

**INSTITUTIONAL REVIEW BOARD ON HUMAN PARTICIPANTS**

Proposal Submission for Protocol Review and Approval Guidelines

**General Instructions**

* Application must be typewritten, completed in its entirety, and saved as: Lastname\_Firstinitial\_Keyword\_IRB\_version#.pdf (eg: Mai\_J\_Balance\_IRB\_v2.pdf). The document should then be sent 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 (scanned signature page)

[ ] Proposal abstract

[ ] NIH Training Certificate

[ ] Informed consent forms (if required).

Note: IRB number must be added when final approval is given.

[ ] Sample of questionnaire, survey, interview questions, test questions, etc. to be used

[ ] Recruitment materials (These may include but are not limited to copies of script for face to face recruitment, a copy of recruitment e-mail, recruitment flyers/posters)

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

* Incomplete applications will be returned un-reviewed.
* Any resubmission must be of a complete application. When saved and submitted please do so with a new version number.
* All required materials must be submitted to irb@clarke.edu
* Allow two to four weeks for processing applications for exempt and expedited reviews. Full IRB reviews may take longer.

**Application**

1. Project Title

|  |
| --- |
| **Principal Investigator (PI) Information**  |
| (Name)  | (Department) |
| (E-mail) | (Telephone) | (NIH Certificate #) |

|  |
| --- |
| **Research Advisor Information**  |
| (Name)  | (Department) |
| (E-mail) | (Telephone) | (NIH Certificate #) |
| **Additional Investigator Information**  |
| (Name)  | (Institutional affiliation and/or Department) |
| (E-mail) | (Telephone) | (NIH Certificate #) |

**Note:** Copy and paste the bolded section above and complete for each additional investigator.

3. Type of Submission

|  |  |
| --- | --- |
| New  |  |
| Continuation (Attach progress report) |  |

4. Is this project funded by an outside agency?

|  |  |
| --- | --- |
| Yes |  |
|  | Sponsor’s name (If this project is funded by an outside agency) |  |
| No |  |

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

Yes Please check appropriate box below and continue to limitations.

No Continue to limitations

|  |  |
| --- | --- |
|  | a. A major goal of the project is to practice some of the skills related to conducting research (such as administering a previously created tool in order to learn about data collection and analysis procedures). |
|  | b. 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*). |
|  | c. The major goal is to conduct original research, but there may be limitations in the study (participant pool is too small to make strong generalizations based on the quantitative findings, the need to use my colleagues as participants means that I will not be able to ask deeper questions, etc.).  |
|  | d. None of these apply. |

Limitations

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

6. What are your anticipated start and end dates?

\*\*Note-Research cannot start until IRB approval has been obtained. Please allow four weeks for the IRB review process. Once approved, there is one year to move forward with the research. If the research continues past the one year deadline, a continuation form must be submitted to the IRB committee.

1. Student researchers:

|  |  |
| --- | --- |
| Expected time to begin the study |  |
| Data collection (estimated time—days, weeks, months) |  |
| Data analysis (estimated time—days, weeks, months) |  |
| Final Presentation (estimated date) |  |

\*\*Research is considered complete when

1. Non-student researchers

|  |  |
| --- | --- |
| Expected time to start and end data collection |  |
| Start date |  |
| End date |  |

7. 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 layman’s terms, provide background and rationale for your project.
2. **Research Questions:** List all research questions that will be asked. Questions must be approved by a research advisor if the PI is a student.
3. **Participants:**

I. 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) |  |

II. 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 you are using

|  |  |
| --- | --- |
| Yes, all participants will participate in a language in which they are fluent.  |  |
| Yes, translations will be offered. Provide evidence that you are using an appropriate translator to create forms and/or to conduct interviews. |  |
| No, participants are not used in study.  |  |

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

IV. If you will use a specific sampling method, indicate which sampling method you will use in the table.

|  |  |
| --- | --- |
| Simple Random Sampling |  |
| Stratified Sampling |  |
| Cluster Sampling |  |
| Systematic Sampling |  |
| Multistage Sampling |  |
| Convenience Sampling |  |
| Volunteer Sampling |  |
| Other |  |

1. **Recruitment**

I. Recruitment Location (Check all that apply)

 Clarke University

 Public areas not located at Clarke. Please list specific areas.

 Social media (for example Facebook, Instagram, Twitter, etc.)

 Other (businesses, other institutions, agencies, etc.) Please list.

 \*\*\*You must secure and include in the application a written statement of approval for your work to be done at these location(s).

1. If applicable, will these other locations require IRB approval or will they be using the Clarke University IRB approval? If they require a separate IRB approval, please include your IRB approval notification in your application.
2. How will you contact potential participants in order to recruit them? Please include a copy of the e-mail, script, flyer, or advertisement to be used to recruit potential participants.
3. Is informed consent required? (Research using previously recorded data may not require informed consent.)

|  |  |
| --- | --- |
| Yes.  |  |
| No. |  |

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

|  |  |
| --- | --- |
| Informed Consent Form with Cover Letter  |  |
| Parent/Guardian Informed Consent Form with Cover Letter |  |
| Assent Form |  |
| Verbal Consent (with Script) |  |
| Participation Consent (for Web and Phone Surveys) |  |

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

 Clarke University

 Public areas not located at Clarke. Please list specific areas.

 Social media (for example Facebook, Instagram, Twitter, etc.)

 Other (businesses, other institutions, agencies, etc.) Please list.

 \*\*\*You must secure and include in the application a written statement of approval for your work to be done at these location(s).

1. If applicable, will these other locations require IRB approval or will they be using the Clarke University IRB approval? If they require a separate IRB approval, please include your IRB approval notification in your application.
2. Indicate which of the collection tools will be used during your research and attach all relevant documents. (Check all that apply)

|  |  |
| --- | --- |
| Survey, questionnaire(s) created by researcher: Attach tool |  |
| Survey, questionnaire(s) routinely collected by the site: Attach tool |  |
| Survey, questionnaire(s) created by other researcher: Attach tool and permission or documentation that the survey is in the public domain |  |
| Interview: phone/in-person: Attach interview tool or questions being used |  |
| Focus group: Attach questions being used |  |
| Analysis of student test scores or routine assignments: Attach sample tests and assignments |  |
| 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 if relevant |  |
| Direct observation of people in public places: Attach tool if relevant |  |
| Collection of physical specimens (blood, saliva, etc.) |  |
| Collection of data or physical specimen through non-invasive means |  |
| Other (please specify) |  |

1. How will subjects participate? (email, phone, mail, face to face, etc.) Include the web address, email, script, survey, or other relevant information.
2. How often will participants be expected to meet with you and for how long (two one-hour meetings, two weeks apart; 10-minute survey; etc.)?
3. 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.
4. How will you ensure the accuracy of the data collection? For instance, pilot testing, interrater reliability, single or double blind, etc. (IRB may request raw data in order to assess accuracy.)
5. Will your 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 |  |

1. How will data be *collected* in order to protect the confidentiality and privacy of participants?
2. How will data be *stored* in order to protect confidentiality and privacy of participants (locked file, password protected file, etc.)? Per government regulations, data needs to be retained for three years.
3. How and when will data be destroyed? Per government regulations, data needs to be retained for three years.
4. Describe the specific quantitative or qualitative analysis that will be used to answer your research questions.

8. It is the responsibility of the researcher to consider any potential risk that a 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 assumed by your participants in the table below. Explain how you will try to minimize the risk to your participant(s) and how you will handle the risk if a participant complains.

|  |  |  |
| --- | --- | --- |
|  | Level of risk |  |
| A. Psychological stress greater than daily life (potential to perceive topic or materials as threatening, offensive, degrading, etc.) | Not applicable |  |
| Minimal risk |  |
| Substantial risk |  |
| Describe circumstances that could lead to risk if applicable. Explain how you will try to minimize the risk to your participant(s) and how you will handle the risk if a participant complains.  |  |
| B. Social or economic stress greater than daily life (potential to perceive experience as potentially damaging to financial standing, to employability or ability to retain job, or to reputation) | Not applicable |  |
| Minimal risk |  |
| Substantial risk |  |
| Describe circumstances that could lead to risk if applicable. Explain how you will try to minimize the risk to your participant(s) and how you will handle the risk if a participant complains. Attach additions if necessary. |  |
| C. Physical or medical risk greater than daily life (potential for physical injury or negative impact on health) | Not applicable |  |
| Minimal risk |  |
| Substantial risk |  |
| Describe circumstances that could lead to risk if applicable. Attach additions if necessary. Explain how you will try to minimize the risk to your participant(s) and how you will handle the risk if a participant complains. |  |
| D. Unintended disclosure of confidential information (such as school or medical records) | Not applicable |  |
| Minimal risk |  |
| Substantial risk |  |
| Describe circumstances that could lead to risk if applicable. Explain how you will try to minimize the risk to your participant(s) and how you will handle the risk if a participant complains. Attach additions if necessary. |  |
| E. Perceived coercion to participate because of existing or potential relationship between researcher and participant (teacher–student, employer– employee, etc.) | Not applicable |  |
| Minimal risk |  |
| Substantial risk |  |
| Describe circumstances that could lead to risk if applicable. Explain how you will try to minimize the risk to your participant(s) and how you will handle the risk if a participant complains. Attach additions if necessary. |  |
| F. Confusion resulting from experimental deception (use of placebo, for example) | Not applicable |  |
| Minimal risk |  |
| Substantial risk |  |
| Describe circumstances that could lead to risk if applicable. If so, explain how you will try to minimize the risk to your participant(s) and how you will handle the risk if a participant complains. Attach additions if necessary. |  |
| G. List any other risk that may apply: | Not applicable |  |
| Minimal risk |  |
| Substantial risk |  |
| Describe circumstances that could lead to risk if applicable. Attach additions if necessary. |  |

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

10. Assurance Statements:

PI: 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 PI is a student:*

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

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Date Faculty Advisor’s Signature (if applicable)