# FULL IRB APPLICATION FOR 2021-2022

# \*\*PLEASE READ THE FOLLOWING INSTRUCTIONS PRIOR TO COMPLETING THE APPLICATION. REMOVE THESE INSTRUCTIONS PRIOR TO SUBMITTING THE APPLICATION\*\*

**Instructions for Submission of IRB Projects**

**Sage IRB Website Address:** <https://www.sage.edu/academics/research/the-institutional-review-board/>

In order to submit an application for review to the Sage IRB, please follow these steps:

1. Email the Sage IRB Chair at sageirb@sage.edu and request a new project number. To do this, please provide the chair with the following information.
	1. PPI (Primary Principal Investigator) Name, Email Address, Phone Number, Department, Campus Address

***\*\*If you are a student, remember that a faculty member is considered the Primary Principal Investigator for your project, even though you are conducting the research****.*

1. There are two applications. Please read below to determine which application to submit. If, after reviewing all the relevant materials on the Sage IRB website, you are unsure which application is appropriate to your project, please send an email to the IRB chair, sageirb@sage.edu for consultation.
	1. *Limited Review IRB application*- If your project is considered “no risk”, you should fill out the Limited Review IRB application which can be found on our website. Definitions of No Risk research projects can be found in the IRB policy manual and on the Limited Review IRB application. If this applies to your project, **STOP HERE** and go to the Limited Review IRB application, available on the Sage IRB website.
	2. *Full Review IRB application*- If your project is considered “minimal risk” or “risk”, then you must fill out the full review IRB application. Minimal risk projects will undergo the expedited review process. Risk projects will undergo the full board review process.
2. Fill out the appropriate IRB Application. Please read all instructions prior to filling out the application. Remove all instructions prior to submitting the application. The application, signature page and all related appendices (Ethics certificates, agency support letters, recruitment materials, data collection materials, informed consent, etc.) should be consolidated into one document prior to submission. Please label your file with the IRB project number (For example IRB XXX-2021-2022)

IRB does not require the original hard copy of signatures to IRB. We accept scanned or electronic signatures. This does not include Typed Names without a signature. Please contact sageirb@sage.edu if there are any questions or concerns.

1. Email the completed IRB application to sageirb@sage.edu. Please put the IRB project number in the subject line: SUBMISSION IRB # XXX-2021-2022. If you do not get acknowledgment that your project has been received by the IRB within three working days (excluding weekends), you may contact the IRB by email: sageirb@sage.edu to ask about any concerns. This notification is done by the IRB Chair.

All communications about your project should be done through sageirb@sage.edu.

Questions and further correspondence about your project should be sent by email to: sageirb@sage.edu with the project number in the subject line of your email. Be sure that the PPI is included as a cc: for any correspondence that comes from other researchers.

Once submitted, the IRB chair will communicate with your regarding your project going out for review. Please allow 3 days for response. If you have not heard a response from the chair in this time, please confirm that your project was received by the IRB.

# HOW DO I COMPLETE THE FULL IRB PROJECT REVIEW APPLICATION?

The following includes an application form. It is a Word document, in table format. Do not submit attachments to answer the questions in the application. (Attachments are additional materials requested in the application form.) Simply replace the instruction text in each box in the right-hand column with your own project-specific information. Be sure to delete all instructions, including this instruction page and the instructions in the right column of the table. Material that does not fit in the blocks in the right-hand column may be included after the signature page of the application, in the same file. Please indicate in the relevant block where the material is located (e.g., “see Appendix A”).

Submit the completed application form with all required attachments (including human participants certifications, surveys, tests, consent forms, cover letters, agency permissions letters, etc.) via email to sageirb@sage.edu. This application should be submitted as one continuous document with all supplementary materials, CITI Certifications, and signature pages included as part of the application.

Once all required materials are submitted, your project will be reviewed. The chair will review each submission and assign it to reviewer(s). Projects that are deemed “risk” projects will always be asked to appear before the full IRB board at our monthly meeting. The IRB chair will send you the information at the time of submission. The IRB will approve, approve conditionally, or not approve the project. If approved conditionally, you will be asked to provide additional information to respond to the concerns identified. You may be asked to resubmit the entire application or simply respond to specific issues raised. Please submit changes by “reply” email to IRB, including your responses in a reply to the reviewers. If the IRB requests additional information, you must respond within one month or the project will be withdrawn. You may request an extension, if needed. If the project is not approved, you may request that the IRB reconsider its decision. Projects that are approved, are approved for one year only. They may continue for up to 3 years if so requested (in an annual report) and approved, after which a new application is required.

If you have questions, email the IRB Chair, Dr. Francesca Durand at: sageirb@sage.edu or contact any other IRB member. (See our website at <https://www.sage.edu/academics/sage-research-institute/the-institutional-review-board/> for names of IRB Board members.)

**FINAL REPORT/ANNUAL REPORT**

Projects judged to contain No Risk do not require a final report or an annual report (unless individual academic department policy requires it). Those involving Minimal Risk or Risk *always* require a final report. The final report indicates that the project is finished and identifies any problems regarding the subjects’ participation that were encountered in the study. If the project continues longer than a year (from the anniversary of IRB approval), an annual report including a request for continuation is required (before the anniversary of IRB approval). This report summarizes progress to date and identifies any problems regarding human subjects’ participation that were encountered in the study to date. Projects lasting more than 3 years must be resubmitted for approval. If either or both of these reports are required (as indicated in your formal approval letter), submit your report(s) using the Final Report/Annual Report form found on our website.

Reports must contain original signatures of the Principal Investigator(s) and Student Investigator(s). However, an electronic copy of that original signature is acceptable for IRB.

**Russell Sage College Institutional Review Board**

**Check Sheet for Full Review Application Submission**

**(Remove prior to submission- this is for researcher use only)**

Please use the following check list to be sure your application includes all relevant documentation, as well as re-reading carefully all the instructions for submissions. Incomplete applications will not be reviewed and will result in a delay.

An application submitted to the IRB email (sageirb@sage.edu) should contain the following in ONE document:

* + A completed application form
	+ Signatures of all researchers, including the Primary Principal Investigator, and other Principal Investigator(s), Student Investigator(s), and any Other Investigators. (Be sure that the type of investigator on your application matches the designation on the web submission site.) Electronic signatures or scanned signatures are acceptable.
	+ Certification of human participants research competency for all researchers and all others involved in collecting data or working with confidential data (issued within 5 years of the application)
	+ A cover letter or script to participants
	+ A copy of survey or interview or focus group questions (if any)
	+ Agency permission(s), including other institutions’ IRB approval (if any). (Concurrent review by other IRBs is permissible.)
	+ Participants’ informed consent form (if required). Note that only the form should be included. You must not contact participants before obtaining IRB approval, and so your application should not have their signatures.
	+ Participants’ debriefing form (if required)
	+ Removed all instructions and replaced all blue instructional text in the form with black text related to your project.

Revised August 2021

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| **APPLICATION FOR FULL IRB PROJECT REVIEW****RUSSELL SAGE COLLEGE INSTITUTIONAL REVIEW BOARD****2021-2022****\*\*Please read all sections carefully before proceeding\*\***To complete this application please read the IRB Guidelines for Principal Investigators available on our website: https://www.sage.edu/academics/sage-research-institute/the-institutional-review-board/. Also see, on that page, our instructions for the electronic submission process.**For each item below, read the directions in blue carefully, and then replace the instructions [in brackets] with your relevant project information and change the font color to black to indicate it is completed. When you finish, none of the original instructions in the second column should remain; all should have been deleted and replaced with your information; or if that row is not relevant to you, the right-hand block should marked N/A. (The first two pages of instructions must also be deleted before submission, so this page is the first page.)**When you have completed this application, submit it to sageirb@sage.edu This is a Word document. If you convert it to use other software, please be sure that there are no changes in the numbering of items. You should compile this with any other documents that are part of your project, into a Word document or a PDF document. Before submitting your project, be sure to delete (or accept) any marked changes (if you use that feature in Word). (It is not sufficient to simply not view the marked changes, since the IRB may use that feature and view changes.)  |
| **IRB PROJECT NUMBER:** | [Put here the application number assigned by the IRB Chair] |
| **NEW or REVISED APPLICATION:** | [Indicate whether this is a new application or a revision of an earlier application. If a revision, indicate the Project Number of the earlier application.] |
| 1. **Title of Project:**
 | [Be as specific as possible in identifying the topic under investigation] |
| 1. **Proposed Starting Date:**
 | [Give your best estimate. Be sure to allow time for project review (three to six weeks for most reviews, once all required information has been submitted; six to eight weeks or more for projects involving special populations and/or more than minimal risk)] |
| 1. **Funded By:**
 | [Who is paying for the project? The researcher, department, college, outside source, or a grant? If Not Applicable, please put self-funded or NA] |
| 1. **Risk Category:**
 | **Please check (or highlight) the category which identifies your study as Minimal Risk or Risk to participants*** Surveys or interviews on sensitive topics.
* Survey, interview, observation of public behavior made by audio or videotape, studies using existing records, and studies using educational tests in which BOTH the participants can be identified in any way AND the disclosure of responses outside of the research could place participants at risk (risk of criminal/civil liability, financial standing, employability, reputation or stigmatization).
* Clinical studies of drugs or medical devices
* Collection of blood samples by any method
* Prospective collection of biological specimens for research purposes by noninvasive means
* Collection of data through noninvasive procedures in clinical practice
* Research involving vulnerable population
* Research involving deception
* Research outside the United States, regardless of procedure or population

**If none of these categories applies to your study, STOP HERE and fill out the LIMITED IRB PROJECT REVIEW APPLICATION.** |
| 1. **Researchers conducting this study:**
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| 1. **Primary Principal Investigator (PPI)**
 | [Name the one Principal Investigator who is responsible for checking and submitting all documents. This person has primary responsibility for overseeing the project. It must be a faculty member or other professional; it cannot be a student. Please provide the following information about the PPI:**PPI NAME****PPI Position and Department****PPI Phone Number****PPI Campus Address****PPI Email Address**] |
| 1. **Other Principal Investigator(s) (PI)**
 | [In addition to the Principal Investigator listed in 4(a), are there additional Principal Investigators? If yes, name them here. If they are not members of the Sage Community, identification of their affiliations should be included. For each PI on this project, please include the following information:**PI NAME****PI Position and Department****PI Phone Number****PI Email Address** |
| 1. **Student Investigator(s) if this is a student project**
 | [If this is a student project, name the student(s) whose project this is.For ALL students:**Student NAME****Department****Student Phone Number****Student Email Address** |
| 1. **All others involved in collecting data or working with confidential data**
 | [Any other person who has data collecting responsibility or will be working with confidential data must be listed. Persons who provide data for studies using existing records, but are not otherwise involved in the study, are not included here. If these persons do not interact with participants – for example, if they only transcribe recordings – an ethics certificate may not be required, but a confidentiality agreement may be substituted. Ask if you have questions.] |
| 1. **Qualifications of the researchers:**
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| 1. **What qualifications does each of the researchers have to conduct this study?**
 | [Specifically identify your background (courses and experience) relevant to the topic to be studied and background (courses and experience) relevant to the conduct of research. Information must be provided for all Principal Investigators, Student Investigators, and others involved in collecting data or working with confidential data.] |
| 1. **For each Human Subjects Research certification (CITI or other approved certification) on file in the IRB office, put the name and date certification was obtained:**
 | [All researchers and others involved in collecting data or working with confidential data must demonstrate competency regarding ethical issues involved in research on human participants. Acceptable certificates of competency may have been acquired from other institutions. Online courses are available to give you this competency. At the Sage Colleges we use the CITI program. You may sign up for free and get certification. This information is available on our website.Although it is not required, faculty may file one certification with the IRB Office (sent separate from any project application) and thereafter simply state on the application that the certification is on file, giving the certification number and the date of certification. If a faculty certificate was previously submitted with another project but not separately to be “on file,” then it must be resubmitted with this application. Student certificates are not kept on file, and so must always be submitted with each IRB Project application.]The following format should be used for all PPIs and PIs whose certificates are on file:**Name, CITI certification number (or other approved training certification number), Date Obtained.** |
| 1. **List the names and date of certification for all researchers whose ethics certificates are being submitted with this application. (See Guidelines.)**
 | [All researchers and others involved in collecting data or working with confidential data must demonstrate competency regarding ethical issues involved in research on human participants. Acceptable certificates of competency may have been acquired from other institutions. Online courses are available to give you this competency We recommend CITI certification that covers human participants’ research at Sage IRB. Links to the CITI Program website and training can be found on the IRB website. All certifications must have been acquired within 5 years of the date of the submission of the IRB application. The certificates must be attached at the end of this application.The following format should be used for all PPIs and PIs and students whose certificates are attached at the end of the application as an appendix.**Name, CITI certification number (or other approved training certification number), Date Obtained.** |
| 1. **Description of Study:**
 | [Provide a thorough description of the research question(s) for the project being considered and the purpose of the study. Please note that reviewers may not be from your academic discipline and provide reviewers with enough context and refrain from jargon or acronyms without explanation.] |
| 1. **Participants in the project:**
 |
| 1. **Identify the participants.**
 | [Identify the potential participants in your study. Please do not provide names or identifying information to IRB. Estimate the number of participants you expect to study. Identify your potential participants ages and gender] |
| 1. **Estimate the number of participants that will be included in the study.**
 | [Estimate the number of participants you expect to study.] |
| 1. **Place an X in the box next to any of the following special populations involved in this study, if applicable.**
 | **( ) Minors****( ) Prisoners****( ) Individuals with impaired decision-making abilities****( ) Other vulnerable population- please identify****( ) None of the above** |
| 1. **Ages:**
 | [Put age range in years. (.e.g, “ages 65 – 85 years” or “age 18 years and older.”] |
| 1. **Can the study have any adverse effects on pregnancy?**
 | **Yes ( ) No ( ) If yes, please explain:**  |
| 1. **Where is your research based?**
 | **( ) In the United States only****( ) In the United States and another country** **( ) Outside the United States only****If outside the U.S.: Please state what country and describe how you will address any cultural, political, or social conventions in that country.**[Address how you as a researcher will be aware of being culturally sensitive, politically aware, and socially appropriate] |
| 1. **State how participants will be recruited and what remuneration they will receive.**
 | [What kind of sample will this be (random, convenience)? How will participants be recruited? What compensation will they receive, if any? Compensation includes any kind of reward or enticement to participate.] |
| 1. **Include the cover letter or script to the participants, if any.**
 | [This letter (or script if given orally) briefly describes the project, the nature of the person’s participation, any benefits or risks, and asks for the person’s participation. If a cover letter or script is used in your research, you must attach it at the end of this form.] |
| 1. **Research Methodology:**
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| 1. **What form of data collection will this research take? Check all that apply:**
 | **( ) Survey** **( ) Experiment****( ) Interview (Group)****( ) Interview (Individual)****( ) Existing Records** **( ) Observation****( ) Other (Explain): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| 1. **Describe the procedures involved in the collection or review of the data in sufficient detail so that the IRB can evaluate safety and risks to human participants.**
 | [Describe the procedures used to collect data from the participants. The description should be complete enough that the reader could replicate the study. Attach copies of any materials (tests, interview questions, surveys, etc.) used in the study must be included in this application as an appendix] [Describe in detail any equipment or apparatus used in the study. Take care to describe the nature of any interactions with the participants.] |
| 1. **COVID-19 Precautions**
 | [Describe how you will address any safety protocols to make sure you and your participants are safe during COVID 19 pandemic. This must include following all current CDC guidance, state and local requirements, and making your participants feel safe at all times. Regardless of vaccination status, if there are mask requirements where data collection is occurring, please note that you will follow the organization’s requirements. If data collection is occurring remotely, please note that and that COVID precautions are not relevant} |
| 1. **Anonymity / Confidentiality.**

**If the responses are NOT anonymous, explain the procedure you will follow so that the responses will held in confidence.** | **Is your study anonymous? ( ) yes ( ) no****If study is anonymous, STOP you should be filling out the LIMITED IRB FORM****If not anonymous, is your study confidential? ( ) yes ( ) no**[For confidential studies, please provide, in detail, how you will keep the responses confidential] |
| 1. **Data Safety and Reporting:**
 | [Describe how data collected from participants will be stored (including how long data will be maintained) and in what ways will the data be shared (publications, presentations). Be specific as to the location and security of data storage, and who will have access to it. Describe when and how data will be destroyed, if that applies.] |
| 1. **Level of Review:**
 |
| 1. **Researcher’s classification of the project.**

**Identify the potential risks and what steps you will take to lessen those risks.** | **( ) Minimal Risk****( ) Risk**[This description must be detailed and complete, and the risks identified should match your informed consent description to participants. Your informed consent form should be attached as an appendix as well.] |
| 1. **Informed Consent Form. For any risks are identified in 10 above, you must submit an Informed Consent Form for approval.**
 | **( ) See attached** **( ) Not applicable** [All projects involving minimal risk or risk require informed consent by the participant. Consent forms should be in appropriate language and at a level of understanding for your population. Special consent procedures may be required if any participants come from a special population (Item 8c) or have other reasons to be thought unable to provide informed consent voluntarily, without coercion. Assent procedures should be described for populations (e.g., children) who cannot give consent, describing what would constitute evidence of assent, and of withdrawal of assent. You may use the consent form found on our website, with modifications as needed for your specific proposal. Directions for completion of this form are given there. Participants must be provided with two copies of this form, one to sign and return to the investigator and one to retain for their records. Consent of participants is obtained only after the IRB approves your project and your specific consent form, so your application contains blank forms, without signatures and without participant names.] |
| 1. **Will deception (purposefully misleading participants as to the purpose of the study) be used?**

**If yes:**1. **Describe the deception.**
2. **Justify the use of deception.**
3. **Explain how participants will be debriefed as to the real purpose of the study.**
4. **Attach a copy of the debriefing statement or script.**
 | **YES ( ) NO ( )**[If this is a deception study, you must explain what the deception is, why the use of deception is necessary, why it is justified (risk/benefit analysis), and how participants will be informed of the real purpose. Attach a copy of the written debriefing statement (or script if you will explain orally) at the end of this application or as a separate file upload on the electronic submission website.]  |
| 1. **List all other institutions co-operating in the project. Attach written permission from each to your application.**
 | [If any other organization is involved in the project (because an investigator is a non-Sage person, or the other organization requires their own IRB approval, or the organization is providing equipment, facilities, or other relevant materials to the research), it must be listed and written permission must be obtained from that organization. \*Organizations that have people who are participating in data collection in any way are considered co-operating institutions. Examples include health care organizations, higher education institutions with co-operating researchers, nursing homes, and others.The letter must be on official letterhead, signed by the appropriate administrator, and with a legible copy of the name. Include his/her title. Electronic submission is expected. You may submit your project for our IRB review while waiting for agency permission. If the other organizations have IRBs that must review the project, our final approval will be contingent on their approval. Their IRB approval must be in writing. These reviews are usually done simultaneously; differences between the reviews may have to be resolved.The original letters (from other organizations and, if relevant, from their IRBs), with original signatures, must be submitted in hard copy to the IRB office. In addition, scanned copies must be included with this application.If there are any questions about this please contact the IRB chair at sageirb@sage.edu] |
| 1. **Attach a copy of the survey or interview questions associated with your project.**
 | **( ) See attached (Appendix #)****( ) Not applicable**  |
| 1. **The IRB requires original signatures to the application, however they may be electronically scanned and then submitted.**
 | [No project will be reviewed without the signatures of all investigators. Each investigator must sign for himself or herself. Follow the directions on the Signature Page. The date when the page is signed must be included. If it is difficult, because of distance, to have all signatures on the same physical page, you may submit separate signature pages for individual researchers and compile them in your application. Signatures may be scanned versions – in other words, you must sign and then scan. You may not send a typed signature in a scripted font in place of your signature] |

**Signature Page**

IRB Project Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (required)

I (we) certify that:

1. I (we) have read this completed proposal, and the information provided for this project is accurate.
2. No other procedures will be used in this project.
3. Any modifications in this project will be submitted for approval prior to use.
4. The IRB will be notified immediately of any harm or injury suffered by participants while participating in the study or of any potential or emergency problems posing additional risks to participants.
5. If required by the IRB, a final report will be filed with the IRB with 90 days of completion of the project.
6. If the project will take longer than a year to complete, the researchers will file an annual report and request a continuation before the one-year anniversary of IRB approval.

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Signature of Primary Principal Investigator/Faculty Advisor Date

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Please print name legibly (Primary Principal Investigator)

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Signature of Principal Investigator

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Please print name legibly (Principal Investigator)

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Signature of student (if student project) Date

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Please print name legibly (Student Investigator)

\* Duplicate the above lines if there are more than one Principal and/or Student Investigator.

\* Scan this signed page to submit with your IRB electronic application.

Revised August 2021

**APPENDICES (ATTACH HERE)**

Please attach all appendices. Appendices should be in the order they appear in the application. These may include:

* Additional Signature Pages (if needed)
* Data Collection Tools (e.g., Surveys, Interview Protocols, Observation Protocols, Diagrams, etc)
* CITI Certificates (or other approved Human Subjects Research training certification)
* Confidentiality and/or Informed Consent Forms
* Recruitment Materials
* Agency letters