

**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 mailed to “Chair, IRB, MS 1521”. Complete applications include the following:
  + This form with faculty signature if PI is a student
  + Proposal abstract
  + NIH Training Certificate
  + Sample of questionnaire, survey, interview questions, test questions, etc.
  + Informed consent forms (if required)
  + Permission statement from research location if research is to be conducted outside of Clarke University
  + Expedited, exempt, or full form if either applies. Please place form at front of application packet.
* Incomplete applications will be returned un-reviewed.
* Any resubmission must be of a complete application.
* All required materials must be submitted to the IRB chair. Allow two to four weeks after the posted committee meeting for processing applications for exempt and expedited reviews. Full IRB reviews may take longer.
* If your research requires a full review, please submit six copies of your application materials.

**Application**

1. Principal Investigator (PI) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Additional Investigators \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Advisor (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Project Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. PI Telephone number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. PI Email address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Department \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3a. NIH Training Certification: Yes No

b. NIH Certification Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Type of Submission

|  |  |
| --- | --- |
| New |  |
| Renewal (Attach progress report) |  |
| Continuation |  |
| Modification (Explain changes) |  |

5. Is this project funded by an outside agency?

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

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

Yes Proceed to limitations

No Move to #7

|  |  |
| --- | --- |
|  | 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:

7. Start and End Dates

\*\*Note-Research cannot start until IRB approval has been obtained. 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.

|  |  |
| --- | --- |
| Start Date |  |
| End Date |  |

8. Research Location

|  |  |
| --- | --- |
| Clarke University |  |
| Other Please name:  If other than Clarke, you must secure a written statement of approval for your work to be done at the other location. This is required for your application to be considered complete. |  |

9. Participants (Please estimate maximum numbers)

|  |  |
| --- | --- |
| Normal adult volunteers |  |
| 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 |  | |

10. Procedures

|  |  |
| --- | --- |
| **Select 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 to use the tool |  |
| Interview: phone/in-person: Attach interview schedule and tool or questions being used |  |
| Focus group |  |
| 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: Attach tool if relevant |  |
| 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.) |  |
| Other (please specify below) |  |

11. IRB must consider the research design in order to assess the risks and benefits of this study. Please indicate your research questions and how your research will lead to answers to those questions.

|  |  |
| --- | --- |
| **Research Question**  List your research question below. If you have more than one question, please attach additional responses to each prompt. Questions must be approved by faculty if PI is a student. |  |
| **Data Collection Tools**  What *tools* or *research process* will collect the data connected to this question? |  |
| **Data Points**  Which questions on the tool, variables, or aspect of your process will address this question? |  |
| **Data Source**  Which persons, documents, etc. will provide the data? |  |
| **Data Analysis**  Briefly describe the specific quantitative or qualitative analysis that will address this question. |  |

12. Do you have additional research questions?

|  |  |
| --- | --- |
| Yes. Please attach additional responses. |  |
| No |  |

13. What will the participants experience? Be specific and include all procedures from recruitment through data collection and termination. If you are not using research participants, only records, documents, etc., proceed to number 18.

*Recruitment*

A. What criteria will you use to decide who you would like to recruit? Be sure to adequately indicate the population from which you will be recruiting participants and identify inclusion/exclusion criteria for participation.

(Examples: I will randomly choose 50 patients at clinic *x* with hypertension and depression; I will interview all 4th graders at elementary school *x* who perform at or above the 95th percentile on their fall 2011 ITBS.)

B. Indicate the sampling method you will use if you are sampling.

C. Location of participants at recruitment[[1]](#footnote-1):

D. How will you contact potential participants in order to recruit them (email, phone, in person, internet, etc.)? Be specific:

*Research Process*

E. Explain the total experience of participants during the research (focus group then an exam, complete survey, etc.):

F. Duration (two one-hour meetings, two weeks apart; 10-minute survey; etc.):

G. Exact location of data collection:

H. Means of participation (email, phone, mail, etc.):

14. 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.

|  |  |  |
| --- | --- | --- |
|  | 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. Attach additions if necessary. |  | |
| 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. 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. |  | |
| 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. 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. 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. 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. |  | |

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

16. Will your data be anonymous? Anonymous data are data collected with absolutely no identifiers available to the researcher.

|  |  |
| --- | --- |
| Yes: proceed to 20. |  |
| No |  |

17. Will your data be confidential? Confidential data do include one or more identifiers available to the researcher. The researcher must keep identifiers private and must ensure voluntary participation. Anonymous data are preferred.

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

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

19. How will data be *stored* in order to protect confidentiality and privacy of participants (locked file, password protected file, etc.)?

20. Will participants be able to participate in a language in which they are fluent?

|  |  |
| --- | --- |
| Yes, all participants will be competent English speakers. |  |
| Yes, translations will be offered. Provide evidence that you are using an appropriate translator to create forms and/or to conduct interviews. |  |
| Not applicable. |  |

It is not acceptable to include participants who are not able to fully understand the consent materials or the tool you are using.

21. Has approval been obtained from the authorities where the research is to be conducted or where the records are to be collected if the location is other than Clarke? (Attach consent form from institution other than Clarke).

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

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

|  |  |
| --- | --- |
| Yes. Include informed consent form with application. |  |
| No. Proceed to 25. |  |

23. If it is not possible to obtain a written consent form, describe how an understandable explanation will be given to the participants.

24. If the participants are minors, an active parental consent is required. Are any participants minors?

|  |  |
| --- | --- |
| Yes. Include a copy of this consent form. |  |
| No |  |

25. How and when will data be destroyed?

26. How will you ensure the accuracy of the data collection? (IRB may request raw data in order to assess accuracy.)

**If this study has already been approved by another institution, include a copy of that institution’s IRB protocol forms and approval letter.**

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Date Principal Investigator’s Signature

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Date Faculty Advisor’s Signature (if applicable)

Faculty signature indicates that the faculty member has read the application and worked with their student(s) to ensure that ethical and procedural concerns have been addressed. Faculty signature indicates that the faculty supports the research project and finds the researcher(s) competent to conduct the research.

1. If this location is not Clarke University or a public space, then you must include a permission statement from the organization where you are recruiting participants. This statement must be included with your application submission in order for your application to be considered. [↑](#footnote-ref-1)