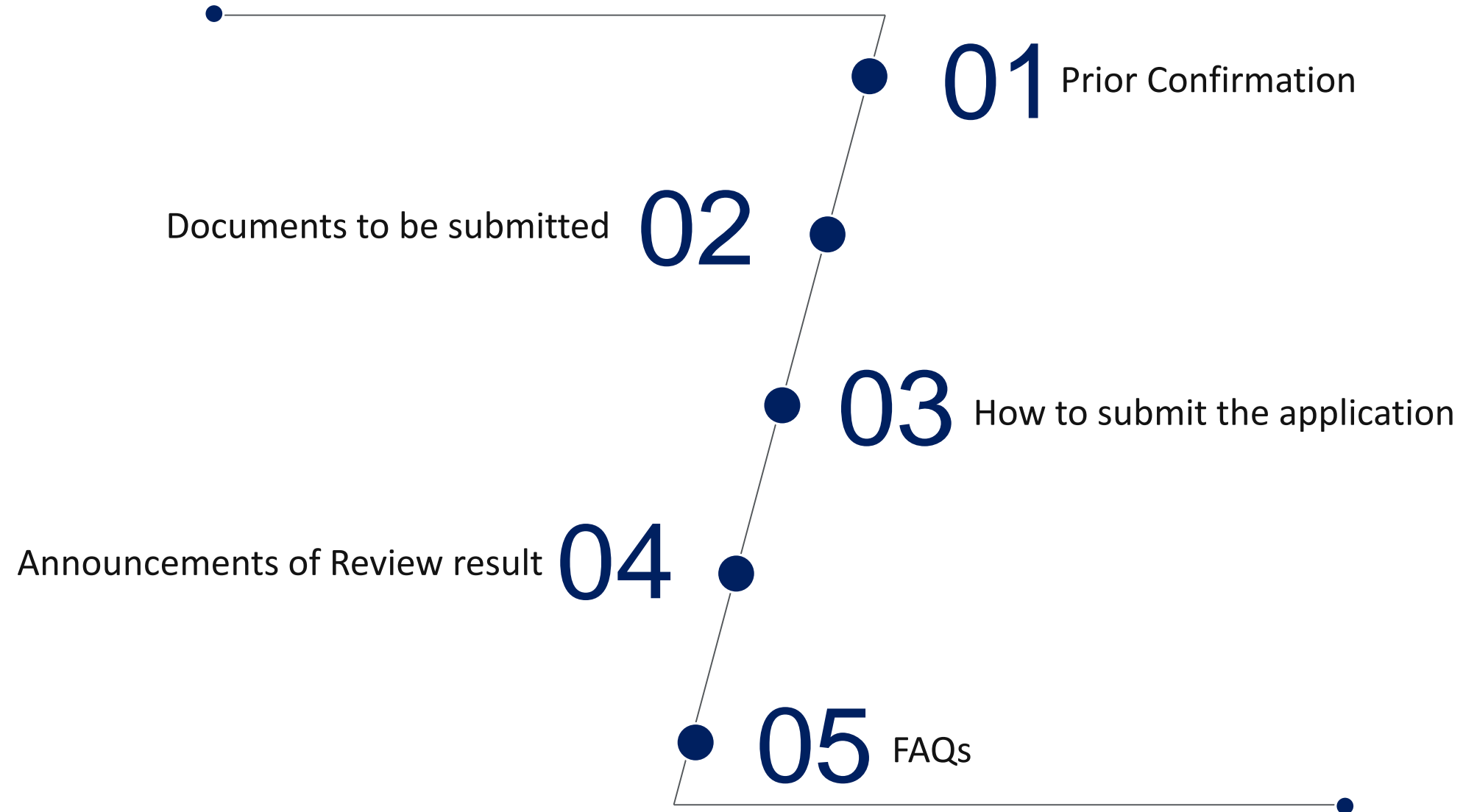


Application Process of SOKA University Institutional Review Board for Human Research

**SOKA University IRB Office
June 17, 2021**

AGENDA



1.St

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)-**



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

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**



**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>

2.nd

How to submit the application

(1)Submission flow

(2)Submission Deadline

SUBMISSION FLOW



1 Complete all required application documents

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 to the e-mail.

*The designated e-mail address will be displayed upon submission of the Online Application Questionnaire.

*Please submit all electronic files as PDF.

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.

The new application
due date has been
applied since April
2021



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

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 2022

- Paper submission deadline:
⇒ January 5, 2022
- IRB application deadline:
⇒ July 10, 2021

*Since there is no IRB committee meeting in August

For Graduate students to complete in September 2022

- Paper submission deadline:
⇒ June 30, 2022
- IRB application deadline:
⇒ February 10, 2022

3rd

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/advisor extensively about your research plan, research methods, etc.
- Have your application documents reviewed by your supervisor.
- 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.



(1) DOCUMENT TO BE SUBMITTED

1

F01 IRB Application Form

5

F06 Permission to conduct a research
(if applicable)

2

F02 Explanatory Form

3












F03 Informed Consent Form

4

Sample surveys/Interview questions

YOU CAN DOWNLOAD LATEST APPLICATION FORMS FROM THE FOLLOWING URL

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

	F01 IRB Application Form.docx		
	F01 IRB Application Form (Sample) *Please rea...	V2	
	F02 Explanatory Form Sample.docx	V2	
	F03 Informed Consent Form Sample.docx		
	F04 IRB Protocol Change Form.docx		
	F06 Permission to conduct a research Sample.docx		
	FAQs for the IRB Application Procedures(2021ver).pdf		
	Soka University Code of Ethics for Human Research_2017...		
	Soka University Detailed Rules Regarding Ethics Revi...	V2	

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

① 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
*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>

- ① The data retention period should be 10 years from the date of the release of research results.
- ② Research 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.
- ② In case it is just shown like "None", it is not acceptable.

② 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. _____

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

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.

- 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.
- Please note that you may use the Google Form or other tools to conduct your research if such tools are mentioned in the Form and approved by the IRB Committee.

← Please delete the text boxes in red

③ 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.**

④ 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.



⑤ 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 (yy/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.

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

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

<https://forms.gle/6MNW9Uq2opgvH7cs9>

 <p>創価大学 Discover your potential 自分力の発見</p>	<p>●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.</p> <p>●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</p> <p>●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.</p> <p>●Please submit the original signed application forms (F01) and required documents to the IRB office (The postal mail submission is also acceptable).</p> <p>[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.</p> <p>[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</p> <p>●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.</p> <p>*必須</p>	<p>所属機関名 Institution *</p> <p><input checked="" type="radio"/> 創価大学 Soka University</p> <p><input type="radio"/> 創価女子短期大学 Soka Women's College</p> <p><input type="radio"/> その他 _____</p>
<p>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</p> <p>*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、下記に必要な事項をご記入の上、回答を送信してください。</p> <p>●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。</p> <p>●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。</p> <p>●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）</p> <p>【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</p> <p>【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 学事部学第2課 Tel: 042-691-6904 （学第2課・研究管理室） Email: researchmanagement@soka.ac.jp</p> <p>●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場合があります）</p> <p>●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.</p> <p>●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</p>	<p>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.</p> <p>Graduate School of International Peace Studie</p>	<p>属性 Attribution *</p> <p><input type="radio"/> 教職員 Faculty or Staff</p> <p><input checked="" type="radio"/> 大学院生 Graduate Student</p> <p><input type="radio"/> その他 _____</p>
	<p>メールアドレス *</p> <p>メールアドレス _____</p>	<p>研究課題名 Study Title *</p> <p>XXXXXX _____</p>
	<p>研究代表者名 Principal Investigator Name *</p> <p>フルネームでご記入ください。 Please provide your name in full.</p> <p>回答を入力 _____</p>	<p>計画区分 Applying for *</p> <p>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.</p> <p><input type="checkbox"/> 実施計画 Research Plan</p> <p><input type="checkbox"/> 公表計画 Releasing Result</p>

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

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

For a master's thesis or doctoral dissertation, please check both the “Research Plan” and “Releasing Result”, as the research results are expected to be published.

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

研究開始予定日 Research will be started from *

原則として審査対象月の翌月 1 日以降としてください。既に調査を開始してしまっている研究は、受理できません。In principle, enter any date in the month following the month in which the application is reviewed. If for a Research and Survey has already been started, the application cannot be accepted.

日付

2021/07/01 


- 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.

(3) 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（3月18日または9月11日）を研究終了予定日（公表日）としてください。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 18th for Spring intake or September 11th for fall intake). 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

2022/03/18 

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
- September 11th for those graduating in September

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

匿名化の方法 Means of Anonymizing Personal Info *

- ☐ 個人情報を収集しない Not collecting any personal information
- ☐ 連結不可能匿名化（匿名化し、対応表を作成しない） Unlinkable Anonymizing (anonymize without correspondence table)
- ☒ 連結可能匿名化（匿名化し、対応表を作成する ※個人を特定できるようにする） Linkable Anonymizing (anonymize with correspondence table *Personal info can be identified)
- ☐ 匿名化しない No Anonymizing

上記の匿名化の方法を選択した理由 Reason for choosing the above means of anonymizing *

特に、「連結可能匿名化」あるいは「匿名化しない」はリスク管理の観点から積極的に選択されるべきではなく、これらを選択した場合は、その必要性が分かるように記述してください。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 them in a way that shows the necessity.

The reason why I chose "Linkable anonymizing"

- 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.

(3) HOW TO SUBMIT “IRB APPLICATION QUESTIONNAIRE” (GOOGLE FORM)

「授業内」で調査を実施する場合、成績評価に無関係であることを説明し、同意を得る計画ですか If the survey will be conducted during class, are you planning to explain that it is irrelevant to the grading evaluations and to obtain consent?
前の質問で「授業外」を選択された方は、回答不要です。 If you selected "out of class" for the previous question, you are not required to reply.

☐ はい YES

☐ いいえ NO

(Mainly for Faculty members)

If you wish to use the data collected in the past in your classes for your research, you will be required to obtain an informed consent from the participants even after the fact. Please indicate this in your application form.

4th

Review results

(1) Notification on the review results

(2) Examples of review results

NOTIFICATION ON THE REVIEW RESULTS

Application
acceptance

Review by the IRB
committee is
conducted

Review Results will
be announced

In case of “Approval with
Conditions”, resubmit revised
documents



Applications will be accepted once submission of application documents is completed.



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



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



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

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.

02

Continuous Review

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.

03

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. 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.



SOKA University

