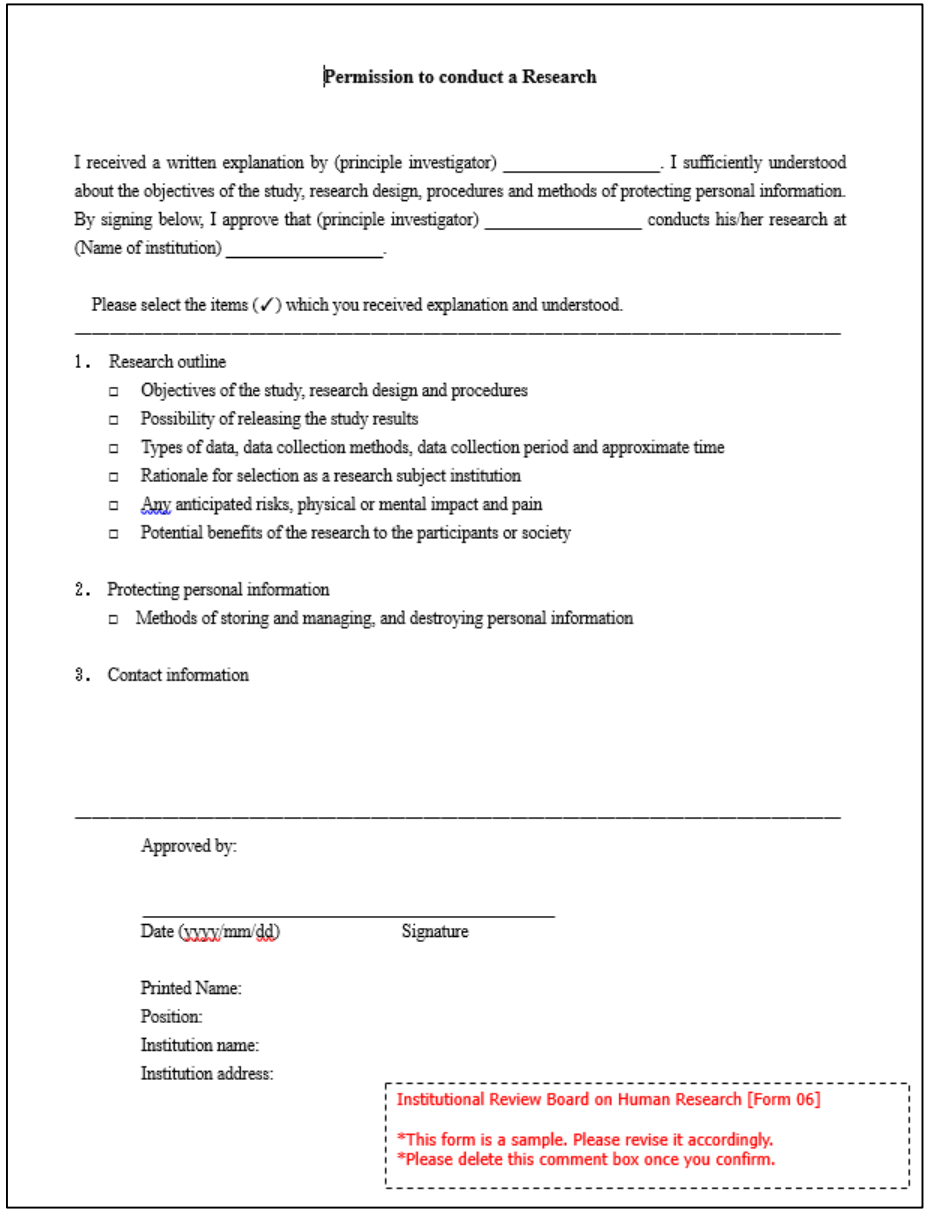
- An informed consent form is a document that confirms if a research participant understands and agrees to the contents of the explanatory document.
- Please prepare check lists that correspond to the contents of the explanatory form.
- Please use the checkboxes as much as possible, and carefully check the contents of each agreement.
- You may use a web survey form such as Google Form, instead of a paper form, as long as the contents of the form can be submitted in a manner that the IRB Committee can check and review. It is advisable to design a web survey form which requires its respondents to tick all checkboxes before moving to the following sections of the form.
- A COMMON MISTAKE: **Please have the participants complete this form AFTER the application is approved by IRB committee.**
- **For the IRB review, please submit a sample form.**

SAMPLE QUESTIONNAIRE/INTERVIEW QUESTIONS

- If you plan to conduct surveys or interviews, please submit sample surveys/interview questions (any format can be acceptable)
- Please make sure to indicate the expected time required for the surveys/ interviews in the F01 and the explanatory form.
- If you are using Google form to conduct the survey, please submit the screenshot of the survey as a PDF file.

Google Forms

F06 PERMISSION TO CONDUCT RESEARCH (IF APPLICABLE)



Permission to conduct a Research

I received a written explanation by (principle investigator) _____. I sufficiently understood about the objectives of the study, research design, procedures and methods of protecting personal information. By signing below, I approve that (principle investigator) _____ conducts his/her research at (Name of institution) _____.

Please select the items (✓) which you received explanation and understood.

1. Research outline
   - □ Objectives of the study, research design and procedures
   - □ Possibility of releasing the study results
   - □ Types of data, data collection methods, data collection period and approximate time
   - □ Rationale for selection as a research subject institution
   - □ Any anticipated risks, physical or mental impact and pain
   - □ Potential benefits of the research to the participants or society

2. Protecting personal information
   - □ Methods of storing and managing, and destroying personal information

3. Contact information

Approved by:

_____

Date (yyyy/mm/dd) Signature

Printed Name:
Position:
Institution name:
Institution address:

Institutional Review Board on Human Research [Form 06]

*This form is a sample. Please revise it accordingly.
*Please delete this comment box once you confirm.

- If you wish to conduct a survey with the cooperation of companies, schools, or medical institutions etc., you will need to submit the “Permission to Conduct Research” form.
- Please ask the head of each institution (school principal) to sign the form in advance, and submit it with other application materials.
- This document should be submitted in the “application” process before approval is given by the IRB committee.

IRB CHECK LIST

Soka University Institutional Review Board for Human Research
Checklist for Application

After completing the application documents, please ensure that each item below is satisfied, and please submit this checklist along with the application documents.

1. IRB Application Questionnaire（Google Form）

Please check if your documents meet the requirements below, and check the checkboxes accordingly.		YES	NO	N/A
①	The category of applying for "Research Plan" and/or "Releasing Result" is selected correctly.	☐	☐	☐
②	The research is going to be conducted on/after any date in the month following the month in which the application is reviewed.	☐	☐	☐
③	In case the data will be released, the expected date of publication was set as the date of completion of the research. (In case of Thesis/Dissertation, the date of research completion is the date of graduation ceremony)	☐	☐	☐
④	All research method is selected and the detail for each of them are described in the application form.	☐	☐	☐
⑤	The means of Anonymizing Personal Info was correctly selected with reference to p.18 of the IRB application manual on the website.	☐	☐	☐

2. IRB Application Form (F01)/Explanatory Form (F02)

Please check if your documents meet the requirements below, and check the checkboxes accordingly.		YES	NO	N/A
①	The significance and purpose of the research are clearly described.	☐	☐	☐
②	The Research Plan and Methods section describes in detail when, where, how, and how much (both length and frequency) the survey and/or interview will be conducted and how the collected data will be analyzed.	☐	☐	☐
③	In case the interviews, etc. are recorded or videotaped, it is clearly stated that the collected data is used with meticulous care.	☐	☐	☐
④	A detailed description of the attributes & number of research participants and methods & reasons for selection is provided.	☐	☐	☐
⑤	It is stated that the survey will be conducted outside of class hours. (If you chose "No," please describe the rational reasons why the survey must be conducted during class time and the considerations for students who refuse to participate (e.g., preparation of	☐	☐	☐

- Key points to be especially reviewed for each document are compiled in the IRB check list.
- Once you have completed the preparation of the application documents, please use the checklist to verify the documents.
- When submitting the application, please attach the checklist at the beginning of the application documents, ensuring that all items are checked.

4.th

Review results

(1) Notification on the review results

(2) Examples of review results

NOTIFICATION ON THE REVIEW RESULTS

Application acceptance

Applications will be accepted once submission of application documents (both paper and electronic data) is completed.

<u>*Attachments file size must be no larger than 7MB.</u>

Review by the IRB committee is conducted

Applications received by the 10th will be reviewed by the IRB Committee except for August.

Review Results will be announced

The IRB office will inform the applicants of the review results via e-mail by the end of the month.

In case of "Approval with Conditions", resubmit revised documents

If the review result is "Approval with Conditions", "Continuous Review", please revise the submitted documents and resubmit them to IRB office.

***Please be advised that you cannot start your research activity until you get approval.**

EXAMPLE OF REVIEW RESULTS

Approval

Your application is fully approved. You can start your research as scheduled. If there are some recommendations, they are indicated as “notes”. This does not necessarily require the revision of your application documents.

01

Approval with Conditions

02

The IRB office shall notify the researcher of the matters requiring amendments and then the “Approval” shall be decided upon confirmation of the results of the amendments by the Review Board.
*Please be advised that you cannot start your research activity until you receive the approval notice submitting revised application documents.

Continuous Review

03

Some considerable amendments are required in the research plan. The researcher may apply for a second review in the next month after revising the application documents.
*Please be advised that you cannot start your research activity until you receive the approval notice after submitting revised application documents.

04

Disapproval

“Disapproval” shall be decided in the event that the research plan is deemed to violate Article 4 of the Code of Ethics for Research. Re-submission is not allowed.

IN CASE OF “APPROVAL WITH CONDITIONS”

- Please submit the revised documents via email.
- The revised sections should be indicated **in red.**
- Printed documents are not required to submit.
- The revised application documents will be reviewed at any **time without waiting for the next meeting of the IRB Committee. (It may take 7-10 business days at least)**
- Please be advised that you cannot start your surveys or interviews until you receive the approval notice after the submission of your revised application documents.

Please submit your IRB application as early as possible in anticipation of a possible delay due to the approval with conditions.

5.th FAQs

FAQs

Q. If I want to change the approved research plan, what procedures do I need to follow?
A. You need to submit the “F04 IRB Protocol Change Form” and get an approval from IRB committee. Please fill in the form and submit to IRB office once you prepared the documents. This application will be reviewed at any time without waiting for the next meeting of the IRB Committee. (It may take 7-10 business days at least)
Q. Is it possible to modify or add documents after the application documents have been submitted?
A. In principle, it would not be acceptable for any modification and changes after the submission, however, please consult with the IRB office first. Also, if you would like to cancel the application, please contact the IRB office at your earliest convenience.
Q.I am going to conduct the survey overseas, I am preparing the necessary documents for the survey (documents related to informed consent, questionnaires, etc.) in the local language. May I submit documents in the local language when applying?
A. In principle, please create the required documents and conduct your research in the language that the research participants use in their daily lives. If you need to use a language other than the one spoken by the research participants, please provide valid reasons in the application form. Please make sure to attach the translation documents (Japanese or English) if you prepare the documents in the local language.
Q. How should I respond to the "Notes" section in the IRB review results?
A. In the section of ”Notes”, the list of recommendations that the applicant should keep in mind is indicated. It does NOT mean that the applicant is required to revise/resubmit the application documents. It is on the discretion of the application whether/how to respond to the notes.

FAQs

Q. I am planning to conduct surveys/interviews at companies, hospitals, or educational institutions.

A. Please obtain “F06 Permission to conduct research” from the head of the institution in advance, and submit it to IRB office together with the other application documents.

Q. How long should my research data be stored?

A. The data retention period should be 10 years from the date of releasing research results according to the guidelines implemented on April 1st, 2019.
*As for the graduate students, the day of the completion Master's or Doctor's program can be regarded as the releasing date of the master's thesis or the doctoral dissertation (March 18th for those graduating in Spring or September 11th for those graduating in fall)

Q. Are there any designated means on how to store my research data?

A. Research data should be stored in an external storage device that is not accessible via the internet and should be secured with a password.

Q. Can I use the questions and answers from the final/mid-term examinations for my research?

A. In principle, the use of questions and answer sheets in the final/mid-term exams for research is not permitted, as they are information that should be treated with the utmost care and security for the purposes of both teaching and management of personal information. However, the use of final/mid-term exam questions and answer sheets for research is permitted only if the following conditions are met.

- Prior consent must be obtained from the students.
- The student’s personal information must be anonymized.

FAQs

Q. Should I prepare the explanatory form and the informed consent form for both questionnaire and interview each by each?
A. If the participants differ between the questionnaire and interview, or if you select interview participants from the questionnaire, it is considered appropriate to create separate explanatory forms and consent forms. However, if you are conducting both questionnaires and interviews with the same participants simultaneously, it is possible to combine them into a single explanatory form and informed consent form.
Q. Is it ok to contact a potential Target Person informally in advance to check if they are interested in the research, without asking interview questions?
A. There may be situations where informal communication with your research participants is unavoidable before requesting their participation in your research. The IRB committee does not oversee or regulate such preliminary communication. An explanatory form, informed consent form, and interview questions cannot be sent until the IRB committee approves; however, it is ok to contact potential Target participants in advance to make sure they have any interests in your research.

SOKA University