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## Institutional Review Board

## Research Protocol Form

**Application Directions**

* This protocol must be approved prior to conducting research.
* Before completing and submitting this form you must review the following documents found at our website (irb.edgewood.edu): Investigator Responsibilities, IRB Review Process, and Instructions for Obtaining Consent.
* Complete the applicable sections and include all necessary appendices. A checklist can be found at the end of this application.
* All research personnel must complete the appropriate [CITI](http://irb.edgewood.edu/Home/CITI-Ethics-Training-and-Tutorial) training on Human Subjects Research and submit certificates.
* Submit the completed application and appendices (including consent forms, recruitment materials, information sheets, surveys, questionnaires, training certificates etc.) electronically via [IRBNet](http://www.irbnet.org/)

Protocols are reviewed on a rolling basis; there is no deadline for submission. Upon submission, the IRB Administrator completes a brief pre-review (within the first three days) to determine if the documentation provided in the application is sufficient to be reviewed. If the IRB determines that the protocol in incomplete the application will be returned to the investigator with a request for additional information. Once a completed application is submitted, the IRB will initiate formal review and may request revisions to protocol documents to secure approval. Investigators will be notified of the IRB determination through IRBNet.

Reviews are typically completed in 2-3 weeks, depending on the level of complexity of the underlying project. Protocols which require Full Board Review will likely take longer to review than exempt or expedited protocols. Protocols submitted during holidays and the summer months may also take longer to review.

The application 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:**      **Funding Source (if applicable):**       | **Anticipated Completion Date:**       |
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| **Principal Investigator Status:**  |
| [ ]  Full-time Faculty [ ]  Adjunct or Part-time Faculty | [ ]  Undergraduate Student[ ]  Master’s Student |
| [ ]  Staff  | [ ]  Doctoral Student |
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Additional InvestigatorsProvide the names, titles and affiliations of all investigators (all students AND advisors) involved in this investigation. IRB training is required for all investigators (and advisors). 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/>*Make sure you have electronic signatures for all investigators included in your submission to IRBNet.*

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

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| Type of Project: |
| [ ]  Thesis | [ ]  Class project--Please specify class: |       |
| [ ]  Dissertation | [ ]  Independent Research | [ ]  Other. Please specify: |       |

**NOTE:** If you are uncertain if your project requires IRB review, or if you have a class project and are uncertain if IRB review is required, please contact the IRB Administrator, David Lambert, at lambert@edgewood.edu.

**NOTE:** If your project is a collaborative effort with another institution, please contact the IRB for assistance early in the process to determine which IRB will be the institution of record.

**Principal Investigator (PI) Assurance Statement**

By signing this form, **I, the Principal Investigator,** certify that:

1. the information provided in this application is correct
2. I have read and understand Edgewood College policies regarding protection of human participants in research;
3. I will not begin research (including recruitment of research participants) until notification of approval is received
4. I take responsibility for the research design, and will make best efforts to ensure all personnel engaged in the research are compliant with the requirements of the Edgewood college IRB;
5. I will be available to answer questions from the IRB regarding the application and am willing to attend convened IRB meetings to answer questions about the application, if requested to do so;
6. I will seek approval from the IRB in advance of implementation of any changes ([*Change to Approved Research Form*](https://irb.edgewood.edu/));
7. I will immediately inform the IRB of to report to the IRB any serious adverse reactions or unexpected effects on participants
8. If I continue my research beyond the one-year approval from the IRB I agree to submit a status report for continuation review 30 days prior to expiration of approval ([*IRB Continuing Review Form*](https://irb.edgewood.edu/));
9. **For ALL student projects, the advisor has thoroughly reviewed the application, received ethics training, provided signatory testimony that the application exhibits clarity and completeness. Adequate supervision from the advisor (or designated individual) will be provided to students conducting research.**
	1. **Doctoral committees must approve student’s research proposals prior to IRB submission.**

PI Name:       Date:

By entering my name above I certify that I am in compliance with the Principal Investigator (PI) Assurance Statement outlined above.

**For Students**

An Edgewood College **faculty advisor or supervisor’s name is required in the box below. Both you and your advisor are required to “sign” the research project in IRBNet.** In signing the research project in IRBNet, 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 share your proposal with your Advisor, and that your Advisor has provided their certificate and signature prior to submission to IRBNet.***

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| **Name of Faculty Research Advisor:**       | **Phone:**       |
| **Department/School or Affiliation:**       | **Email:**       |
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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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##### 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. Specifically, what is the purpose of the research? What question(s) do you hope to answer? 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. Briefly describe research that has already been done in this area. How will your study contribute to the knowledge of this topic? Please cite one or two scholarly references where appropriate.

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#### **Research Participants**

Describe in detail the participants including the ***anticipated*** number, age ranges, gender, ethnic background, and health status. Explain why you have chosen this particular group to study. Indicate if you will be applying selection criteria in choosing participants, and justify any exclusions of sub-groups. For instance, if you will be selecting only right-handed women, this should be stated and justified.

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 OF PARTICIPANTS**

Describe in detail how and from where potential participants will be recruited and select for this study. From what population will the sample of subjects be drawn? Who will be contacting the participants. If these people have dual or authority relationship with potential participants, please describe. (Ex: caregiver, teacher, employer, service provider, etc.)

The investigator must assure that each participant, or their 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, friend) the nature of that relationship needs to be explicitly stated and the procedures that will be implemented in order to minimize coercion and to ensure that participation is voluntary 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 (where, when, how) regarding the process of obtaining consent should be such that the IRB can determine that no coercion or undue influence will occur. Additionally, you must 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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