IRB Institutional Review Board (IRB) Overview

The Institutional Review Board (IRB) is responsible for reviewing and approving all research conducted at the university. While the primary 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 also reviews research proposals for non-human subjects research. This review is conducted to confirm that a project does not meet the definition of human subjects research and to promote the responsible conduct of research to ensure all research upholds ethical standards and receives required approvals before research activities are initiated.

Non-Human Subjects Research Description

The term "non-human subjects research" refers to any research study that does not interact or intervene in any way with human participants to collect data for the study. Researchers may use data from publicly available datasets and/or receive permission to use data from private institutions. Owners of identifiable data typically impose restrictions on the use of the data that they provide researchers. Institutions may release de-identified data publicly, but only release identifiable data to researchers with IRB approved data protection plans. De-identification is the process used to prevent someone's personal identity from being revealed.

Generally, research using only non-human subjects data does not require review by an Institutional Review Board (IRB) as it does not involve human subjects. However, at Westcliff University the IRB will provide a review of the application to ensure the highest standards in research practices, investigator conduct, and educational standards regarding ethical research to support 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. Also, include if the research will be funded and/or if research assistants will be involved.
Data information and security	Provide information about the data that will be used in the study, including how you plan to gain access to the data. Describe any potential benefits and risks associated with the data being used for research purposes. Describe how the data will be kept secure.
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. Data collection and/or analysis 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. When the data collection 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 any research activities under amended protocol. IRB approval of amendments does not change the approval expiration date for the study. The researcher is 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.

Please complete all sections of the application fully with 11-12 pt font. The application begins on the next page.

IRB Non-Human Subjects Research Application

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.

	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.

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

Procedure	Involved	Notes
Audio or video recordings	☐	If original data was collected from human participants, then there is an acknowledgement in the data use agreement or terms and conditions that participants were notified that the data may be used in the future for research purposes.
Data, private or proprietary	☐	Permission and an explanation of the type of data should be included in the site permission letter.
Data, publicly accessibe	☐	Cite the public source of the data (e.g., the url, the name of the source).
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.

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 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., access to company data, availability of office space or any company resources).

Research Assistants: Research assistants are persons, other than the principal investigator, who contribute to the implementation of the study, including 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 data 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 the data.

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 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 removes the identifiers.	☐	☐
Research using data with personally identifiable information in which the researcher does not 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.

	Yes	No
External Funding	☐	☐
Internal Funding	☐	☐
Unfunded	☐	☐

Compensation. Will organizations receive compensation or other incentives to provide data for the research study?

	Yes	No
Compensation or incentives will be made available to organizations.	☐	☐

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

SECTION III | Data Information and Security

Data information: Provide a clear description of the data to be used for the study, including how you plan to gain access to the data. If the data being used is 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). Describe any potential benefits and risks associated with the data being used for research purposes.

Data collection: Provide an overview of all data collection methods (e.g., forms to collect data, review guides, checklist for reviewing records, observation guides/checklist, data mining tools) and the source of the data. Cite the source from where you are getting the data (e.g, url for public data, site permission for proprietary data). If applicable, provide the name and URL for any publicly accessible data sources to be used in the study.

Privacy and confidentiality: If any personal identifying information is in the data you will use, provide the steps that will be taken to de-identify the data. If original data was collected from human participants, there must be an acknowledgement in the data use agreement that participants were notified that the data may be used in the future for research purposes.

Data security: Describe how the data will be kept secure, including what procedures will be used to protect the data during data collection, storage, analysis, and reporting. Describe how data 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 IV | Investigator Acknowledgement

Potential Conflict of Interest:. If this study involves or presents a potential conflict of interest, additional information may need to be provided.

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

Conflict of Interest Disclosure Statement: I have identified below any areas where I foresee a possible conflict of interest and described my plan for mitigating risk.

Conflict of Interest or Potential Conflict of Interest	Yes	No	Actions taken to minimize threats posed by the conflict of interest. (Complete for all questions answered "Yes.")
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.	☐	☐	
I am using data from a Westcliff facility	☐	☐	
I am using data from entities who do business with Westcliff facility	☐	☐	
I am using data from my place of employment.	☐	☐	
I am using data from my family or close friends.	☐	☐	
I hold a position of authority over entities from which I am using data.	☐	☐	
Other – Describe:	☐	☐	

Principal Investigator Assurance Statement
I have disclosed above any potential conflicting interests that might influence or be perceived to influence how I professionally conduct my research study or certify that I have no conflicting interests that might influence or be perceived to influence how I professionally conduct my

research study. Furthermore, I understand the IRB's policies and attest:

- ☐ that the information in this application is complete and accurate;
- ☐ that research efforts, including 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	

Dissertation Chair Signature (if applicable):

Dissertation Chair Name	
Dissertation Chair Signature	

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, permission letters, data sources).