IRB IRB Reviewer Rubric and Feedback Form

Date Review Completed:

Reviewer Determination:

The IRB reviewer issues the following determination:

☐	The application and all documentation are APPROVED.
☐	Application is DEFERRED. The application and all documentation require revision and review (see *Reviewer Comments*).
☐	Full Board Review Required
☐	The application and all documentation are DENIED after a Full IRB Board Review. *(see comments below).*

Reviewer Summary Comments and/or Recommendations:

	IRB Response		Reviewer comments
	Yes	No	
Human/Nonhuman Research			
The proposed research study involves human participants.	☐	☐	*Please note: For non-human participant research, information about participants and informed consent is not necessary.*
I. Investigator details			
The principal investigator's name and contact information are included.	☐	☐	
If applicable, the contact information of the dissertation chair or faculty mentor is included.	☐	☐	

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	IRB Response		Reviewer comments
	Yes	No	
The investigator acknowledged that required CITI training is complete and certificates of completion are attached to the application.	☐	☐	
II. Research study overview			
The purpose of the study and the importance of the knowledge expected to result from this research is clearly stated.	☐	☐	
The investigator has clearly explained the research activities that will involve human participants.	☐	☐	
The methods and instruments to be used for data collection are clearly described and appropriate for the study.	☐	☐	
If applicable, the instrument(s) has/have been provided.	☐	☐	
If applicable, permission for instrument use has been provided.	☐	☐	
The reliability and validity of the instrument(s) to be used have been provided.	☐	☐	
The location(s) where research activities will occur are clearly defined, including location name, address, and/or url).	☐	☐	

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	Yes	No	
The l appropriate permissions have been received for the location(s) where the research will occur..	☐	☐	
The study involves vulnerable populations.	☐	☐	
The study is subject to FDA regulations.	☐	☐	
The study utilizes HIPAA or other protected information.	☐	☐	
The research requires registration with ClinicalTrials.	☐	☐	
III. Participant information			
The inclusion criteria stated for the participants are appropriate, meet ethical standards, and any exclusions are unbiased and appropriate for the research.	☐	☐	
A clear description of how participants will be recruited and selected is provided with appropriate procedures outlined.	☐	☐	
All appropriate materials to be used for participant recruitment are included and, as necessary, permissions have been provided.	☐	☐	
The selection process for participants is equitable and appropriate for the proposed research.	☐	☐	

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	Yes	No	
Sampling method is provided and explains why the method was chosen and the sample size is appropriate.	☐	☐	
If applicable, compensation or incentives provided to participants for their participation will not result in coercion.	☐	☐	
The risks associated with participation in the study are clearly explained and outweighed by the benefits of the study.	☐	☐	
The investigator outlines a clear approach to ensure risks are minimized and offers resources for support to participants as needed.	☐	☐	
IV. Informed consent			
Informed consent form(s) includes the required information outlined in the template and is attached with application.	☐	☐	
The consent form is complete and easy to understand for the participants.	☐	☐	
The study utilizes a simple consent process that is ethical and is appropriate for the participants and study.	☐	☐	
The consent form makes it clear that participation is voluntary.	☐	☐	

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	Yes	No	
The consent form clearly discusses potential risks and benefits associated with participation in the study.	☐	☐	
The consent form explains how data will be protected, including a statement about keeping records in a clearly identified secure location for an extended duration.	☐	☐	
The consent form reports all relevant contact information for the investigator and the IRB chair.	☐	☐	
The consent form has an appropriate process and signature line or acknowledgement method (secure digital or inked signature) for the study .	☐	☐	
V. Privacy and confidentiality			
The investigator outlined a secure process to adequately protect participant privacy and confidentiality.	☐	☐	
The investigator outlined a n appropriate approach to manage, store, and secure all data.	☐	☐	
VI. Researcher acknowledgment			
The investigator indicated there are no known conflicts of interest.	☐	☐	
The investigator attests to understanding the IRB policies and	☐	☐	

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	IRB Response		Reviewer comments
	Yes	No	
agrees to comply with IRB requirements.			
The investigator acknowledges that IRB approval must be received prior to contacting participants or collecting data.	☐	☐	
The IRB Application is (electronically) signed and dated.	☐	☐	
Required Supporting Documentation			
All required CITI certificates of completion for ethics training are attached.	☐	☐	
For students and J1 scholars, the dissertation chair or faculty mentor's CITI certificates are current.	☐	☐	
Doctoral candidates have successfully completed their preliminary defense.	☐	☐	
All instrumentation, protocols, recruitment letters, site permissions and permissions required for instrument use are attached with application.	☐	☐	
Informed consent form(s) conforms to the Westcliff University template and is attached with the application.	☐	☐	
If the study documents are being translated into different languages, the	☐	☐	

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	Yes	No	
professional translator or translation services qualifications are attached for a bi-directional (English to other language and then one back to English and a comparison is made between the two English documents). The two translators/transcription services should be from different companies.			
Other Documentation Requirements per study protocol.	☐	☐	