APPENDIX B

Expedited (Level 2) Application for IRB Certification of

Compliance Minimal Risk

This level of application is reserved for research projects with minimal risk. See the Levels of IRB Review and Certification section of the IRB Handbook for a description of review levels.

Expedited 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. *Please be advised that research projects involving interaction with human participants must have an Informed Consent form(s) attached. If a minor or individual of any age with impaired decision-making ability is involved, parent/legal guardian permission must be included.*

3. *Parental permission does not negate the child's right to choose not to participate.*

4. *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.*

5. *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.*

6. *If you are conducting the research outside of the United States, attach a letter of assurance that you will abide by the laws and regulations of the governing bodies that preside over the location where the research is being conducted.*

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

- ☐ Institutional Permission Letter (where research is taking place)
- ☐ Assurance of Adherence to Governmental Regulations concerning Human Subjects (if research project is conducted outside the US)
- ☐ Letter(s) of Informed Consent
- ☐ Data gathering instruments: observation, interview, survey, other
- ☐ CITI Completion Report for principal investigator, research supervisor, and committee member.
- ☐ Conflict of Interest Disclosure Statement
- ☐ Signatures of the principal investigator and faculty research supervisor

Application for IRB Review and Certification of Compliance Expedited (Level 2) Cover Sheet

IRB#: _____

Date Logged: _____

Expedited Review (Level 2) Application, Minimal Risk

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

Principal Investigator/Researcher's Name:_____

Student ID Number: _____

Type of Research Project (CRP, 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: _____

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, addition of participants, or study design 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. The research project is certified for the specific period noted in this application; any collection of data from human participants after this period is in violation of IRB policy.

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

6. Any correspondence will be directed to the principal investigator and faculty research supervisor and include the assigned IRB research project number and the project title.

NOTES:

- *Please complete this cover sheet and the application in detail. Every question must be answered.*
- *Please type your answers.*
- *Attach the appropriate documents and submit the entire application 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 or recruit participants until IRB Certification is obtained.*
- *If any change occurs in the procedure, sample size, research focus, site, 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 OR RECRUIT PARTICIPANTS PRIOR TO RECEIVING IRB CERTIFICATION*

Application for IRB Review and Certification of

Compliance Expedited (Level 2) Review Application

Minimal Risk

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

Research with minors, prisoners, individuals with impaired decision-making ability, fetuses, in vitro fertilization, and/or individual or group studies where the investigator manipulates the participant's behavior, or the participant is exposed to stressful or invasive experiences do not qualify for Expedited status.

Please completely answer the requested information. (N/A is not acceptable for any question.) DO NOT attach your research proposal – answer each specific question in the area provided. Begin typing in the gray boxes.

1. Purpose of the study:

2. Provide a brief but detailed summary of the study's methodology (Specify all information related to recruitment, study procedures, measures and materials):

3. Participant Demographics:

   a. Anticipated sample size :

   b. Special ethnic groups (describe):

   c. Institutionalized or other protected group: ☐Y ☐N If yes, describe:

   d. Age group:

   e. General state of health:

   f. Other details to describe sample group.

4. Will deception be used in the study? ☐Y ☐N (If yes, describe)

5. Will audio or videotapes be used in the study? ☐Y ☐N (If yes, describe)

6. Confidentiality protection issues (pertains to audio and video as well as written documents.)

    a. What precautions will be taken to ensure the privacy and anonymity of the participants (e.g., closed doors, private rooms, handling of materials where participants' identify could be discovered, etc.)?

    b. What specific precautions will be taken to safeguard and protect participant's confidentiality while handling the data (audio/video/paper) both in principal investigator's possession and in reporting the findings (e.g., coding, removal of identifying data, encrypting recordings)?

    c. Describe procedures where confidentiality may be broken by law (e.g., minor abuse, suicidal intent).

7. Review by institutions outside of Westcliff University ☐ Y ☐ N (Attach copies of permission letters, IRB certifications, and any other relevant documents).

8. Informed Consent and Assent (Attach copies of all relevant forms). If consent is not necessary (e.g., anonymous interview), describe how you will inform all participants of the elements of consent (see Elements of Informed Consent section).

9. If written or oral informed consent is required, describe the manner in which consent will be obtained.

10. Describe any possible physical, psychological, social, legal, economic, or other risks to participants.

a. Describe the precautions taken to minimize risk to participants.

b. Describe procedures implemented for correcting harm caused by participating in the study (e.g., follow up calls, referral to appropriate agencies).

11. Potential benefit of the study:

    a. Assess the potential benefit(s) of the study for the participants:

    b. Assess the potential benefits(s) to the professional community:

Attach any other required forms, including the CITI completion certificate for principal investigator, 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