## C:\Users\lambert\Pictures\logoOriginal.png

## Institutional Review Board

## Research Protocol Form

Directions: Submit this completed Protocol Submission Document along with any additional information, including consent forms, recruitment materials, information sheets, surveys, questionnaires, etc. via IRBNet at <http://www.irbnet.org>

Note: Before completing and submitting this form you should review Investigator Responsibilities, IRB Review Process, and Instructions for Obtaining Consent.

The proposal form utilizes a series of embedded text fields. When completing sections of the form that require typewritten responses, place the cursor over the shaded areas, left-click, and begin entering the requested information. When addressing portions of the form that require a “checked box” response, place the cursor over the desired box, double left-click, select “checked” under the heading “default value,” and select “ok.”

##### SECTION I: GENERAL INFORMATION

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| **Project Title:** |
| **Principal Investigator:**       |
| **Department/School or Affiliation:**       |
| **Email Address:**       | **Phone:**       |
| **Proposed Start Date:**       | **Anticipated Completion Date:**       |
|  |
| **Principal Investigator Status:**  |
| [ ]  Faculty | [ ]  Graduate Student |
| [ ]  Staff  | [ ]  Undergraduate Student |
|  |
| Type of Project: |
| [ ]  Thesis | [ ]  Class project. Please specify: |       |
| [ ]  Dissertation | [ ]  Independent Research | [ ]  Other. Please specify:  |       |
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**Principal Investigator (PI) Assurance Statement**

In signing my IRBNet submission, I agree to accept primary responsibility for its scientific and ethical conduct as approved by the IRB, to obtain approval from the IRB prior to instituting any change in the research project, to report to the IRB any serious adverse reactions or unexpected effects on participants, and if applicable to submit a status report for continuation review at 12 month intervals. The project cannot begin until the PI has received documentation of IRB review and final approval.

**For Students**

An Edgewood College **faculty supervisor’s name is required in the box below.** In signing the description of the research project, the faculty supervisor certifies that they have reviewed the research plan, approved the scientific and ethical aspects of this research, and proofread this document. The faculty supervisor will supervise all compliance with the human participants’ guidelines**. *Make sure your Advisor has also provided their certificate and signature prior to submission to IRBNet.***

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| **Name of Faculty Research Advisor:**       |
| **Department/School or Affiliation:**       | **Phone:**       |
| **Email Address:**       |

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| **Having read the Investigator Responsibilities and the IRB Review Process, in my opinion, the appropriate review process should be:**  |
| [ ]  Exempt | [ ]  Expedited Review | [ ]  Full Review |
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##### Additional Investigators

##### Provide the names, titles and affiliations of all investigators (students included) involved in this investigation. IRB training is required for all investigators. If an ethics training tutorial has been completed in the last two years the completion certificate should be uploaded. If not, Training Completion Certificates can be obtained by completing the CITI Online Tutorial. You can register and complete the tutorial at <https://about.citiprogram.org/en/homepage/>

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##### Please note that any collaborative work with another institution requires the submission of that institution's IRB approval letter.

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| Name | Institution | Phone Number | Completed Tutorial\* |
|  |  |  | [ ]  Yes |
|  |  |  | [ ]  Yes |
|  |  |  | [ ]  Yes |
|  |  |  | [ ]  Yes |

##### SECTION II: SPECIFIC STUDY INFORMATION

**Instructions:** Please address in detail each section listed below.

#### **STUDY OBJECTIVES**

Explain in language understandable to a non-expert the specific objective(s) of the research project. Avoid using discipline or topic related jargon. Be sure to include defining the major variables to be measured in your study, and detail the hypothesis and/or research questions to be examined.

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#### **Research Participants**

Describe in detail the participants including the ***anticipated*** number, age ranges, gender, ethnic background, and health status. If vulnerable populations are included in the study, explain the rationale. Refer to “Definitions for Research Involving Human Participants” for further discussion of vulnerable populations.

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#### **PLANS FOR RECRUITMENT AND SELECTION OF PARTICIPANTS**

Describe in detail how and from where you will recruit participants, including who will contact the participants. From what population will the sample of subjects be drawn? What criteria will qualify a participant to be included in the study? What criterion disqualifies a participant from being in the study?

The investigator must assure that each participant, or his or her legal representative, voluntarily agrees to participate in the study, and that recruitment should avoid any impression of coercion or undue influence due to the special relationship between parties. If the investigator is associated in any way with the potential participants (e.g., teacher, supervisor, co-worker) the nature of that relationship needs to be explicitly stated and the procedures that will be implemented in order to minimize coercion must be outlined.

If payments are offered for participating in the research, payments should be paid on a reasonable prorated basis with partial payment to participants who withdraw before the completion of the research.

If deception or experimental manipulation is used, please explain why it is necessary (as opposed to convenient) for this study. Include plans for how and when subjects will be debriefed.

All recruitment materials must be uploaded with your protocol (posters, emails, follow-up emails, etc.).

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#### **METHOD OF OBTAINING CONSENT FROM PARTICIPANTS**

Explain the method of obtaining informed consent from participants (written consent, implied consent, oral consent). The level of detail regarding obtaining consent should be such that the IRB can determine that no coercion or undue influence will occur. Please upload the appropriate Informed Consent Form with your submission. Templates of the appropriate informed consent forms are located in the forms library at http://www.irbnet.org.

Written parental consent is required of parent(s) or the child’s guardian for each child under the age of 18 who will be a participant of research in a non-exempt category. In addition to parental consent, written assent is required of each child ages 8 through 17.

Some exempt or expedited projects may NOT require written informed consent forms unless requested by the IRB. However, participants still must need to receive adequate information to enable them to give consent.

If you are using oral consent, describe the rationale, how it will be documented, and include a copy of the oral presentation; it must include all information required of written informed consents.

If you intend to use an informed consent document in a language other than English please provide both the English and non-English versions.

**To download a copy of the appropriate Consent/Assent Template, please click on the forms library at http://www.irbnet.org**

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#### **RESEARCH PROCEDURES**

Describe in detail all procedures to be carried out with each participant. Upload all research materials (i.e., questionnaires, interview questions, cover letter, etc.). Explain where the research will be conducted, the data collection methods used, precisely what participants will do or have done to them, and the amount of time of active involvement for the participants. If applicable, outline the technical assistance available, monitoring techniques to be used, and planned safeguards in case of emergencies or unusual events.

If the study involves recording participants you must identify whether audiotapes, videotapes, and/or photographs will be used, and whether the study requires the use of images that are identifiable. Data is identifiable if it contains distinguishing characteristics that would make the individual recognizable to anyone outside the research team. This includes voice and speech patterns, accents, unusual mannerisms, tattoos, scars, or other markings, etc. If identifiable characteristics are removed or blocked out, the information is not identifiable.

Note: If the research will be conducted in a school or institution other than Edgewood College, explain the nature of your cooperative arrangement and upload a letter, on letterhead stationery, of permission from that institution and/or approval of its IRB.

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#### **POTENTIAL RISKS AND DISCOMFORTS**

The purpose of this section is to determine if subjects will be placed "at risk" -- i.e., exposed to the possibility of physical, psychological, sociological, or other harm as a consequence of any activity proposed in the research project. Note that according to HHS Regulations, minimal risk means "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Thus, the concept of risk goes beyond physical risk and includes risks to subjects' dignity and self-respect as well as psychological, emotional, legal, social, or financial risk. Even minimal risks, such as discomfort answering questions, must be identified and included on the consent form.

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| Having read the Investigator Responsibilities and the Guidelines Involving Human Participants and understanding the definition of minimal risk, this proposal, in my opinion, places participants at:  |
| [ ]  Minimal Risk | [ ]  Greater than Minimal | [ ]  Other: Please specify:  |

If the classification is minimal risk, please explain below why that category is appropriate.

If the classification is greater than minimal risk, describe all of the foreseeable risks in detail, indicating probability of occurrence, and severity. What precautions have been taken to minimize these risks and what is their likely effectiveness? Describe other alternative and accepted procedures, if any, that were considered and why they will not be used. Describe how the research will be monitored to ensure the participant’s safety.

For studies involving deception, please justify the deception and indicate the debriefing procedure, including the timing and information to be presented to subjects. If applicable, describe provisions for ensuring the availability of necessary medical or professional intervention in the event of adverse effects to the participants.

If this study involves vulnerable populations, including minors, pregnant women, prisoners, educationally or economically disadvantaged, what additional protections will be provided to minimize risks?

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#### **BENEFIT**

Explain in language understandable to a laypersonhow the information gained in this study will benefit the participants. If there are no direct benefits to the individual participants in this research that should be acknowledged. If the risk in this study is more than minimal, explain how the risks are reasonable in relation to the benefits. An assessment of the potential benefits to the advancement of knowledge, and/or to serve the good of society may also be provided to participants.

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#### **SAFEGUARDING CONFIDENTIALITY OF INFORMATION**

Describe plans to protect the participants’ identities as well as the confidentiality of the data. This is of special concern in social and behavioral projects utilizing personality inventories, interviews, questionnaires, or the use of observation, photographs, taped records, or stored data. Explain the mechanisms that have been devised to safeguard confidentiality, (e.g., the use of numbering or code systems, safely locked files in private offices, online survey tools such as Qualtrics). Describe who will have access to the data and plans for final disposition or destruction of such records.

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