WESTCLIFF UNIVERSITY
Educate. Inspire. Empower.

IRB Institutional Review Board (IRB) Overview

The Institutional Review Board (IRB) is responsible for all human research subjects, in accordance with the Department of Health and Human Services (DHHS). All research conducted at the University must be in accordance with the Code of Federal Regulations Title 21 and IRB standards and all Subparts of 45 CFR 46. The Westcliff University IRB is registered with the Office for Human Research Protections (OHRP).

The mission of the IRB is to protect the rights, dignity, welfare, and privacy of the human subjects in all research conducted by individuals affiliated with the University. The IRB process adheres to the principles outlined in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report and the regulations of the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), and other applicable agencies. We are committed to advancing the ethical treatment of research participants, promoting the responsible conduct of research, and ensuring and protecting the rights of every human research volunteer. Further, we are committed to the following goals:

- Ensuring that all research involving human subjects receives required approvals before research activities are initiated.
- Creating an environment at the University of respect for, and understanding of, the rights and welfare of research participants.
- Educating the university community about federal, state, and university research regulations, policies, and practices pertaining to the protection of human subjects.

Three basic principles of the Belmont Report are central to the ethics of research involving human subjects and guide the IRBs in ensuring that the rights and welfare of research participants are protected. These are:

- Respect for persons–applied by obtaining informed consent and considering privacy, confidentiality, and additional protections for vulnerable populations.
- Beneficence–applied such that the potential benefits of research are maximised and possible risks are minimized to the persons involved.
- Justice–evidenced in the equitable selection of research participants.

The IRB will enforce the requirements of Code of Federal Regulations Title 21, decision charts, and the Westcliff University IRB standard operating procedures to ensure the highest standards in ethical research, investigator conduct, and education regarding ethical research while supporting successful degree completion.

Westcliff University IRB Application Process and Requirements

All IRB applications at Westcliff University must be submitted via the online submission form at https://writingcenter.westcliff.edu/westcliff-irb/applications/.

The IRB application must be completely filled out, and all required documentation must be attached with the IRB application at the time of submission. If any information is missing, it will cause the application to be delayed or deferred. The following table describes the key sections of the IRB application. To ensure the IRB can understand the details presented in the IRB application, enter information clearly, concisely, and consistently throughout the application and in the associated study documentation. For more information and to review sample responses for each section, please refer to the IRB website for additional resources.

Section	Description of information required
Investigator details	Include the title of the study and the principal investigator's name and contact information. If applicable, include the name of your dissertation chair or faculty mentor (J1 scholars) and any co-researchers. You must acknowledge the required Collaborative Institutional Training Initiative (CITI) certification training is complete and the researcher's certificates must be uploaded with the application.
Research study overview	Briefly describe the purpose of the study, research design, and procedures to be used, including a description of the location of the research. Indicate what data will be collected and what instrument(s) will be used to obtain data. Also, include if the research will be funded and/or if research assistants will be involved.
Participant information	Provide information about the targeted study population, including how many participants are anticipated, inclusion criteria, and the methods to be used for recruitment and screening. Describe any potential benefits and risks of harm to the human subjects.
Informed consent	If Informed Consent is required, describe the informed consent process and upload consent documents with your application. Use the Informed Consent Form Template on the IRB website. If Informed Consent is not required, explain why.
Privacy and confidentiality	Describe how the data/information collected will be stored to ensure privacy, security, and confidentiality during and after the study.
Researcher acknowledgement	Acknowledge that you understand the IRB's policies and accept responsibility for all aspects of the research. Attest that the information provided in the application is accurate and complete, and you will comply with IRB requirements and decisions.

The IRB Office will provide written notice to each principal investigator following the review of their application. The review period will begin on the date of the submission, and the IRB committee will typically respond within 10 business days for exempt and expedited reviews. Upon completion of the review, a letter will be sent to the primary investigator (PI) or faculty member submitting the application (for doctoral students and J1 scholars) either authorizing the initiation of the project or containing stipulations that must be met before approval is granted. The

involvement with human subjects or data collection for non-human subjects research, may begin only after all stipulations have been satisfactorily addressed and the application has been approved.

If the application is approved, the letter will include the IRB Approval Number and expiration date of the approval. The research must be conducted according to the application that was certified by the IRB, and any changes to the application must be reported to and certified by the IRB before the changes may be implemented. All future correspondence must include the IRB approval number and the title of the study. Research participants must be provided with a copy of the informed consent document certified by the IRB for use in this study. When the study is complete, you must notify the IRB office by submitting the IRB Close-Out Form.

All amendments to approved study applications must receive IRB approval before involving human subjects in the revised protocol. IRB approval of amendments does not change the approval expiration date for the study. The researcher is also responsible for reporting the occurrence of any adverse events to the IRB and suspending all research activities until the IRB has completed a review. For more information about requesting an amendment, reporting an adverse event, or filing for an extension, please review the Westcliff University IRB Website for addendums, extensions, and renewals.

(The application begins on the next page)

WESTCLIFF UNIVERSITY
Educate. Inspire. Empower.

SECTION I | Investigator Details

Title of the Study	
Principal Investigator	
Email Address of Principal Investigator	
Phone Number of Principal Investigator	
Name of Dissertation Chair or Faculty Mentor (if applicable)	
Email of Dissertation Chair or Faculty Mentor (if applicable)	
Co-Researcher(s) (For Faculty Research & Exchange Scholars only)	
Date of IRB Application	

Ethics Training: All investigators and faculty mentors must file current CITI certificates for all required CITI courses. Please note that the University IRB will not approve a research project if the researcher(s) are lacking current CITI certification. For more information about the CITI certificates required at Westcliff University, please refer to the IRB website for training resources. For doctoral candidates and exchange scholars, the faculty chair/mentor's certificates also must be on file with the Dissertation Department.

IRB Application

	Yes	No
Principal investigator's required CITI certificates are complete, up-to-date, and are submitted with this application.	☐	☐

SECTION II | Research Study Overview

Research Study Description: Summarize the proposed research study using non-technical language that someone outside the discipline can easily understand. The summary should include the purpose of the study, objectives of the research, and a brief explanation of the importance of the knowledge that may reasonably be expected to result from the study. Use grammatically correct English and complete sentences (limit 300 words not including citations).

Research Methodology: State the specific qualitative (e.g., case study, narrative inquiry, grounded theory) or quantitative design (i.e., correlational, quasi-experimental, experimental) you have chosen for your research. If you are using a mixed methods approach, please list all research designs used that correspond to the chosen methodology. Provide an overview of all data collection methods and instruments to be used (e.g., surveys, questionnaires, interview questions), including the frequency of these procedures. For human-subjects research, provide an explanation of the research activities and the estimated time commitment for participants.

Instrumentation: Provide a description of the instruments that will be used for data collection. Include the reliability and validity for each instrument (see Westcliff University Policy on Instrument Validation on the IRB website). Include at least inter-item consistency and at least concurrent validity for each instrument and agree with Westcliff University's Policy on Instrument Validation on the IRB website.

All instruments must be attached when submitting this application. State whether the instrument(s) is/are researcher-designed or being used from an alternative source. Researchers wishing to use an existing instrument or measure that has been copyrighted must receive permission from the copyright or licence holder and attach this with the application submission.If an instrument that has not been copyrighted is to be used, a copy of the notice that it is public and available for research must be included.

If the research involves any of the following, check the appropriate box.

Procedure	Involved	Notes
Audio or video recordings	☐	The consent form must indicate whether recording is optional or required for the study. If optional, provide an opt-in/opt-out section within the consent form.
Data, private or proprietary	☐	Permission and an explanation of the type of data should be included in the site permission letter.
Data, publicly accessible	☐	Cite the public source of the data (e.g., the url, the name of the source).
Deception	☐	Inclusion of deception will require additional context and information.
Focus group, interiews, or survey instruments	☐	Include focus group, interview, or survey instruments.
Translated documents	☐	Provide the qualifications of the professional translators. The translation process should involve three steps: translating from English to a non-English language, then translating back from that non-English language to English, and finally translating once more from English to the non-English language. After completing these steps, a comparison should be made to determine if the translations are equivalent.Different professional translators and/or translation companies should be used for each step in the translation process. Include material in English and its translated equivalent.
Waiver of documentation of informed consent.	☐	The IRB may waive documentation of informed consent per 14 CFR 1230.117. In this case, the IRB requires the investigator to submit a written statement regarding the reasons for the waiver and provide for the participants to retain general information about the study.
Waiver of parental consent/permissions.	☐	There are additional regulatory and consent requirements for research that involves vulnerable populations (21 CFR 56.111(b).

If applicable, provide the name and URL for any publicly accessible data sources to be used in the study.

Location of Research: List the location(s) where the research activities will be conducted. All locations involved in the study that are not publicly available will need site permissions (e.g., company, business organization, school, hospital.). Please provide the exact legal name and address of each location. Letters granting permission to recruit participants or conduct research at a specific location must be attached with the application submission.The approval on official letterhead of the site or sent from the organization's email address must be signed or written by the person at the site who has authority to permit the research activities and include their contact information.

Site permission letters must specifically state the activities that are being permitted (e.g., recruitment through the site providing employee contact information, availability of office space to conduct interviews). If the location for research is virtual/online (for example, interviews will be conducted using Zoom, Microsoft Teams, Google Meet, or another virtual meeting platform), permission is still required if the company or organization has allowed you to contact potential participants through them or use company resources during the research in any way.

Research Assistants: Research assistants are persons, other than the principal investigator, who contribute to the implementation of the study, including interaction with participants and/or access to data, but do not participate in the design and development of the study protocol.

	Yes	No
Will research assistants be involved in any aspect of your proposed research study (e.g., collecting or interpreting data, statistical analysis, etc.)?.	☐	☐

If you answered yes, please describe how the research assistants will be involved and their qualifications to ensure the rights and safety of the participants will be adequately protected. Documentation must be provided for all research assistants including, CV/resume, ethics training completion certificates, and any study-specific training needed to adequately protect participants.

Categorization of Research. Check "Yes" or "No". At least one of the following must be selected as "Yes".

	Yes	No
Research conducted in established or commonly accepted educational settings involving normal educational practices	☐	☐
Research involving survey procedures, interview procedures, or observations of public or private behavior	☐	☐
Research involving the collection or study of existing data, documents, records that cannot be identified directly or through identifiers linked to the participant	☐	☐
Research using data with personally identifiable information in which the researcher undertakes to immediately remove the identifiers.	☐	☐

General Exclusions from Exempt Status. Checking "Yes" for any of the following implies the research is *not exempt*. Please note that the University *will not approve* research requiring FDA approval, registration with ClinicalTrials.gov, or HIPAA-protected information.

	Yes	No
The research is FDA regulated.	☐	☐
The research requires HIPAA-protected information.	☐	☐
The research requires registration with ClinicalTrials.gov	☐	☐

Funding. Indicate whether the research is externally funded, internally funded, or unfunded.

☐	External Funding
☐	Internal Funding
☐	Unfunded

SECTION III | Participant Information

Population & characteristics: Provide a clear description of the target population and characteristics associated with the sample (e.g., all inclusion or exclusion criteria related to the study and how you plan to gain access to the potential participants). Provide a clearly defined sample size, support for that number (e.g., power analysis for quantitative research, literature basis for qualitative research), and the sampling method. Criteria for inclusion in your study population should be as specific as possible and included in the research application and consent forms.

Vulnerable populations: Please indicate if any of the following vulnerable populations will be included in your study. There are additional regulatory and consent requirements for research that involves vulnerable populations (21 CFR 56.111(b). Please note that the University will not approve research requiring participants to be prisoners, pregnant women, or adults lacking the capacity to consent.

	Yes	No
The research requires participants to be children/minors.	☐	☐
The research requires participants to be persons with intellectual or developmental disabilities.	☐	☐
The research involves prisoners.	☐	☐
The research requires participants to be pregnant women.	☐	☐
The research requires participants to be economically or educationally disadvantaged persons.	☐	☐

Recruiting: Describe how participants will be recruited and selected. If participants are being recruited from an organization, school, hospital, etc., you must attach letters of permission from all participating site locations on their official letterhead *(see section on Location of Research)*. Attach copies of all proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, oral/written scripts) with your application submission.

Risk Assessment for Participants: Check the appropriate selections.
Definition of Minimal Risk: Risks are minimal where the probability and magnitude of harm or discomfort (physical, psychological, social, or economic) anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

☐	The research involves no more than minimal risk to participants (not greater in magnitude to ordinary life or during routine physical or psychological examinations or tests).
☐	The research involves greater than minimal risk.

If your research involves greater than *minimal risk*, describe all reasonably expected risks, harms, and discomforts, including physical, psychological, social, reputational, legal, and economic risks, harms, and discomforts. Discuss the severity and likelihood of greater than minimal risks that might occur and what measures you will have in place to mitigate those risks.

Compensation. Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement, and/or entry into a raffle) to participate in the research study?

☐	Yes
☐	No

If you answered yes, describe all compensation and/or incentives that participants will receive. The IRB will assess any incentives, gifts, or payments in your research protocol with regard to impact on participants, especially with respect to coercion.

WESTCLIFF UNIVERSITY
Educate. Inspire. Empower.

SECTION IV | Informed Consent

Informed consent waiver: The IRB may approve a waiver of the requirement for a signed consent form in accordance with federal regulations per § 1230.117. If the research meets requirements for a waiver, the IRB may require the investigator to submit a written statement regarding the reasons for the waiver and provide participants with information sheets to retain.

	Yes	No
The research meets requirements for a waiver of documentation of informed consent.	☐	☐

If the researcher meets the requirements for a waiver of documentation of informed consent, the investigator must submit a written statement in the box below regarding the reasons for the waiver, provide supporting evidence, and include the general information about the study that will be provided to participants.

Informed consent process: Explain the procedures that will be followed to obtain informed consent from participants, including how consent will be obtained (e.g., written, oral, electronic) and how participants will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation. Use the Informed Consent Form template on the IRB website and attach all consent form(s) when this application is submitted. If the research is not anonymous, describe the process the investigator will take to withdraw participants and their data if they decide not to continue to participate at any time during the study.

SECTION V | Privacy and confidentiality

Privacy and confidentiality: Describe how privacy and confidentiality will be protected, including how information will be handled and stored and who will have access to the information. Include an explanation of security measures for both electronic and hard copy records. Research data must be retained for a minimum of 3 years after the final project closeout. Discuss how you will dispose of the data once the retention requirement has been reached.

SECTION V | Investigator Acknowledgement

Potential Conflict of Interest: Federal Guidelines require IRBs to assure that there are no conflicts of interest in research projects that could affect human subject participation. If this study involves or presents a potential conflict of interest, additional information may need to be provided.

Investigators conducting human subject research may have conflicts of interest, including financial conflicts of interest, if they or their family stand to benefit as a result of their human subject research. Investigators with a financial interest in the entity sponsoring their research should inform the IRB of this and potentially also inform the participants.

Does the principal investigator, any co-investigators, or any of their family members, have a financial or other business interest in the source(s) of funding, materials, or equipment related to this study?

- ☐ Yes
- ☐ No

Principal Investigator Assurance Statement
I understand the IRB's policies and attest:

☐	that the information in this application is complete and accurate;
☐	that research efforts, including recruitment and data collection will not commence before IRB approval;
☐	to the scientific merit and importance of the study;
☐	to my competency as an investigator to conduct the research project; and
☐	that all instruments and equipment are adequate to conduct the research project

I agree to:

☐	comply with IRB requirements and decisions;
☐	accept responsibility for all aspects of the research project;
☐	obtain prior approval from the IRB before amending or altering the study or its documents;
☐	report to the IRB in the event of adverse event(s) or unanticipated problems;
☐	complete and submit all required IRB forms; and
☐	notify the IRB immediately upon the discovery of a potential conflict of interest not disclosed in this application.

Electronic Signature/Agreement

Investigator Signature	
Date of IRB Application	

SUPPORTING DOCUMENTATION REMINDER

Please note: All required supporting documentation must be attached with your submission or your application will be deferred. (e.g., CITI certificates, site permission approvals, instruments with proof of reliability and validity, recruiting materials, informed consent, permission to use instruments)