

INSTITUTIONAL REVIEW BOARD ON HUMAN PARTICIPANTS

**Application for IRB Review and Approval Guidelines**

**General Instructions**

Application must be typewritten, completed in its entirety, and saved as:

Lastname\_Firstinitial\_Keyword\_IRB\_version#.pdf (e.g., Mai\_J\_Balance\_IRB\_v1.pdf).

This Application and supporting documents should be sent as one PDF file to irb@clarke.edu.

Complete applications will include the documents listed below. These documents should be scanned into a single PDF **in the order listed**.

[ ]  Exempt, expedited, or full review cover sheet

[ ]  This form with faculty signature if PI is a student

[ ]  Proposal abstract

[ ]  Appropriate CITI Training Certificate

[ ]  Informed consent forms (if required)

**Note:** An IRB number will be assigned when final approval is given. This IRB number must be added to the consent form.

[ ]  Research tool(s) (e.g., questionnaire, survey, interview questions, test questions)

[ ]  Recruitment materials (including but not limited to copies of script for face to face recruitment, a copy of recruitment e-mail, social media post, recruitment flyers/posters)

[ ]  Permission statement from research location(s) if research is to be conducted outside of Clarke University

* All required materials must initially be submitted to irb@clarke.edu.
* Incomplete applications will be returned un-reviewed.
* Revised Applications must be submitted as a complete Application and sent directly to the reviewer who reviewed the first version. When saved and submitted, please do so with a new version number (e.g., Mai\_J\_Balance\_IRB\_v2.pdf).
* Exempt and expedited applications may take up to four weeks to review per submission. Full IRB reviews may take longer.

**NOTE:** When completing this form, the text boxes in which to insert content do not display spell check or grammar check notifications (i.e., no red squiggly lines). Applicants may want to compose some answers in a separate MSWord file before pasting into the Application.

**TIP:** Tab from text box to text box or from check box to check box instead of using a mouse. Boxes can be checked using the space bar.

**IRB Application**

1. Project Title:

|  |
| --- |
| **Principal Investigator (PI) Information**  |
| (Name)  | (Department)  |
| (E-mail)  | (Phone)  | (CITI Certificate #)  |

|  |
| --- |
| **Faculty Research Advisor Information**  |
| (Name)  | (Department)  |
| (E-mail)  | (Phone)  | (CITI Certificate #)  |
|  |  |  |
| **Additional Investigator(s) Information**  |
| (Name)  | (Department)  |
| (E-mail)  | (Phone)  | (CITI Certificate #)  |
| (Name)  | (Department)  |
| (E-mail)  | (Phone)  | (CITI Certificate #)  |
| (Name)  | (Department)  |
| (E-mail)  | (Phone)  | (CITI Certificate #)  |

\*\*If more “Additional Investigators” are required, please include them in the Appendix

II. Is this project funded by an outside agency?

[ ]  Yes; Sponsor’s name is

[ ]  No

III. If research is being conducted to meet course or graduation requirements, please check all of the following that apply:

[ ]  A major goal of the project is to practice skills related to conducting research (e.g., administering a previously created tool to learn data collection and analysis procedures).

[ ]  A major goal of the project is to apply previously researched principles to a specific population (are hand washing procedures being followed by clinic staff and what are the related infection rates at clinic *X* OR does reading skill improve when applying this previously studied technique to my students at school *Y*).

[ ]  A major goal is to conduct original research, but there may be limitations in the study (e.g., participant pool is too small to make generalizations, the need to use my colleagues as participants means that I will not be able to ask personal questions).

[ ]  None of these apply. Continue to Question IV

A. Explain any limitations to the research project that might relate to the statements above:

IV. What are the anticipated start and end dates?

\*\* Recruitment for research cannot start until IRB approval has been obtained. Please allow four weeks for the IRB review process.

|  |  |
| --- | --- |
| Desired date to begin recruitment for the study |  |
| Anticipated date for completion of data collection |  |
| Anticipated date to submit Completion Form |  |
| For Student Researchers only:Final Presentation (estimated date) |  |

\*\* Research is considered complete once data collection is completed. Once completed, researcher(s) must submit a Completion of an Approved Researech Project Form to irb@clarke.edu.

V. IRB must consider the research design in order to assess the risks and benefits of this study. This includes recruitment of participants, data collection, data analysis, and dissemination of the results. Please respond to the questions and statements below so that IRB can complete this evaluation.

1. **Rationale:** Using ordinary, non-specialized terms, provide background and rationale for the project.

1. **Research Questions:** List all research questions that will be asked. Questions must be approved by a research advisor if the PI is a student.

1. **Participants:**

1. Participants (Please estimate maximum numbers)

|  |  |
| --- | --- |
| Adult volunteers (patients are not to be included in this number) |  |
| Students within a classroom setting |  |
| Minors (under 18) |  |
| Patients as experimental participants |  |
| Patients as controls |  |
| Persons whose first language is not English |  |
| Pregnant women or fetuses |  |
| Adults with cognitive disabilities |  |
| Prisoners, incarcerated  |  |
| Other (please specify):  |  |
|  |  |
| Total anticipated participants (maximum) |  |

2. Will participants be able to participate in a language in which they are fluent? (Check all that apply) It is not acceptable to include participants who are not able to fully understand the consent materials or the tool being used.

[ ]  Yes, all participants will participate in a language in which they are fluent.

[ ]  Yes, translations will be offered. Provide evidence that an appropriate translator is being used to create forms and/or to conduct interviews.

[ ]  No, participants are not used in study.

3. What inclusion and exclusion criteria will be used to determine eligibility to participate?

4. If using a specific sampling method, indicate which sampling method(s) will be used.

[ ]  Simple Random Sampling

[ ]  Stratified Sampling

[ ]  Cluster Sampling

[ ]  Systematic Sampling

[ ]  Multistage Sampling

[ ]  Convenience Sampling

[ ]  Volunteer Sampling

[ ]  Network Sampling

[ ]  Snowball Sampling

[ ]  Purposive Sampling

[ ]  Quota Sampling

[ ]  Other:

1. **Recruitment**

1. Recruitment Location (Check all that apply)

[ ]  Clarke University

[ ]  Public areas not located at Clarke. Please list specific areas:

[ ]  Social media (e.g., Facebook, Instagram, Twitter, etc.). Please list sites & groups:

\*\* Applicant must secure and include documentation of approval to recruit from non-public virtual communities or interest groups (e.g., moderator of a closed Facebook group).

[ ]  Other location(s) (e.g., businesses, other institutions, agencies, etc.). Please list:

\*\* Applicant must secure and include documentation of approval to recruit at these location(s). Please include copies of permissions in the Appendix.

2. Will these other locations require this project to be approved by their own IRB?

[ ]  Yes, the following other locations will require this project to be approved by their own IRB:

\*\* Note: If Applicant is able, please include the project’s IRB approval notification(s) from these other location(s) in this application.

[ ]  No, these other locations will rely on the Clarke University IRB approval process.

3. How will potential participants be contacted in order to recruit them? Please include a copy of the e-mail, script, flyer, or advertisement to be used to recruit potential participants. Refer to IRB website for policy on incentives.

4. Is informed consent required? (Research using previously recorded data may not require informed consent.)

[ ]  Yes

[ ]  No

5. How will consent be obtained? Check all that apply. (Include with the application)

[ ]  Informed Consent Form with Cover Letter

[ ]  Parent/Guardian Informed Consent Form with Cover Letter

[ ]  Parental Notification Letter (for Action Research only)

[ ]  Assent Form

[ ]  Verbal Consent (with Script)

[ ]  Participation Consent (for Web and Phone Surveys)

6. If it is not possible to obtain written consent, describe how an understandable explanation will be given to the participants and consent will be acknowledged.

1. **Data Collection and Analysis**

1. Data Collection and Analysis Location (Check all that apply)

[ ]  Clarke University

[ ]  Public areas not located at Clarke. Please list specific areas:

[ ]  Social media (e.g., Facebook, Instagram, Twitter, etc.). Please list:

\*\* Applicant must secure and include documentation of approval to collect data from non-public virtual communities or interest groups (e.g., moderator of a closed Facebook group).

[ ]  Other location(s) (e.g., businesses, other institutions, agencies, etc.) Please list:

\*\* Applicant must secure and include documentation of approval to collect data at these location(s). Please include copies of permissions in the Appendix.

2. If applicable, will these other locations require their IRB to approve of the project?

[ ]  Yes, the other location’s IRB approval is attached.

[ ]  Yes, but the other location has yet to provide notification of IRB approval.

[ ]  No, the other location will be using the Clarke University IRB approval.

3. Indicate which of the collection tools will be used during research and attach all relevant documents. (Check all that apply)

[ ]  Survey, questionnaire(s) created by researcher: Attach tool(s)

[ ]  Survey, questionnaire(s) routinely collected by the site: Attach tool(s)

[ ]  Survey, questionnaire(s) created by other researcher: Attach tool(s) and permission or documentation that the survey is in the public domain

[ ]  Interview: phone/in-person: Attach interview tool(s) or questions being used

[ ]  Focus group: Attach questions being used

[ ]  Analysis of student test scores or routine assignments: Attach sample test(s) and assignment(s)

[ ]  Analysis of existing public records or documents

[ ]  Analysis of medical or other private records

[ ]  Direct observation of people in school, workplace, or other non-public location: Attach tool(s) if relevant

[ ]  Direct observation of people in public places: Attach tool(s) if relevant

[ ]  Collection of physical specimens (e.g., blood, saliva, etc.)

[ ]  Collection of data or physical specimen through non-invasive means (e.g., weight)

[ ]  Other(s) (please specify):

4. How will participants complete the study (e.g., email, phone, mail, face to face)? Include the web address, email, script, survey, or other relevant information.

5. How often will participants be expected to meet with researcher(s) and for how long (e.g., two one-hour meetings, two weeks apart; 10-minute survey)?

6. Explain in detail the total experience of participants during the research. Be sure to include scripts, forms, surveys, and other documents related to the study.

7. How will the accuracy of the data collection be ensured (e.g., pilot testing, interrater reliability, single or double blind)? IRB may request raw data in order to assess accuracy.

8. Will data be anonymous or confidential? *Anonymous data are data collected with no identifiers available to the researcher. Confidential data include one or more identifiers which is available to the researcher.*

[ ]  Anonymous

[ ]  Confidential

9. How will data be *collected* in order to protect the confidentiality and privacy of participants?

10. How will data be *stored* in order to protect confidentiality and privacy of participants (e.g., locked file in a particular room, password protected file on a specific computer)? Be specific.

11. How and when will data be destroyed? The federal government requires data to be retained for at least three years.

12. Describe the specific quantitative or qualitative analysis that will be used to answer the research questions.

VI. The researcher is responsible for considering any potential risk that a research participant might experience. Risk to participants may be tolerable in research as long as it is necessary to gather the information and as long as the researcher has provided appropriate ways to minimize the risk. Carefully estimate risk level for participants of this study. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.

|  |  |
| --- | --- |
| A. Psychological stress greater than daily life (e.g., potential to perceive topic or materials as threatening, offensive, or degrading) |  Level of risk [ ]  Not Applicable  [ ]  Minimal risk [ ]  Substantial risk |
| Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled. |  |
| B. Social or economic stress greater than daily life (e.g., perception of experience as potentially damaging to financial standing, employability, job retention, or reputation) |  Level of risk [ ]  Not Applicable  [ ]  Minimal risk [ ]  Substantial risk |
| Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.  |  |
| C. Physical or medical risk greater than daily life (e.g., potential for physical injury or negative impact on health) |  Level of risk [ ]  Not Applicable  [ ]  Minimal risk [ ]  Substantial risk |
| Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled. |  |
| D. Unintended disclosure of confidential information (e.g., school or medical records) |  Level of risk [ ]  Not Applicable  [ ]  Minimal risk [ ]  Substantial risk |
| Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled. |  |
| E. Perceived coercion to participate because of existing or potential relationship between researcher and participant (e.g., friend-friend, teacher–student, employer–employee) |  Level of risk [ ]  Not Applicable  [ ]  Minimal risk [ ]  Substantial risk |
| Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled. |  |
| F. Confusion resulting from experimental deception (e.g., use of placebo) |  Level of risk [ ]  Not Applicable  [ ]  Minimal risk [ ]  Substantial risk |
| Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled. |  |
| G. List any other risk that may apply:  |  Level of risk [ ]  Not Applicable  [ ]  Minimal risk [ ]  Substantial risk |
| Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled. |  |

VII. Conflicts of Interest (COI)

**A. Financial COI:** Do any of the researcher(s) (or their spouse(s), domestic partner(s), significant other(s), and/or dependent children) have financial interests related to this study?

[ ]  Yes

[ ]  No

1. If Yes, please disclose this financial COI:

2. If Yes, please explain how relevant researcher(s) will manage the influence of this financial COI to avoid any actual or seeming compromised judgement related to the collection, analysis or reporting of this research project. Note: Any COI should be disclosed in publications or presentations.

**B. Other COI:** Do any of the researcher(s) (or their spouse(s), domestic partner(s), significant other(s), and/or dependent children) have any other personal considerations that may compromise—or have the appearance of compromising—an investigator’s professional judgment in conducting or reporting research for this project?

[ ]  Yes

[ ]  No

1. If Yes, please disclose this other COI:

2. If Yes, please explain how relevant researcher(s) will manage the influence of this personal COI to avoid any actual or seeming compromised judgement related to the collection, analysis or reporting of this research project. Note: Any COI should be disclosed in publications or presentations.

VIII. Describe the potential benefits of this research to individual participants or to society.

IX. Assurance Statements

I understand and agree to follow all of Clarke University’s IRB policies and requirements.

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Date Principal Investigator’s Signature

*If the PI is a student, then the Faculty Advisor must agree to the following:*

I reviewed this application and approve of the protocols. I worked with this student to ensure that all ethical and procedural concerns have been addressed. I support this research project and attest to the ability of the researcher to conduct this study.

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Date Faculty Advisor’s Signature (if applicable)

If the Student PI is unable to obtain a Faculty signature (e.g., Faculty Advisor is out of town), then student must CC the faculty member when submitting the Application and any revisions. The Faculty Advisor must then “Reply All” confirming approval before the Application or Revision will be considered for review or approval. This alternative signature process is only for exceptional circumstances. Please indicate why this alternative process was necessary.