Institutional Review Board

Continuing Review and/or Final Report

IRB Log # _____

Date Submitted: _____

Date Approved:_____

The OSCC Institutional Review Board (IRB) is required by federal regulations to provide **continuing review** of approved research protocols not less than once per year. To conduct this "substantive and meaningful" review, the IRB asks you to answer the following questions and provide copies of the informed consent documents as well as surveys and/or questionnaires currently used in your study. Please complete this form and send it electronically (saved as a pdf) to the IRB Administrator.

The IRB realizes that some studies are completed in less than one year. Therefore, this form also serves as a **final report** to the IRB. Please complete the form and send it electronically (saved as a pdf) to the IRB Administrator.

Title of Research Project: _____

Principal Investigator/Project Director: _____ Phone Number: _____

What is the purpose of this report? ☐ Continuing Review ☐ Final Report Date of last review:_____

Please complete the following questions if this is for a continuing review or a final report.

1. Have you completed data collection from your survey? ☐ Yes ☐ No ☐ NA
2. Have you closed enrollment of new subjects for your study? ☐ Yes ☐ No ☐ NA
3. Are your remaining research activities limited to data analysis? ☐ Yes ☐ No ☐ NA
4. Have any changes in leadership/responsibility/key personnel occurred since the last review? ☐ Yes ☐ No
   If yes, then please fully describe the changes in the space below.

5. Have the objectives changed since the last review? ☐ Yes ☐ No
   If yes, then please fully describe the changes in the space below.

6. Have the procedures changed since the last review? ☐ Yes ☐ No
   If yes, then please fully describe the changes in the space below.

7. Have the informed consent documents changed since the last review? ☐ Yes ☐ No
   If yes, then please fully describe the changes in the space below.

8. Was the subject population representative of the population base from which subjects could be selected with respect to gender? ☐ Yes ☐ No
   If no, then please explain in the space below.

9. Was the subject population representative of the population base from which subjects could be selected with respect to race/ethnicity? ☐ Yes ☐ No
   If no, then please explain in the space below.

10. Have any subjects withdrawn from the study since the study began? ☐ Yes ☐ No
    If yes, then please explain in the space below.

11. Are you aware of any breach in confidentiality? (e.g. unauthorized access to records) ☐ Yes ☐ No
    If yes, then please describe the breach in the space below.

12.. Have any unexpected problems occurred during the study? ☐ Yes ☐ No
    If yes, summarize in the space below the unexpected problem(s), the number of occurrences, and indicate whether they required consent document changes, particularly in the "Risks" section. If risks are affected, describe how they are minimized and reasonable in relation to expected benefits.

13. Please provide a listing of all publications, presentations, and reports that have resulted from this work since the last review. If none, so state.

Please complete the following questions if this report is for a continuing review.

14. Are there revisions/amendments to the protocol, consent form(s), questionnaire(s), etc. that are included with this renewal?
☐ Yes ☐ No
If yes, provide a brief description below and highlight the changes on the document(s) to be reviewed.

15. Will the revisions/amendments change the scope or the research objectives of the protocol? ☐ Yes ☐ No
If yes, provide sufficient documentation to allow the IRB to review and approve the changes prior to initiation.

16. Will the revisions/amendments change the risks to subjects? ☐ Yes ☐ No
If yes, provide sufficient documentation to allow the IRB to review and approve the changes prior to initiation. In particular, describe how risks are minimized and reasonable in relation to expected benefits.

As **Principal Investigator,** I acknowledge that I am responsible for reporting any emergent problems; that I will submit any proposed procedural modifications to the IRB for its review and approval and, except where necessary to eliminate apparent immediate hazards, no such modifications will be put into effect without prior IRB approval; that unless otherwise directed by the IRB Chairperson, I will renew this application with the IRB no less than annually; that the research project is being conducted in compliance with the IRB's understanding and recommendations; that the IRB is provided all the information on the research project necessary for its complete review; and that this research project will not be put into effect until final IRB approval is received.

Signature of Principal Investigator/Project Director_____

Date:_____

Signature of Faculty Advisor (if the principal investigator is a student) _____

Date:_____

FOR IRB USE ONLY

☐ Approved ☐ Approved with Conditions ☐ Referred for Full Committee Review

Signature of IRB Chair:_____

Date:_____