IRB Application

Please note: All applicants must complete the application form and data security assessment form prior to submission to the IRB. The IRB Committee retains submitted applications for no more than three years. Please keep a copy of your submission for your future use.

IRB Case Number

IRB Application Status

Application Date

SECTION ONE: SUMMARY INFORMATION

Title of Research *

Principal Investigator

Applicant Name

Applicant's Status at Carleton

Applicant Email Address

Applicant Details

Consultants or Co-Investigators and Institutional/Department Affiliations (if any)

Project Background

Is Carleton IRB the "IRB of Record" for this project?

Select "yes" if Carleton College is the only institution involved in your project. If your project will involve research subjects at multiple institutions with IRBs, one IRB *only* must be designated as the IRB of record. If the Carleton IRB is not the IRB of record, you should not submit an application here. Please contact the IRB chair for further instructions.

YES / NO

Will the proposed project be conducted wholly or partially outside the United States?

YES / NO

INTERNATIONAL PROJECTS

If the proposed project will be conducted wholly or partially outside the United States, provide additional information about the institution or researcher under whose auspices the project will be conducted.

Be sure to include name, institution, and contact information.

Does the local institution approve research projects with a body equivalent to an institutional review board? Have you contacted this organization about obtaining their approval of your project?

If no local institution can approve your project, have you consulted with an expert - a Carleton faculty member, a researcher who works in the area where you will conduct research, etc. - who can guide the research process and provide advice on local ethical standards to the Carleton IRB?

If so, please provide contact information about this person. If not, please make such contact immediately; IRB approval may be contingent on such a relationship.

Is this research being carried out at multiple institutions within the US? YES / NO

Is this research being conducted with the support of a grant from the U.S. federal government?

Examples: the National Science Foundation , the National Institutes for Health, etc.

YES / NO

Please give funding agency and grant number, if known *

Is this research in connection with a fellowship application or a grant-funded project? (including Carleton grants and fellowships)

YES / NO

Please identify the fellowship(s) and/or grants which will support this research. *

Purpose of project (in one or two sentences)

Intended Use of Information Gathered

This might be for a comps paper, for a public presentation on campus, for a presentation at an academic meeting, for possible publication, to assist the library staff in planning, etc.

Location of Study

For example: on campus, in Northfield schools, in the Twin Cities, in Los Angeles, etc.

Anticipated Start Date of Project

Anticipated End Date of Project

Information About Subjects

Estimated number of subjects

Age range of subjects

Sex/gender of subjects
Indicate if you will be using all genders in your study, or if you will be selectively sampling particular genders. Note that for demographic purposes, participant genders should be measured with open-ended prompts, such as 'Man,' 'Woman,' or 'I identify my gender as _____ (please specify)'

SECTION TWO: INFORMATION FOR IRB REVIEW

Please answer each specific question and use as much space as needed to answer fully. A response of "See attached description or grant application" is not sufficient.

2-1 Historical Background

Provide a brief description of the project with reference to the investigator's personal experience and to pertinent scientific literature.

2-2 Plan of Study

(A) State the hypothesis or research question you intend to answer. Describe the research design, methods, interventions, and procedures (including standard or commonly used interventions or procedures) to be used in the research. Specifically, identify any interventions, procedures, or equipment that are innovative , unusual, or experimental.

(B) Describe any private information you will be collecting from subjects. Is any of this information sensitive? Data are considered sensitive when disclosure of identifying information could have adverse consequence for participants (such as criminal prosecution or disciplinary action) or damage their financial standing, employability, insurability, or reputation. Even information that could embarrass a participant if accidentally disclosed should be described here.

(C) Are there any deception procedures?
(Examples of deception used for research purposes: withholding relevant information, use of a confederate [someone who poses as someone they're not], false performance feedback, offering fictitious information about the true purpose of the study, etc.)
YES / NO

(D) Describe any deception procedures employed in this investigation, explaining why deception is necessary, describing possible risks caused by these deceptions, and detailing precautions to minimize or eliminate these risks.

3-3: Possible Risks

(A) Indicate what you consider to be the possible risks (or inconveniences) to subjects and indicate the precautions to be taken to minimize or eliminate these risks. If any data monitoring procedures or **data security measures** are needed to ensure the safety and privacy of subjects and/or confidentiality of data, describe them. (If you are unsure, please read more about sensitive information and data management).

(B) If deception is used, please explain possible risks and precautions to be taken to minimize or eliminate these risks.

SECTION THREE: SELECTION OF SUBJECTS AND THE INFORMED CONSENT PROCESS

3-1: Special Populations

(A) Indicate whether this project involves any of the following subject populations.

- Prisoners or other kinds of inmates (including inhabitants of halfway houses)
- Minors (Minors or "children" are defined in Minnesota law as persons under age 18)
- Prisoners and Minors
- No Special Population

(B) If you indicated working with any of the above-listed special populations, additional safeguards may need to be implemented in order to protect these populations from excessive risk, coercion, or undue influence. **Please describe the precautions that you will take to minimize all possible risks** given the unique setting or circumstance faced by these individuals. Federal guidelines about human subjects research may provide useful information about the precautions needed to conduct research with these special populations. *

4-2: Recruitment and Consent

(A) Describe how subjects will be recruited.

(B) Will you be asking your subjects to consent to research?

- Yes
- No, it isn't possible to document consent

(C) Describe how consent will be sought from subjects or from the subjects' legally authorized representative.

If children are subjects, discuss whether their assent will be sought and how the permission of their parents or legal guardians will be obtained. *

3-3: Compensation of Subjects

(A) Will subjects receive any compensation for participation in cash or in kind (i.e., food, course credit, etc.)?

YES / NO

(B) What kind of compensation will be provided? If course credit, note that Students must be offered an equally desirable, non-research option for receiving the same amount of course credit.

SECTION FOUR: INVESTIGATOR'S PLEDGE

By entering my name here, I certify that the information furnished concerning the procedures to be taken for the protection of human subjects is correct. I will seek and obtain prior approval for any modification in the project design or informed consent document and will report promptly any unexpected or otherwise significant adverse effects encountered in the course of this study. I certify that all individuals named as consultants or co-investigators have agreed to participate in this study. Certification is recorded by submitting this form via the Carleton IRB online application system.

SECTION FIVE: ATTACHMENTS

Download a blank IRB Consent Form
Be sure to save your completed form before re-uploading

Attached Documents (1)

Document Name	Attachment Type
IRB Application Consent Form	Consent Form (Required)

SECTION SIX: COMMON PITFALLS TO AVOID

In most cases your application will be processed within 10 days. There are certain conditions that may elevate risk to the point where we would require adjustments (e.g. removal, restatement, etc.) and/or further clarification and justification. This process takes time, and in some cases, may result in non-approval. In order to expedite your review, please consider and address the following possible pitfalls in your application, if relevant:

1. **Photos, audiotapes, names (identifiable information):** The IRB considers the privacy and confidentiality of all participants to be of utmost importance. Thus, if at all possible, you will want to avoid obtaining names and other identifiable information (e.g. photos), or at the very least, keep names/identities separate from the data obtained. If, however, you intend to reveal the identity of your participants, you must fully explain and justify this need for the purpose of research (i.e. using photos and names simply to enhance the entertainment value of a public presentation would not, in most cases, be allowed). And you must fully inform, request and obtain explicit permission to use such information in the informed consent process.
2. **Unfamiliar populations (e.g. prisoners; citizens of remote countries):** Please keep in mind that the IRB may not be familiar with the context in which certain individuals live and the possible risks faced by such people, thus you will want to fully explain the nature of risk given the participant's local context; and when obtaining informed consent, insure that participants fully understand the nature and scope of their participation (e.g. what they will do and who will hear about it). This may require the involvement of a local translator and detailed, culturally sensitive explanation of your research.

All applicants must complete this form. Not all sections of the form may apply to your project, but all relevant sections must be completed.

Part A - Personal Information and Identifiers to be collected (check all that apply):

- ☐ **Name**
- ☐ **Age**
- ☐ **Class Year (for students)**
- ☐ **Address (full or partial)**
- ☐ **Education**
- ☐ **Race/Ethnicity**
- ☐ **Nationality/Citizenship**
- ☐ **Biological Sex**
- ☐ **Sexual Orientation/Gender Identity**
- ☐ **Religious Affiliation**
- ☐ **Biometric identifiers (e.g., fingerprints)**
- ☐ **Audio recording of voice**
- ☐ **Facial photo/video images**
- ☐ **Other photo/video (e.g., walking, gesture, etc.)**
- ☐ **Electronic mail address**
- ☐ **Social security number**
- ☐ **Student ID number**
- ☐ **Telephone number**
- ☐ **Fax number**
- ☐ **Internet protocol (IP) address (Web-based survey)**
- ☐ **Medical record number(s)**
- ☐ **Device identifiers/serial numbers (Web-based survey)**
- ☐ **Web Universal Locators (URLs)**
- ☐ **Professional Certificate/license number**
- ☐ **Vehicle identifiers and serial numbers, including license plate numbers**

For **ALL** the identifiable data collected above, will you be coding the data by removing the identifiers and assigning a unique study ID/code to protect the identity of the participant?

○ Yes ○ No

Indicate how the coded data will be stored separately from the identifiable data:

Will you be collecting any **sensitive data**?

○ Yes ○ No

Data are considered to be sensitive when disclosure of it, along with identifying information, could have adverse consequences for participants (such as criminal prosecution or disciplinary action) or damage their financial standing, employability, insurability, or reputation. Even information collected that could simply embarrass a participant if accidentally disclosed should be described here.

Part B - What technologies will be used to collect data?

Mobile Phone App

☐ **Not Applicable**

1. Name of the app

2. Identify the mobile device platform(s) (IOS/Android/Windows) to be used

3. Whose device will be used?
- ○ Participant's personal phone
- ○ Researcher provides phone

4. Will data be stored on device for any period of time?
○ Yes ○ No

a. Please describe (e.g. queue on phone and then transmit to server, stored on devide indefinitely) *

5. How is the app secured on the device

a. Is a password or PIN for app required?
○ Yes ○ No

b. Is a password or PIN for the device required?
○ Yes ○ No

6. Will the app be able to access other device functionality such as Location, Contacts, etc.?
○ Yes ○ No

7. When data is transmitted from the device, please list all locations where it will reside (even temporarily)

Web-based site, survey or similar method

☐ **Not applicable**

1. What survey tool will you be using?
- ○ Qualtrics
- ○ Google Forms
- ○ Amazon Mechanical Turk
- ○ Other

a. If other, specify how data access will be managed *

b. Will personal information be collected via the web-based survey? Yes No

Wearable Device (e.g., Fitbit, Smartwatch, etc.)

☐ **Not Applicable**

* Also complete the mobile app section above if a mobile app will be used with the wearable device

1. Name of device

2. Is wearable provided by participant or researcher
○ Personal device
○ Researcher provides device

3. Is wearable registered by participant or researcher
○ Participant registers
○ Researcher registers device

4. Is identifiable data (phone numbers, GPS locations, etc) collected with the data?
○ Yes ○ No

a. Please list identifiable data collected *

b. Is identifiable data available to third parties (e.g., device and/or software manufacturer)? *
○ Yes ○ No

5. When data is transmitted from the device, please list all locations where it will reside (even temporarily)

Electronic audio, photographic, or video recording or conferencing

☐ **Not applicable**

1. Describe the method/device used for capturing the photograph, video, or audio

2. Describe how and where the A/V files will initially be stored

3. Describe how and where the A/V files will be archived for data analysis

4. Will the photographs, video or audio be transmitted over the internet?
○ Yes ○ No

5. How & when will the photographs, video or audio be secured to protect against unauthorized viewing or recording

Text messaging

☐ **Not applicable**

1. What text messaging software will you be using?

2. Whose device will be used?

○ Participant's personal phone
○ Researcher provides phone/device

3. Will message be limited to appointment reminders?

○ Yes ○ No

a. If no, what is the content of the messaging? *

4. Is the communication one-way or two-way?

Part C - Once data collection is complete, how/where will it be transmitted, processed, and stored

1. Computers Used for Data Storage

Carleton-provided computer
(•) Yes ( ) No

Is anti-virus software installed and up to date? *
( ) Yes ( ) No

Is the operating system kept up to date with Windows or Apple updates? *
( ) Yes ( ) No

Researcher's personal computer
( ) Yes ( ) No

Is access password protected? *
( ) Yes ( ) No

Is anti-virus software installed and up to date? *
( ) Yes ( ) No

Is the operating system kept up to date with Windows or Apple updates? *
( ) Yes ( ) No

Third-party computer
( ) Yes ( ) No

Is access password protected? *
( ) Yes ( ) No

Is anti-virus software installed and up to date? *
( ) Yes ( ) No

Is the operating system kept up to date with Windows or Apple updates? *
( ) Yes ( ) No

2. Carleton-Managed Cloud Storage (check all that apply)

- [ ] **Carleton Dropbox**
- [ ] **Carleton Google Drive**
- [ ] **Other**

3. Third Parties

Is there a Third-party collaborator or sponsor?
( ) Yes ( ) No

If yes, provide details *

Part D - During the lifecycle of data collection, transmission, and storage
(DSR required if identifiable, limited data set, or coded data is shared with external site)

1. Who will have access to the data?

2. How will that access be managed?

3. Who is responsible for maintaining the security of the data?

4. Describe what will happen to the electronic data when the study is completed, as college policies require that research records be maintained for at least 3 years after the study has ended?

5. Describe what will happen to any physical data when the study is completed, as college policies require that research records be maintained for at least 3 years after the study has ended?

SIGNATURE

(Note: both the application form and data security form (see tab) must be completely filled out and a consent form sample must be attached prior to submission. To save an incomplete form, leave this box unchecked and click the "Save to Complete Later" button.)

☐ I verify that I am the Applicant named above and I approve the submission of this application.