Institutional Review Board Application

(updated February 2018)

*Please enter your email address.*

The purpose of Centre's Institutional Review Board (IRB) is threefold:

* to protect the rights of human subjects participating in research,
* to assist the researcher in reducing avoidable errors when working with human subjects, and
* to reduce the amount of risk the College takes on by sponsoring research involving human subjects.

Centre College's Policy on the Protection of Human Subjects is available on [Centre's IRB website](https://www.centre.edu/academics/academic-affairs-office/institutional-review-board/). Researchers are strongly encouraged to review the policy before beginning an IRB application in order to find valuable guidance on developing a complete and thorough application.  The website also has a copy of the questions contained in this online application.

All researchers are required to take the [Protecting Human Research Participants](https://phrp.nihtraining.com/users/login.php) online training course and submit their certification numbers to the IRB.

If you access the online application from the same computer and the same web browser, your responses will be saved, and you may complete the application across multiple sessions.

Applicants should submit their proposals no less than thirty (30) days in advance of their intended start date. Most applications will require some modification before they can be approved. If you would like to discuss your application with an IRB member before formally submitting your application, please send a request to irb@centre.edu.

Please select the option that best describes your study.

* [No-risk](#_Short_Application_Eligibility) or minimal-risk study (Take the eligibility quiz!)
* More than minimal risk study (standard application)
* [Renewal of a study that has previously been approved by Centre's IRB](#_Renewal_Application)
* [Revision of a study that has previously been approved by Centre's IRB](#_Revision)
* [Review of a study that has received IRB approval from another institution](#_Off-campus_approval)

## No-risk and Minimal-Risk Study Eligibility Quiz

The following Yes/No questions will be helpful in determining your study’s level of risk.

* Do you seek information from or about children, prisoners, or mentally impaired individuals?
* Do you plan to use deception (the intentional use of misleading or false information) or plan to withhold pertinent information about your study or research goals?
* Consider the types of information you are gathering and the size of your subject pool. If your data is intentionally or accidentally shared with the public, could individual respondents be identified?
	+ Will you collect data that is normally considered private (such as GPA, body weight, income, illegal activities, sexual history, etc.), which may result in the individual experiencing stigmatization or social or legal sanctions if the data is released?
* Could participation in the study result in psychological or physical stress levels beyond those experienced in daily life?
* Will you make observations using body sensors or other equipment, or will test subjects consume anything as part of your research?

# Passed the Quiz? You have options!

While the Institutional Review Board (IRB) cannot make an accurate assessment of the involved risk to human subject research participants without the review of a complete application, based on your responses to the previous questions, it seems likely that your study would be considered to have no- or minimal risk and would be exempt from further IRB oversight.

PLEASE NOTE:

* Centre’s IRB recommends that all researchers recruiting human subjects present their study for review.
* IRB approval cannot be granted retroactively. Researchers who think their data may be used as part of a more in-depth study in the future should submit their study protocol for review now.
* Only studies that receive IRB approval are recognized as being compliant with federal regulations regarding the protection of human research subjects ([45 CFR Part 46](https://www.gpo.gov/fdsys/granule/CFR-2000-title45-vol1/CFR-2000-title45-vol1-part46), et. al.).
* All student-led research should be supervised by a faculty or staff member.
* Students conducting human subject research are strongly encouraged to consult with their classroom or research advisors regarding the submission of their research to the IRB for review. Classroom and research advisors, as well as students, are encouraged tocontact the IRB if they have questions regarding the potential risks associated with their studies.

I have read the information above and...

* [I want to submit an IRB application for a no-risk or minimal-risk study.](#_No-risk_or_Minimal-risk)
* [I do not want to submit an IRB application.](#_Registration_of_Studies)
* I want to speak with an IRB member or my advisor before proceeding.

## No-risk or Minimal-risk Study Applications

Enter the title of the study.

The Principal Investigator (PI) leads the research and serves as the primary contact person to the IRB.

* PI's name
* PI's email address
* PI's phone number
* Principal investigator's NIH ethics training number (or specify other ethics training certification)
* Special qualifications needed for this research, if applicable (for example, knowledge of how to use an instrument, certification in a particular skill, etc.)
* If the PI is a student, provide the name of the faculty sponsor. (Enter "n/a" if not a student.)

Add another researcher? (Y/N)

* If yes, provide information about your co-researchers in the following format. First and last name, email, ethics training certification number, special qualifications.
* Separate each researcher with a line return.

Enter the dates of the proposed data collection.

* Start date
* End date

Submit an abstract of your study. The abstract should

* Define the problem
* State the importance of the hypothesis to be tested
* Specify the expected contribution of the research
* State the relation of the proposed research to previous scientific investigations in the field
* Clearly justify the participation of human subjects in the research

Describe the characteristics of your research population and state how they will be recruited.

How many test subjects will participate in your study?

Describe the time commitment needed from the researchers and the test subjects. In particular, address the frequency and duration of data gathering. For example, "I will run ten test subjects a week for five weeks and each testing session will last for half an hour.

Describe the methods that will be used to secure and store the data. Such methods may include using ID numbers instead of names, properly disposing of data sheets and other paper records, limiting access to identifying data, and/or storing research records in locked cabinets and password-protected spreadsheets and computers.

How will you use your data? (Is this purely for a classroom project? Do you plan to present at RICE or give another public presentation? Will you blog about the study?)

Upload the informed consent document, participant information page and waiver of documented consent request form, and/or the waiver of informed consent request form. If needed, combine various items into a single document before uploading it to this application. Only one document may be uploaded in this block.

Upload copies of your data gathering tools (questionnaires, surveys, interview scripts, focus group questions, etc.) If needed, combine various tools into a single document before uploading it to this application. Only one document may be uploaded in this block.

Upload the debriefing script(s) and form(s), if applicable.

If applicable, upload other documents that are pertinent to the implementation of the study or the researcher's ability to conduct the study (international research form, training certifications, proof of access to research site or population, etc). Combine the various evidence into a single document before uploading. Only one document may be uploaded in this block.

If needed, add any additional context or comments that will aid the IRB in evaluating your application.

# Registration of Studies without formal IRB Review

Even if you choose not to complete an IRB application, you are required to register your study using the form below. The registration will serve as evidence that Centre's IRB provided some level of oversight and feedback (through the eligibility quiz), as required by the Health and Human Services' Office for Human Research Protections.

I understand that the study indicated below will NOT be formally reviewed by Centre College's Institutional Review Board, and thus will not be reviewed for compliance with federal regulations regarding the protection of human research subjects ([45 CFR Part 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html), et. al.).

However, because the following is true, this study would likely be considered a no-risk or minimal-risk study.

* This study does not seek information about protected populations (children, prisoners, mentally impaired individuals).
* This study does not use deception.
* This study will not collect data that is normally considered private.
* Participation in this study should not result in increased psychological or physical stress.
* Participants will not be asked to use specialized equipment or consume anything.

I understand that if the risk factors associated with my study change, I am to contact the IRB immediately.

Please provide the following information.

* Name and NIH Training Number of the Primary Investigator
* Names and NIH Training Numbers of co-Investigators, if applicable
* Faculty/Staff Advisor, if applicable
* Title of Project
* Data Collection Start Date
* Data Collection End Date

## Standard Application

Enter the title of the study.

The Principal Investigator (PI) leads the research and serves as the primary contact person to the IRB.

* PI's first and last name
* PI's email
* PI's phone number
* Principal investigator's NIH ethics training number (or specify other ethics training certification)
* If applicable, special qualifications needed for this research, (for example, knowledge of how to use an instrument, certification in a particular skill, etc.)
* If the PI is a student, provide the name of the faculty sponsor. (Enter "n/a" if not a student.)

Add another researcher? (Y/N)

* If yes, provide information about your co-researchers in the following format. First and last name, email, ethics training certification number, special qualifications
* Separate each researcher with a line return.

Does your study involve any of the following?  (Y/N)

(Note: Only select “yes” if your study intentionally seeks out members of these populations groups. For example, if your study population is Centre College students, select “no” next to “persons under 18 years of age” even though there might be a few students in your sample who are 17 years old.)

* Persons under 18 years of age
* Mentally impaired persons
* Incarcerated persons
* Individuals who do not speak English as a primary language
* Deception (not giving your test subjects an honest and full account of your research objectives or procedures)
* The intention to publish or present the study results beyond the classroom (this includes RICE)

Will research subjects in your study be asked questions about any of the following topics? (Y/N)

* Citizenship status
* Alcohol consumption
* Drug use (including legal and illegal substances)
* Illegal activities
* Sexual identity or orientation

Enter the expected start and end date of data collection.

Start date

End date

In what language will your research be conducted?

* English
* Spanish
* Chinese
* Other

Will you collect any data in an international or non-western cultural setting (i.e. reservations, religious communes, etc.)?

* No
* Yes, and I will include a copy of the International and non-Western Culture Research Supplement in the uploaded documents at the end of this application.

If applicable, indicate the source of your research funding.

* Not applicable; this project does not require any financial support.
* Centre College, includes JCY projects, FDC, etc.
* Self-funded
* Other

Submit an abstract of your study. The abstract should

* Define the problem
* State the importance of the hypothesis to be tested
* Specify the contribution the research is expected to make
* State the relation of the proposed research to previous scientific investigations in the field
* Clearly justify the participation of human subjects in the research

Will any group of people be purposefully excluded from your study? (For example, test subjects must be of a certain gender or ethnicity.)

* No one will be purposefully excluded from the study.
* Yes, some groups will be purposefully excluded from the study.
	+ Describe the population that will be excluded from your study and give a reason for the exclusion.

Describe the characteristics of your research population. Such descriptors may include the group’s age, education, affiliation, etc.

How will your respondents will be recruited? Some responses may include the recruitment of students through the SONA system, a convenient sampling of friends, or soliciting permission from a gatekeeper (a school principal or church elder).

How many human subjects do you anticipate testing in the study?

Describe your data collection methodology.

Common methodologies for collecting data are surveys, interviews, focus groups, observation, etc. Describe the methods you will use, and where the research will take place. If applicable, identify standard psychological tests by name and describe devices or activities that are not encountered by subjects in their daily living. Any procedures involving electrical devices, radioisotopes, or drugs must be described in detail.

Describe the time commitment needed from the researchers and the test subjects. In particular, address the frequency and duration of data gathering. For example, "I will run ten test subjects a week for five weeks and each testing session will last for half an hour."

Does your study include deception (not giving your test subjects an honest and full account of your research objectives or procedures)?  (Y/N)

* If yes, describe the deception in your study design or the information that will be withheld from participants. Explain why the proposed deception or the withholding of information is essential to the study.
* Will the participants be told of the deception following the collection of data? (Y/N)
	+ If no, why will participants not be told of the deception following the collection of data?

Describe the potential level of risk to the participants taking part in the study. "Risk" is defined as the probability that physical, psychological, social, legal, or economic harm will come to the participant. Examples of risk include, but are not exclusive of, fatigue, stigma, anxiety, disclosure of illegal drug use, or the loss of a job or advancement. Other types of risk include the possibility of a subject being identified due to a small sample size or discomfort due to the use of graphic images in a study.

What steps are being taken to minimize the risk to participants?

Describe the potential benefits to the test subject for participating in the research study. Benefits may include participation incentives or ways in which a participant may directly benefit from the study itself (such as a clinical trial). Some studies will recognize no immediate benefits, but suggest a long-term emotional reward for furthering scientific research. Researchers are cautioned against undue inducements that may blind a participant to potential risks or prompt subjects to lie or conceal information that, if known, would disqualify them from the study.

Describe the methods that will be used to secure and store the data.  Such methods may include making surveys anonymous, using ID numbers instead of names, properly disposing of data sheets and other paper records, limiting access to identifying data, and/or storing research records in locked cabinets and password-protected databases.

What do you intend to do with your data? (Will you present the information only in class? At RICE? Publish results online or in a journal? Lead a public forum?)

Describe other aspects of your study impacting human subjects that have not been previously disclosed.

The following fields will ask you to upload the documents specified below. The forms, or samples of them, can be found on the Forms and Document Page of the Centre College IRB site.

* Required for all studies
	+ Informed consent document or information sheet
* Required, if applicable
	+ Waiver of signed consent request
	+ Waiver of informed consent request
	+ International and non-Western culture research supplement
	+ Survey instrument(s)
	+ Questionnaire(s)
	+ Interview script(s)
	+ Manipulation protocol(s)
	+ Debriefing script and form(s)
	+ Evidence of cooperation from collaborator(s)
	+ Other documents that are pertinent to the implementation of the study or the researcher's ability to conduct the study

NOTE: If your study uses, for example, multiple surveys, combine the various surveys into a single document before uploading it to this application. Only one document may be uploaded per field.

If needed, add any additional context or comments that will aid the IRB in evaluating your application.

## Renewal Application

Has the study experienced any of the following?

* Adverse effects, complaints by test subjects, or changes in funding sources
* Change in personnel or protocol
* None. The study has progressed as planned and no changes in personnel or protocol have occurred or are requested.

Describe any adverse effects, complaints by test subjects, and/or changes in funding and the impacts of these instances on the study. How were these instances addressed?

Based on your analysis of the adverse effects, complaints, and/or changes in funding, do you believe you need to change the protocol of your research study? (Y/N)

Whom should the IRB contact for information about this application?

* PI's Name
* PI's Email

Provide the protocol number of the study you wish to renew.

How many test subjects have participated in your study thus far?

How many test subjects have withdrawn from your study thus far?

Please upload a "clean" copy of your study's consent form. If approved, this version will be stamped and signed by the IRB for use in your study moving forward.

If needed, add any additional context or comments that will aid the IRB in evaluating your application.

## Revision

Whom should the IRB contact regarding this application?

* PI's name
* PI's email address

Provide the protocol number of the study you wish to revise.

How many test subjects have participated in your study thus far?

How many test subjects have withdrawn from your study thus far?

Summarize the requested revisions to your study. Explain why these revisions are necessary.

If this revision is approved, would you like the IRB to extend the study's end date? (Y/N)

Upload a copy of the research protocol that incorporates the requested revisions. The requested revisions should be highlighted so that the reviewers can easily locate the changes.

If there are changes to the consent form(s) and/or if you are requesting an extended end date, upload a revised or "clean" (unstamped) version of the consent form.

If applicable, upload the revised versions of any surveys, scripts, or other data collection tools your study will employ. Multiple tools must be saved into a single PDF document before being uploaded.

If needed, add any additional context or comments that will aid the IRB in evaluating your application.

## Off-campus approval

Thank you for alerting the Centre College IRB of your research study. Research involving human subjects affiliated with Centre College and/or those physically on Centre's campus CANNOT proceed without the approval of the Centre College Institutional Review Board. Centre uses an authorization agreement to expedite review of studies that have received approval from another IRB.

Whom should the IRB contact regarding this application?

* PI's name
* PI's email address

Please upload a single PDF that contains the research proposal as approved by the non-Centre IRB and the approval documents from that IRB.

If needed, add any additional context or comments that will aid the IRB in evaluating your application.