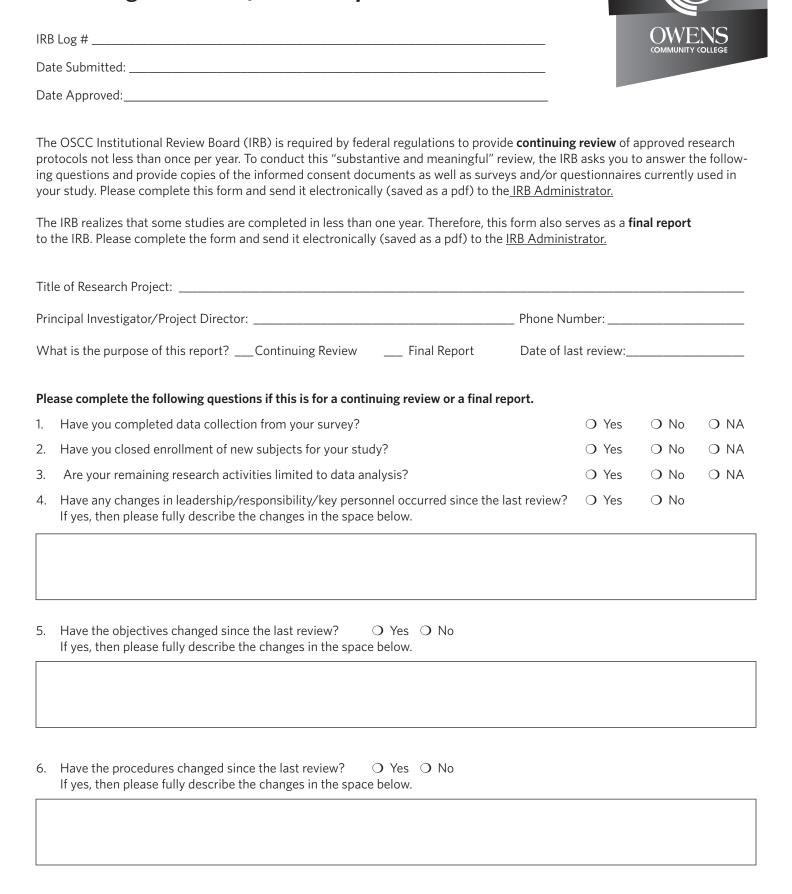
Institutional Review Board

Continuing Review and/or Final Report



7.	Have the informed consent documents changed since the last review? O Yes O 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? O Yes O 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/
<i>)</i> .	ethnicity? O Yes O No If no, then please explain in the space below.
10.	Have any subjects withdrawn from the study since the study began? O Yes O 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) O Yes O No If yes, then please describe the breach in the space below.
12	Have any unexpected problems occurred during the study? O Yes O 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? 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? O Yes O 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? O Yes O 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 O Approved O Approved with Conditions O Referred for Full Committee Review Signature of IRB Chair:_____

Date:____