APPENDIX A

Exempt (Level 1) Application for IRB Certification of Compliance

No or Minimal Risk

This level of application is reserved for research meeting exempt category specifications. See the Levels of IRB Review and Certification section of the IRB Handbook for a description of review levels.

Exempt Application Form Checklist

To the Principal Investigator of a research project:

1. *Please review the documents listed below that pertain to your research project. In the event that your project does require the use of any of the listed documents, attach a copy of that document to the application submitted for IRB review.*

2. *If you are conducting a research project in another institution (e.g., a hospital or school), you must attach a signed permission letter from a supervisor/administrator who is in a position to grant you permission to conduct the research at that site. The letter must be on institutional letterhead and must have an original signature.*

3. *If that institution also has a Human Subjects Review Committee--often referred to as the Institutional Review Board (IRB)-- then written permission from the participating institution's IRB must be attached to your IRB application.*

4. *If you are conducting research outside of the United States, you may not file at the Exempt level.*

The attached Application for Certification of Compliance contains (check all that apply):

- ☐ Institutional Permission Letter (where data are held) or documentation of ability to use data
- ☐ Letter(s) of Informed Consent (may be needed if there is a question about original use of data)
- ☐ Conflict of Interest Disclosure Statement
- ☐ CITI Completion Report for principal investigator, faculty research supervisor, and committee member
- ☐ Signatures of the principal investigator and faculty research supervisor

Application for IRB Review and Certification of Compliance

Exempt (Level 1) Cover Sheet

IRB# _____

Date Logged: _____

Use this form for research involving Exempt (Level I) Research No or Minimal Risk

(Review by one or more IRB Members — May lead to Expedited or Full review)

Principal Investigator/Researcher's Name:_____

Student ID Number: _____

Type of Research Project (Dissertation, Applied Research, describe other) _____

Title of Research Project: _____

Principal Investigator/Researcher's Address: _____

Telephone Number:_____Email: _____

Faculty Research Supervisor's Name: _____

Telephone Number:_____Email: _____

College: ☐ College of Business ☐ Law ☐ Other (specify):

Program of Study:_____ Degree _____

Project Proposed Start Date:_____Project Proposed Completion Date: _____

As the principal investigator, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in participant(s), selection process, change of principal investigator, change in faculty research supervisor, adverse incidents, or completion date of project. I also attest that I will treat human participants' data ethically and in compliance with all applicable state and federal rules and regulations that apply to this study, particularly as they apply to research work conducted in countries other than the United States.

Signature of Principal Investigator _____ _____
Date

Approval/Signature of Faculty Research Supervisor_____ _____
Date

IRB Certification Signature_____ _____
Date

The above named research project is certified for compliance with Westcliff University's requirements for the protection of human research participants with the following conditions:

1. Research must be conducted according to the research project that was certified by the IRB.

2. Any changes to the research project, such as procedures, consent or assent forms, study design, or addition of participants, must be reported to and certified by the IRB.

3. Any and all adverse events or reactions must be reported to the IRB immediately (see Appendix K).

4. When the study is complete, the investigator must complete a Project Completion Report.

5. Any correspondence will be directed to the principal investigator and faculty research supervisor (if applicable) and include the assigned IRB research project number and the project title.

****

NOTES:

- *Please complete this cover and the application in detail. Every question must be answered. Please type your answers.*
- *Attach the appropriate documents and submit the entire application with supporting materials under the cover of a completed Application Checklist to the faculty research supervisor for review and approval prior to submitting to the IRB.*
- *Do not proceed with any research work with participants until IRB certification is obtained.*
- *If any change occurs in the procedure, sample size, research focus, or other element of the project that impacts participants, the IRB must be notified in writing with the appropriate form (see Appendix J).*
- *Please allow 30 days after receipt of a complete application for processing.*
- *DO NOT COLLECT DATA PRIOR TO RECEIVING IRB CERTIFICATION*

Application for IRB Review and Certification of

Compliance Exempt (Level 1) Application

No or Minimal Risk

Read and complete the following statements: If you answer "no" to any of the statements, your research does NOT qualify for Exempt status. (If your project does NOT qualify for Exempt status, complete an Expedited or Full application, based on risk/benefit ratio to participants).

a. A literature review ☐ Y ☐ N

b. Broad consent granted in prior research study that allows secondary research using original data with private individual information ☐ Y ☐ N

c. Routine educational tests, survey or interview procedures or observation of public behavior ☐ Y ☐ N

d. Secondary research use of information that is publicly available or recorded without identifiers ☐ Y ☐ N

e. Secondary research use of information collected by the Federal Government for other purposes and subject to certain privacy laws ☐ Y ☐ N

f. Secondary research use of information covered by HIPAA protections ☐ Y ☐ N

Completely answer the requested information. (N/A is not acceptable for any question). Do not attach your research proposal – answer the questions as stated. Begin typing in the gray boxes.

1. Identify the study site(s): _____

2. Provide a detailed summary of the project, including methodology. Specify all information related to the purpose of the study, recruitment of participants, procedures with participants, and measures and materials for gathering data.

3. Describe the involvement of human participants in the research project.

4. Describe required institutional approvals or other approvals (parental approval as necessary according to institutional policy).

5. Describe how confidentiality will be maintained. Be specific, including the use of secondary documents, audio/video tapes, etc. Describe procedures for the safekeeping and disposal of information stored electronically.

6. Describe why this project fits the Exempt level of risk.

7. Describe review by institutions outside of Westcliff University, if applicable. (Attach copies of permission letters, IRB certifications, and any other relevant documents).

Attach any other required forms, including the CITI completion certificate for principal in*vestigator, faculty research supervisor, and committee member, the principal investigator's Conflict of Interest form, instruments, institutional permission, etc., related to this study. Failure to do so will result in delayed processing of the application.*