COMPLETING YOUR RESEARCH APPLICATION FOR THE INSTITUTIONAL REVIEW BOARD AT EDGEWOOD UNIVERSITY

HTTPS://WWW.EDGEWOOD.EDU/ACADEMICS/INSTITUTIONAL-REVIEW-BOARD/

What is an Institutional Review Board (IRB)?

- A committee formed by an institution to review and approve research protocols involving human participants to ensure it adheres to *ethical guidelines and government established regulations*.
- The primary purpose of an IRB is to assure the protection of the rights and welfare of human participants. This **ALSO** upholds the integrity of the research process and protects investigators and the university.
- The IRB is guided by ethical guidelines from the Office for Human Research Protections (OHRP) within the Department of Health and Human Services (HHS).

What an IRB Does Not Do

- We do not teach research methods. We do not evaluate the scientific merit of a study. We will at times provide methodological suggestions, but these are not required modifications.

- We do not teach research ethics. It is the responsibility of each program to prepare their students for the CITI training. The more thorough the preparation, the more smoothly the training will go for the student.

What an IRB Does Do

- We have provided resources for how to complete your IRB Application. We do provide support for this as needed.

- We have provided resources for how to navigate the submission of your materials through IRBNet. We do provide support for this as needed.

- It is the responsibility of each program to support their students through the IRB Application process and submission through IRBNet. **However, we are available to train the trainers.** It is more efficient for students, research mentors, and the IRB to have programs comfortable with the application process.

What is research and who are human subjects?

- There is often confusion about what types of projects need to be reviewed by the Institutional Review Board.

- **The short answer is that ALL projects involving human participants need to be reviewed at some level.**

What is research and who are human subjects?

- *According to the Code of Federal Regulations:*
  - **Research** is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
  - A **human participant** is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

The Belmont Report

- The Belmont Report is a foundational document in research ethics, particularly regarding human participants research. It outlines three core ethical principles:
  - Respect for Persons,
  - Beneficence, and
  - Justice.
- These principles are the basis for regulations protecting human subjects in research and are used by Institutional Review Boards (IRBs) to evaluate research proposals.
- **All researchers should be familiar with this document!!**
  - www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

1. Respect for Persons

- This principle has two key components: respecting individuals as autonomous agents and protecting those with diminished autonomy.

- Informed Consent
  - Investigator discloses all relevant information to participants
  - Participants (or their have opportunity to ask questions and have them answered
  - No coercion or undue influence on decision to participate

- Respect for Privacy

2. Beneficence

- Beneficence means taking action to benefit others, specifically in research.

- It requires researchers to maximize potential benefits for participants while minimizing potential risks of harm. This principle also suggests making efforts to secure the well-being of those involved in research.

- This is accomplished with competent, trained, investigators, good research design, and honest acknowledgement of the potential risks incurred, however minimal.

3. Justice

- Justice emphasizes fairness in the distribution of the burdens and benefits of research.
- This principle requires equitable selection of subjects and appropriate criteria for inclusion and exclusion of subjects
- Justice also means working to eliminate biases in research that could perpetuate inequalities.

The Application Process

- The Edgewood University Institutional Review Board reviews proposals on a rolling basis, in the order that they are received. There are no submission deadlines.
- Upon submission, the IRB Administrator completes an **initial pre-review screening** process, during which the proposal is reviewed for completeness and compliance. The administrator may ask the investigator to make changes to the submission *before being formally reviewed by the IRB*.
- **Proposals that are incomplete or lack details will be returned to the Principal Investigator (PI) for modifications, further delaying the review and approval process.**
- It is the investigator's responsibility to plan in advance and allow a sufficient amount of time for submission, review, and approval of the study.

The Application Process

- The IRB will initiate formal review after the *completed* application is submitted. Once formal review begins, exempt studies, posing minimal risk to human subjects, take approximately 2 weeks to be processed. Expedited studies take approximately 2-3 weeks to be processed. Studies needing full board review can take up to 4 weeks to be processed.
- These processing timelines on the previous slide ***do not*** include the initial pre-review screening process. These timelines relate to when the IRB is able to initiate formal review of the proposal. Investigators will be notified through IRBNet regarding any modifications that will be required in order to secure IRB approval
- The review timeline for IRB proposal approvals can be impacted by many variables. Proposals of greater complexity or risk will take more time to review. The turnaround time may depend on the volume of submissions received by the IRB office. As all IRB reviewers are faculty at Edgewood University, review of proposals submitted during midterms, finals, or during breaks in the academic calendar may be delayed.

Application Directions

- Your protocol must be approved prior to conducting research.
- Before completing and submitting the proposal form you must review the Investigator Responsibilities and Instructions for Obtaining Consent sections found at our website (https://www.edgewood.edu/academics/institutional-review-board/
- All research personnel must complete the appropriate CITI training on Human Subjects Research and submit certificates (see next slide).
- Submit the completed application and appendices (including consent forms, recruitment materials, information sheets, surveys, questionnaires, training certificates etc.) electronically via IRBNet

REGISTERING FOR CITI TRAINING

CITI TRAINING REGISTRATION STEPS

1. Click on the following link: **Register for Training** and select Register
2. Enter Edgewood University under Select Your Organization Affiliation
3. Check "I Agree…" and "I Affirm…" and select Create a CITI Program Account
4. Enter Personal Information
5. Create your Username and Password
6. Enter Country of Residence
7. Select "NO" to "Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses?"
8. Answer the surveys and marketing information questions and continue to Step 6.
9. Fill out the information sheet and continue to Step 7.
10. Under Select Curriculum:
    a. Question 1: Select "Social & Behavioral Research Investigators"
    b. **You can skip all the other questions**
    c. Click on pre-registration agreement (you won't pay unless you want to do a course that Edgewood does not support), and select Complete Registration

LINKS FOR IRBNET TRAINING

Click on the links below for downloadable PDFs

1. New User Training Energizer
2. New Project Submission Training Energizer

The Application—Section I

- Section I: General Information
  - Provide the following information:
    - Title of Project—this should clearly reflect the focus of your research.
    - Principal Investigator name, affiliation, address, phone number
    - Project Period—provide anticipated start date and completion date
    - Indicate your Principal Investigator Status
    - List Additional Investigators if applicable
    - When completed check tutorial completion and upload certificate
    - Indicate the type of Project
    - You must read and sign the Principal Investigator Assurance Statement
    - For Students: Research advisor name, affiliation, address, phone number--make sure your advisor has read the Research Advisor Statement)
    - Indicate the Appropriate Review Process (see following slides)

TYPES OF REVIEW

Level of Risk Helps Determine Type of Review

Determining Type of Review

- Exempt
  - Research may be exempt when
    - There is no link to identity and no code or link between the participant and the data (anonymous) OR
    - The data already exists OR
    - When the research involves observation of public behavior
  - Exempt research poses no risk to participants
  - Examples of exempt research include studies of *common* educational methods and interviews with public figures

Exemption from (FULL) IRB Review

- While investigators indicate on the proposal their opinion of the appropriate review process, they do not have the authority to determine whether research involving human participants is exempt from review.

- Even if an investigator believes that a project is exempt from full review, an application must be submitted to the IRB for a final determination.

- Thus, designating a proposal as exempt does ***not*** mean it exempt from submitting a proposal to the IRB.

Determining Type of Review

Expedited Review

- Review may be expedited when
  - There is a coded link to subject identity and/or data AND
  - The data do not already exist
- Expedited research poses minimal risk to participants

Full Board Review

- Full review is required when
  - There is a coded link to subject identity and/or data OR
  - Vulnerable populations are involved
- The research poses significant risk to participants (e.g., civil or criminal liability, psychological or emotional harm)

Frequent Issues with IRB Applications

- **Project Title:** The project title in an IRB application should be unique and clearly reflect the focus of your research. It should be the same on all forms. Simply putting *My Dissertation* is not acceptable.

- **General Information Incomplete:**
  - Contact information incomplete
  - Start and completion dates missing
  - Co-investigator information not complete
  - Tutorial completion not indicated
  - PI Assurance statement not signed
  - Research Advisor information missing (for students)
  - Review process not indicated

The Application—Section II

- Section II: Specific Study Information
  - Study Objectives
  - Research Participants
  - Plans for Recruitment and Selection of Participants
  - Method of Obtaining consent from Participants
  - Research Procedures
  - Potential Risks and Discomforts
  - Potential Benefits
  - Safeguarding Confidentiality

#1 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.
- Briefly describe research that has already been done in this area. Begin by discussing patterns of findings in the current literature, identify a gap in that literature, and describe how your study might contribute to the knowledge of this topic? Be sure to include current references.
- 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.

Frequent Issues with IRB Applications

- **Study Objectives:** Insufficient attention to the details surrounding the study objectives.
  - Be sure to include defining the major constructs measured in your study, and detailing the hypothesis and/or research questions to be examined
  - ***Example:*** *Not explaining what a literacy coach does or not describing what transactional leadership means.*

- **Study Objectives:** Jargon is used to describe the objectives.
  - Study objectives should be described in language understandable to a non-expert.
  - ***Example:*** *The purpose of this study is to examine the role of IPT in relationship satisfaction.*

#2 Research Participant Description

- Describe in detail the participants including the *anticipated* number, age ranges, gender, and ethnic background.

- Explain the selection criteria for choosing this particular group of participants to study. Indicate if the participants are being selected for any specific characteristics, like age, sex, race, ethnic origin, religion, or any social or economic qualifications?
  - For example, if you will be selecting only right-handed women, this should be stated and justified.

Research Participant Description

- 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 (children, cognitively impaired, immigrants, prisoners)**.

Frequent Issues with IRB Applications

- **Participants:** Insufficient detail surrounding research participant characteristics.
  - The proposal does not provide the goal number of participants, and does not identify the organization, corporation, business, school, etc. from which participants will be drawn.

#3 Participant Recruitment and Selection

- Describe ***in detail*** how and from where potential participants will be recruited. From what population will the sample of subjects be drawn? Who will be contacting the participants.

- You may need to indicate how you have access to the target population and provide documentation that you have been given permission to recruit them for research purposes.

- 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, employer, 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.

Participant Recruitment and Selection

- You must assure that each participant, or their legal representative, voluntarily agrees to participate in the study.
- If you offer payment for participating in the research, you should include reasonable prorated partial payment to participants who withdraw before the research is completed.
- 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 materials used to recruit participants--flyers, letters, emails, etc.--must be included as attachments with your proposal (do not paste them into the proposal form).

Frequent Issues with IRB Applications

- **Recruitment:** Insufficient attention to the details surrounding participant recruitment.
  - Describe in detail how and from where you will recruit participants. Include all recruitment materials must be included with your proposal. You may need to provide documentation of permission to access the sample (e.g., supervisor approval, school district approval, etc.).

- **Recruitment:** No acknowledgement of potential conflicts of interests.
  - If the researcher has a dual role within the organization, school, institution, business, etc., in which participants will be drawn, then potential conflicts of interest must be explained. The researcher must describe how that conflict is being minimized through recruitment techniques (e.g., a different person is recruiting participants) or is not a risk to participants (e.g., a researcher has no direct supervision over the participant pool) or data collection (e.g., all anonymous data).

#4 Method of Obtaining Consent

- Explain how you will obtain participants' informed consent (written consent, implied consent). This involves more than stating what type consent form will be used.

- This level of detail (who/how/when/where) regarding the process of obtaining consent is needed to provide the committee with enough information that it can be determined that no undue influence or coercion, intentionally or unintentionally, has been exerted to obtain consent to participate

- The consent form should be written directly to the reader, in second person ("you"), as though you are explaining the facts in person. Make sure you write the consent form at an appropriate and understandable level for study participants, avoiding technical jargon or medical terms.

Method of Obtaining Consent

- If children under the age of 18 will be recruited as participants in non-exempt research, written parental consent is required of child's parent(s) or guardian. In addition to parental consent, written assent is required of each child ages 8 through 17.
- If you intend to use an informed consent document in a language other than English, please provide both the English and non-English versions.
- The informed consent form must be included as a separate attachment to your protocol (do not cut and paste the form into this section of the proposal). To download a copy of the appropriate Consent/Assent Template, please click on the forms library at http://www.irbnet.org
- The informed consent document must include all of the required elements of obtaining consent (see next slide).

Elements of Informed Consent

- **Purpose of the Study—**Provide 2-3 sentences about the general purpose of your study.
- **Study Procedures—**Describe in detail what the participant will be asked to do (an activity, completing a survey). Describe the total length of time for participation (how long, how often) , and whether it is online, in person, etc. If any kind of recording (audio, video) will take place, please describe it. If an incentive is provided it should be outlined here.
- **Potential Risks—**Detail any possible risks to participants. Risks can include feeling uncomfortable or distressed about being asked questions about sensitive issues. Outline the procedures that will be used to minimize the risks, such as including a statement that they may skip any question or discontinue involvement at any time.

Elements of Informed Consent

- **Voluntary Nature of Participation—**Participants should be assured that their decision to participate or not to participate will not affect their current or future relations with the academic institution, place of employment, etc. State clearly that participation is voluntary and that the participant may refuse to answer any questions or withdraw from the study at any time without penalty.
- **Contact Information—**Please provide contact information for all principal investigators. If you are a student, you must also provide your advisor's contact information. Include the following statement: *If you have any questions and concerns and would like to talk with someone other than the researchers, please feel free to contact the Institutional Review Board via lambert@edgewood.edu.*
- **Statement of Consent—**Example: *I have read the above information. I have asked any questions I have and have received adequate answers. I consent to participate in the study.*

Implied Consent

- For some survey research, you may be able to obtain *implied consent* rather than written consent if
  - The study poses no more than minimal risk,
  - Doing so will not adversely affect the participants,
  - Participation is truly **anonymous** (there is no link between participants and their identity or data),
- Implied consent is obtained by clearly stating that participation in the research is an indication of consent.
  - "Your willingness to complete the survey indicates your consent to participate in this study."
- All the elements of consent must be still be presented.

Frequent Issues with IRB Applications

- **Consent Section:** Consent form pasted into the consent text box.
  - The consent form must be submitted separately in your IRBNet protocol, not pasted into the consent text box. In the consent section describe in detail how consent forms will be distributed and explained or how they will be accessed and returned by participants.

- **Obtaining Consent:** Insufficient detail or missing information from the consent form.
  - All the elements of consent must be included in the consent form. The IRB recommends using the appropriate informed consent templates available through IRBNet "Forms and Templates" or the IRB website.
  - *The level of detail regarding recruiting participants and obtaining consent should be such that the IRB can determine that no coercion or undue influence has occurred.*

Frequent Issues with IRB Applications

- **Obtaining Consent:** Inappropriate language.
  - The consent form should be written in non-technical language directly to the reader, as though you are explaining the facts in person. Informed consent language should be written in the second person ("you").

- **Obtaining Consent:** Too much unnecessary information.
  - Descriptions of the research should not be overly technical to ensure that all participants understand why the project is being conducted and the goals.
  - For Research Procedures, be sure to focus only on what participants will be asked to do, not focusing on what the research process will be like (e.g., coding data, analyzing statistics, etc.).

#5 Research Procedures

- Explain **precisely** what participants will do or have done to them, including
  - Methodology, measurements, education, training, etc.
  - The length of each session and of the full study (if multiple sessions)
- If you're using a questionnaire or handout, include copies with the application.
- Explain where will the study be conducted. If not being conducted at Edgewood. If not on the Edgewood campus, explain the nature of your cooperative arrangement.

Frequent Issues with IRB Applications

- **Research Procedures:** Insufficient attention to the details surrounding the research procedures.
  - Explain precisely what participants will do or have done to them, including where the study will be conducted. If not on the Edgewood campus, explain the nature of your cooperative arrangement and attach all appropriate forms.

#6 Potential Risks

- Describe in detail any possible immediate or long-range risks to participants that may arise from the procedures used in this study.

- Risks may be physical, psychological, emotional, social, legal, or economic. They would include side effects, risks of placebo, risks of normal treatment delay, etc.

- Even minimal risks, such as discomfort answering questions, must be identified and included on the consent form.

- Indicate any precautions that will be taken to minimize these risks or to provide services in the event of adverse effects.

Minimal risk

Minimal Risk means that 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 tests. (45 CFR 46.102(i))

Issues in Risk Identification

- Never enter “none” in this section.
- Present probabilities and magnitudes of risk in understandable terms in informed consent.
- Demonstrate to IRB in your application that you have researched risks, systematically assessed probabilities, and determined magnitude of harm possible.
- Do not be casual about consequences of any risk identified.

Frequent Issues with IRB Applications

- **Risks:** Insufficient recognition of potential risks to participants.
  - Even minimal risks, such as discomfort answering questions, must be identified and included on the consent form.

  - ***Example:*** *Risks also have to be viewed within the context of the proposal. If the researcher has a conflict of interest (e.g., works for the business where participants are being drawn) and is evaluating the business in terms of employee satisfaction, quality of work, etc., then risk is increased for participants. This increased risk should be clear to participants.*

#7 Possible Benefits

- Describe the anticipated benefits to participants and to society from the knowledge that may be reasonably expected to result from this study.
  - If there are no personal benefits to be realized, say so.
  - Payments, credits in class, participation in a lottery and other inducements are payments, not benefits.
  - Be sure to identify how the research will contribute to the advancement of knowledge but make no extraordinary claims for benefits of the research.

Frequent Issues with IRB Applications

- **Benefits:** Not stating that there are not any direct benefits.
  - Most research conducted at Edgewood does not have direct benefits to the participants. If your study does not, it is recommended to simply state, “there are not any direct benefits.”
  - Incentives such as gift cards etc. are not considered benefits and should be described in the Research Procedures section of the proposal and consent form.

- **Benefits:** Overstating the potential benefits of the study
  - Some research may result in progress for a literature, have an impact on a school district, change business practices, etc. But often research will not have a tangible impact on everyday life for participants and researchers should be cautious in highlighting the indirect benefits of participating.

#8 Confidentiality

- Adequate provisions must be made to protect the privacy of participants and to maintain confidentiality of identifiable information.

- Explain how your procedures accomplish this objective, including location and duration of data storage, description of persons with access to the data, and method of destroying the data when your study is completed.

Frequent Issues with IRB Applications

- **Anonymity and confidentiality confused**
  - Anonymity means *not even the researcher* can connect data to individual participants
  - Confidentiality means a connection could be made by the researcher, but they will protect the data so that others cannot

Frequent Issues with IRB Applications

- **Other common issues with IRB application:**
  - Proposals submitted without enough lead time before research is planned to start.
  - All required documentation not included in the application (recruitment letters, advertisements, surveys, consent letters, etc.)
  - Typographical, grammatical, and punctuation errors

Who to contact with questions:

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THANK YOU!!