

Institutional Review Board
225 South 6th Street, 9th Floor ♦ Minneapolis, Minnesota 55402
IRB Evaluation Form 

Study Title:	
Researcher's Name:	
Mentor's Name:	
School Affiliation:	
IRB Reviewer Name:	
Review Date:	

Initial Assessment	
<p>Yes No</p>	<p>This study is ready for IRB Review. If no stop the review and select the reason(s) below:</p> <p>The application is complete, but lacks clarity and coherence such that it cannot be reviewed.</p> <p>There is serious lack of detail in the study procedures.</p> <p>The IRB application is seriously inconsistent with other documents (informed consent, proposal, supplemental forms, etc.)</p> <p>The research questions and/or hypotheses are not aligned with the research design, so that the proposed design is incapable of answering the proposed research questions.</p> <p>The research design is not aligned with the data collection and/or analysis procedures, so that the data collection and/or analysis is incapable of resulting in meaningful findings.</p>
Reviewer's Rationale	

IRB Review

Researchers:

Read through all comments and directions recorded on this [evaluation](#) and the [decision letter](#). You must upload your revisions into IRBNet and also provide a summary of your revisions in the **Researcher's Summary of Revisions** sections of this form and upload it into IRBNet.

IRB Review Decision

This study is:

This study meets the criteria for expedited category:

This study will require a continuing review cycle of:

If the approval period is granted for less than a year, please provide rationale for this decision:

Consultations	
Yes No	Did you consult with anyone on this review? Name: Reason:
Consultation Summary:	

If you select no for any of the questions below, please provide feedback to the researcher.

Participant Perspective Assessment

Informed Consent Form Document		
I believe the participants for this study will be able to:		
Yes	No	1. Read and understand the form.
Yes	No	2. Understand the language (terms) used within form.
Yes	No	3. Understand that this is a research study.
Yes	No	4. Understand the purpose of the research study.
Yes	No	5. Understand the procedures that will be followed.
Yes	No	6. Understand if any of the procedures are experimental.
Yes	No	7. Understand how much time is required to participate.
Yes	No	8. Understand what will happen to the data collected.
Yes	No	9. Identify who will have access to the data collected.
Yes	No	10. Understand how confidentiality of data collected will be maintained.
Yes	No	11. Identify and explain the risks involved.
Yes	No	12. Identify and explain the benefits of the research study.
Yes	No	13. Identify who to contact with questions about the research procedures.
Yes	No	14. Identify who to contact with concerns about the conduct of the research.
Yes	No	15. Identify who to contact when an injury or unanticipated problem occurs.
Yes	No	16. Understand that participation is voluntary and refusal to participate or discontinuing (withdrawing) will involve no penalties or loss of benefits to which a participant is entitled.

Reviewer Feedback

Researcher's Summary of Revisions

Recruitment Materials and Process ?		
Identify the recruitment materials that were reviewed for this research study.		
<p> Flyer Ad (Web, Newspaper, etc.) Phone Script Radio or Media Script Recruitment e-mail or letter Announcement Script (i.e. announcement read during a meeting, class, etc.) Other: </p>		
Yes	No	1. The recruitment materials accurately represent the proposed study.
Yes	No	2. The recruitment materials are easy to understand.
Yes	No	3. The recruitment materials are free of coercion (language, design, images, etc.).

Reviewer Feedback

Researcher's Summary of Revisions

Risk and Benefits Assessment 		
Yes	No	1. Will the risks and benefits of this research study fulfill <i>The Belmont Report</i> principle Beneficence?
Yes	No	2. Are the risks to subjects minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk? If no , provide feedback.
Yes	No	3. Are the risks to subjects reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result?

Reviewer Feedback

Researcher's Summary of Revisions

Selection of Participants 		
Yes	No	1. Does the selection of participants in this research study fulfill <i>The Belmont Report</i> principle of Selection of Subjects?
Yes	No	2. Is the selection of subjects equitable (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)?
Yes	No	3. Has the researcher obtained the required permission from the research site(s)?

Reviewer Feedback

Researcher's Summary of Revisions

Informed Consent 		
Yes	No	1. Does the informed consent form document and process fulfill <i>The Belmont Report</i> principle of Respect for Persons?
Yes	No	2. Does the informed consent form document and process meet the criteria set forth by 45 CFR 46.116[a](1-8) and if necessary 46.116[b](1-6)?
Yes	No	3. Is the researcher requesting a waiver to alter any elements required by 45 CFR 46.116? If yes , please select which regulation criteria the request meets. 
Yes	No	4. Will informed consent of participants be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117?
Yes	No	5. Is the researcher requesting a waiver of <i>documentation</i> of informed consent? If yes , please select which regulation criteria the request meets. 
Yes	No	6. Does the informed consent document provided embody all the required elements as required by Capella University?

Reviewer Feedback

Researcher's Summary of Revisions

Empty box for the Researcher's Summary of Revisions.

Special Populations
Does Not Apply to this Study



Yes	No	1. Are there adequate provisions to protect this population?
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Reviewer Feedback

Empty box for Reviewer Feedback

Researcher's Summary of Revisions

Empty box for Researcher's Summary of Revisions

Deception Assessment <i>If there is deception, the study must be referred to the full IRB Committee.</i> 		
Does Not Apply to this Study		
Yes	No	1. If deception is utilized in this study, is it necessary for this research protocol?
Yes	No	2. If deception is necessary for this study, has the researcher developed appropriate debriefing measures?
Yes	No	3. If deception is necessary for this study, has the researcher developed appropriate post-informed consent procedures to allow participants (and their data) to opt-out of the research study?

Reviewer Feedback

Researcher's Summary of Revisions

Conflict of Interest Assessment		
Does Not Apply to this Study		
Yes	No	1. Has the researcher managed the potential conflict of interest, ensuring that the rights and welfare of participants are protected (i.e. disclosure of the conflict to participants, an independent data and safety monitoring committee, modification of role(s) of particular research staff, changes in location of research activities, elimination of the conflict of interest, etc.)?
Yes	No	2. Are there other actions necessary to minimize the risks to participants?
Yes	No	3. Should the informed consent process be revised to include information regarding the potential conflict of interest?

Reviewer Feedback

Researcher's Summary of Revisions

Research Proposal Assessment

Yes

No

1. The research proposal reflects the same information provided in the IRB application and other forms. If **no**, the researcher must revise the documents.

Questions for the Researcher

What questions do you have for the researcher that could be answered prior to the next review?

Researcher's Answers