Carroll College

**Application for IRB Review of**

**Human Subjects Research**

**Make sure that you have ALL required documents from the numbered checklist below. Items 1 and 2 MUST be included; items 3-5 are applicable to most applications; and items 6-9 may or may not apply. When the application and all required documents are complete, create a single pdf file that includes all documents in numerical order as they are listed and upload to Upload 1 and Upload 2 on the IRB Moodle page.**

**Go to** [**https://youtu.be/-6Dr0Ynx5KI**](https://youtu.be/-6Dr0Ynx5KI)**, for instructions regarding uploading the application and supporting documents to Moodle. Applications cannot be reviewed until they are submitted to Moodle. IRB review will be delayed if (a) the instructions on this application are not followed and (b) all necessary supporting documents are not uploaded to Moodle. (Note that the video tutorial mentions the option of multiple uploads, however please combine all documents and submit as a single pdf file.)**

**Include the following items with your submission** (where applicable). **Check all that are included:**

|  |  |
| --- | --- |
| Check | Item |
|  | 1. This application. |
|  | 2. Certificate of completion for required training in human research ethics for every investigator participating in the project. [Protecting Human Research Participants Training Moodle course and downloadable certificate available here](https://moodle.carroll.edu/course/view.php?id=1151). |
|  | 3. Consent forms and fact sheets, including scripts for verbal consent if done by telephone. |
|  | 4. All recruitment materials including scripts, flyers and advertising, letters, email text, and other. |
|  | 5. All questionnaires, tests and scripts/guides used for interviews. |
|  | 6. Research proposal, protocol, or grant application supporting this submission. |
|  | 7. Copies of institutional or organizational approvals, e.g. school districts, hospitals,  other colleges. Preferably these will be letters on the cooperating institution’s  letterhead stating willingness to participate. |
|  | 8. Data use agreements that may be required for use of existing data from third parties. |
|  | 9. HIPAA authorization form, where applicable. HIPAA form is part of document 4, Consent Waiver Form, available at [IRB website](https://www.carroll.edu/institutional-review-board/applying-irb-review) |

**Part 1. Contact Information, Agreements, and Electronic Signature**

**Title of Study:**

**Date:**

**Principal Investigator**

Name:

Mailing address or campus box #:

Phone #:

Email Address:

**Faculty Director (for student projects)**

Name:

Mailing address or campus box #:

Phone #:

Email Address:

List **all other project personnel** including co-principal investigators, co-investigators and anyone else who has contact with subjects or identifiable data from subjects. **Include email address for each person who should receive copies of IRB correspondence to the PI:**

**Name 1:**       **e-mail 1:**

**Name 2:**       **e-mail 2:**

**Name 3:**       **e-mail 3:**

**Name of funding source or sponsor:**

Not funded   Federal  State  Industry   Foundation  Carroll College

Other (specify):

**Sponsor or award number:**

**Risk Assessment Summary:**

*Please answer the following questions:*  Yes No

|  |  |  |
| --- | --- | --- |
| Does the proposed project involve obtaining information about **living human subjects?** |  |  |
| Is the proposed project a **systematic investigation** (i.e. research)?"Systematic investigations" begin with specific questions or hypotheses and are conducted with the intent of drawing scientific conclusions. |  |  |
| Do you expect, ultimately, to present the findings of your project to a wider audience, through presentation and/or publication (**generalizable knowledge**)? |  |  |
| Will you obtain data through **intervention** with the human subjects? "Intervention" involves doing something to a human subject (e.g. administering an experimental treatment intervention, drawing blood) or altering the subjects' environment for research purposes. |  |  |
| Will you obtain data through **interaction** with the human subjectsof your research?"Interaction" includes communication or interpersonal contact between the investigator and subject (e.g. surveying, interviewing, focus groups). |  |  |
| Will you obtain informationabout the individuals in your study from which the identity of the subject may be ascertained by the investigator or associated with that information, e.g. by name, code number, or pattern of answers (i.e. **individually identifiable information**)? |  |  |
| Will the study involve the use of **existing** **data**, research records, patient records, and/or human biological specimens? |  |  |
| Will the study involve **videotaping, audiotaping, filming** of subjects (newly collected or existing)? |  |  |
| Is **deception** required for the validity of this study? Deception in research involves lying to or intentionally misleading subjects. Withholding information may or may not be deception, depending upon whether subjects have sufficient information to make an informed choice about whether or not to participate in the research. |  |  |
| Do you plan to enroll subjects from **vulnerable** **populations**:   1. Prisoners, others involuntarily detained or incarcerated, or parolees? 2. Minors (less than 18 years)? ***If yes***, give age range:      to      years 3. Pregnant women? 4. Mentally disabled or decisionally impaired? 5. Economically or educationally disadvantaged? 6. Non-English-speaking? 7. Patients? 8. Persons who are HIV+ or have AIDS? 9. Other? (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| Do you plan to enroll subjects from **select populations** (e.g. people of a specific ethnicity, race, or religion)? |  |  |
| Will you be collecting **sensitive information** e.g. about   1. Sexual behavior? 2. Criminal behavior? 3. Juvenile delinquent behavior? 4. Alcohol or drug use? 5. Recreational drug use? 6. Child abuse? 7. Physical abuse? 8. Immigration status? 9. Medical or psychological history? 10. Other? (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |

**Principal Investigator**:

I have reviewed the following: 1) [*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at [**45 CFR part 46**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html); 3) the *American Psychological Association’s “Ethical Principles in the Conduct of Research with Human Subjects”*; and 4) Carroll College IRB policies and procedures for the protection of human subjects.

I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and institutional policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this application is accurate and complete.

**\*\* Uploading this application to Moodle constitutes an electronic signature. \*\***

Name of Principal Investigator:            Date:

**If the Principal Investigator is a student, then the Faculty/Staff Director listed below must approve the submission by sending an email to Gerald Schafer, IRB Chair, gschafer@carroll.edu, under the subject heading “IRB Faculty Approval.”**

**Faculty/Staff Director if PI is a Student**:

**The faculty/staff director endorses this application and accept responsibility for ensuring that this study complies with all the obligations listed above for the PI.**

Name of Faculty/Staff Director:        Date:

**Part 2. The Research Proposal**

*For all questions, if the study involves only secondary data analysis, focus on your proposed design, methods and procedures, and not those of the original study that produced the data you plan to use.*

**Title of Study.**

**Brief Summary.** Provide a *brief* non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. *Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content.*

**Purpose**:

**Participants**:

**Procedures (methods)**:

**Purpose and Rationale**. Provide a summary of the background information, state the research question(s), and tell give a rationale for the study – that is, state how answering the research question builds on prior research. If a complete rationale and literature review are in an attached grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive rationale and literature review, including references to relevant scholarly research.

**Full description of the study design, methods and procedures.** Describe the research study. Discuss the study design; study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study if applicable; doses; frequency and route of administration of medication and other medical treatment if applicable; how data are to be collected (questionnaire, interview, focus group or specific procedure such as physical examination, venipuncture, etc.). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject; outcome measurements; and follow-up procedures. If the study involves medical treatment, distinguish standard care procedures from those that are research. If the study is a clinical trial involving patients as subjects and use of placebo control is involved, provide justification for the use of placebo controls.

**Subjects: Description and Criteria for inclusion/exclusion.** *You should describe the subject population even if your study does not involve direct interaction (e.g., existing records).* Specify number of participants, gender, ethnicity, race, and age. Specify whether subjects are healthy volunteers or patients. If patients, specify any relevant disease or condition and indicate how potential subjects will be identified. List required characteristics of potential subjects, and those that preclude enrollment or involvement of subjects or their data. Justify exclusion of any group, especially by criteria based on gender, ethnicity, race, or age. If pregnant women are excluded, or if women who become pregnant are withdrawn, specific justification must be provided.

**Benefits to subjects and/or society.** Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained; these should be clearly distinguished. Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is no direct benefit to the individual subject, say so here **and** on the consent form. Do not list monetary payment or other compensation as a benefit.

**Full description of risks and measures to minimize risks.** Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), social harm (e.g. disruption of a group), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury. Describe what will be done to minimize these risks. Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of medical or psychological referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this.

**Data analysis.** State how the qualitative and/or quantitative data will be analyzed. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or an explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies).

**Confidentiality of the data.** Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

**Will you collect or receive any of the following identifiers?** (Does not apply to consent forms.)

No  Yes *If yes, check all that apply*:

1. Names

1. Telephone numbers

1. Any elements of dates (other than

year) for dates directly related to an

individual, including birth date,

admission date, discharge date, date

of death. For ages over 89: all

elements of dates (including year)

indicative of such age, except that

such ages and elements may be

aggregated into a single category of

age 90 and older

1. Any geographic subdivisions smaller

than a State, including street address,

city, county, precinct, zip code and their

equivalent geocodes, except for the

initial three digits of a zip code

1. Fax numbers

1. Electronic mail addresses

1. Social security numbers

1. Medical record numbers
2. Health plan beneficiary numbers

1. Account numbers

1. Certificate/license numbers

1. Vehicle identifiers and serial numbers

(VIN), including license plate numbers

1. Device identifiers and serial numbers

(e.g., implanted medical device)

1. Web universal resource locators (URLs)

1. Internet protocol (IP) address numbers

1. Biometric identifiers, including finger and

voice prints

1. Full face photographic images and any

comparable images

1. Any other unique identifying number,

characteristic or code, other than

dummy identifiers that are not derived

from actual identifiers and for which the

re-identification key is maintained by the

health care provider and not disclosed

to the researcher

**Data sharing.** With whom will *identifiable* (contains any of the 18 identifiers listed above) data be shared outside the immediate research team? For each, explain confidentiality measures. Include data use agreements, if any.

n/a (you checked “no” above regarding the collection of those 18 identifiers)

No one

Coordinating Center:

Statisticians:

Consultants:

Other researchers:

Registries:

Sponsors:

External labs for additional testing:

Journals:

Publicly available dataset:

Other (specify):

**Data security for storage and transmission.** Please check all that apply.

*For electronic data:*

Secure network  Password access  Encryption

Other (describe):

Portable storage (e.g., laptop computer, flash drive)

*Describe how data will be protected for any portable device:*

*For hardcopy data (including human biological specimens, CDs, tapes, etc.):*

Data de-identified by research team (stripped of the 18 identifiers listed above)

Locked suite or office

Locked cabinet

Data coded by research team with a master list secured and kept separately

Other (describe):

**Post-study disposition of identifiable data or human biological materials.** Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers, if you will do so.

**Part 3. Questions for Studies that Involve Direct Interaction with Human Subjects**

→ ***If your study does not involve direct interaction with human subjects, do not submit this section. Please skip to Part 4 of this application.***

**Methods of recruiting.** Describe how and where subjects will be identified and recruited. Indicate who will do the recruiting, and tell how subjects will be contacted. Describe efforts to ensure equal access to participation among women and minorities. Describe how you will protect the privacy of potential subjects during recruitment. Provide the IRB with the script that you will use when you recruit subjects for this study and indicate if this will be emailed, spoken, etc. *For prospective subjects whose status (e.g., as patient or client), condition, or contact information is not publicly available (e.g., from a phone book or public web site), the initial contact should be made with legitimate knowledge of the subjects’ circumstances. Ideally, the individual with such knowledge should seek prospective subjects’ permission to release names to the PI for recruitment. Alternatively, the knowledgeable individual could provide information about the study, including contact information for the investigator, so that interested prospective subjects can contact the investigator.*

**Informed Consent Process.** Describe your process for how you will give subjects adequate opportunity to provide informed consent to participate in this study. Informed consent is a process, not merely a document. An individual invited to participate in a research study should be given a description of the study that is clear and complete enough for the individual to determine whether or not she/he wants to participate. Subjects should know about any risks before participating in the study. This process should be designed to provide potential participants with readily understandable information commensurate with the level of risk of participating. In most studies, participants will sign a document which documents that the study – together with risks, amount of time required, etc. – has been clearly explained to them and they have elected to participate. You will need to attach all scripts and your Consent Form to this application. A template Consent Form with instructions is available among the MyCarroll IRB documents.

**Deception.** If any withholding of complete information is required for the validity of this study, explain why this is necessary and attach the script of your debriefing statement to subjects once they have participated. (Debriefing is required whenever deception is used.)

**Protected Health Information (PHI).** If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a ***limited waiver of HIPAA authorization*** (complete and attach the “Consent Process Waiver” form, available at the [IRB website, document 4](https://www.carroll.edu/institutional-review-board/applying-irb-review)). If this applies to your study, please provide the following information:

a. Will the information collected be limited only to that which is necessary to contact the subjects to ask if they are interested in participating in the study?  Yes  No

b. How will confidentiality/privacy be protected prior to ascertaining desire to participate?

1. When and how will you destroy the contact information if an individual declines participation?

**Duration of entire study and duration of an individual subject’s participation, including follow-up evaluation if applicable.** Include the number of required contacts and approximate duration of each contact.

**Where will the subjects be studied?** Describe locations where subjects will be studied, both on and off the Carroll College campus.

**Privacy.** Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope).

**Inducements for participation.** Describe all inducements to participate, monetary or non-monetary. If monetary, specify the amount and schedule for payments and how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it. For compensation in foreign currency, provide a US$ equivalent. Provide evidence that the amount is not coercive (e.g., describe purchasing power for foreign countries). Include food or refreshments that may be provided.

**Costs to be borne by subjects.** Include child care, travel, parking, clinic fees, diagnostic and laboratory studies, drugs, devices, all professional fees, etc. If there are no costs to subjects other than their time to participate, indicate this.

**Part 4. Questions for Studies using Data, Records or Human Biological**

**Specimens without Direct Contact with Subjects**

→ ***If your study does not involve the use of pre-existing data, do not fill in this section.***

What **records, data or human biological specimens** will you be using?  *(check all that apply)*:

Data already collected for another research study

Data already collected for administrative purposes (e.g., Medicare data, hospital discharge data)

Medical records (custodian may also require form)

Electronic information from clinical database (custodian may also require form)

Patient specimens (tissues, blood, serum, surgical discards, etc.)

Other (specify):

For each of the boxes checked above, how were the original data, records, or human biological specimens collected? Describe the **process of data collection** including consent, if applicable.

For each of the boxes checked above, **where do these data, records or human biological specimens currently reside**?

For each of the boxes checked above, from whom do you have **permission to use the data**, records or human biological specimens? Include data use agreements, if required by the custodian of data that are not publicly available.

If the research involves **human biological specimens**, has the purpose for which they were collected been met before removal of any excess? For example, has the pathologist in charge or the clinical laboratory director certified that the original clinical purpose has been satisfied? Explain if necessary.

Yes  No  Not Applicable (explain):

Do all of these data records or specimens exist at the time of this application? If not, explain how **prospective data collection** will occur.

Yes  No *If no, explain:*