Troy University
Institutional Review Board
Continuing Review Application

To help us keep our records current, please complete the following and return it to the Institutional Review Board, at irb@troy.edu. If you have any questions, please email the Institutional Review Board at irb@troy.edu or call us at 334-808-6294.

Principal Investigator's Name(s) _____

Project Title: _____

Protocol #: _____

Check all items that apply to your protocol and provide requested information. (You may attach additional sheets if necessary.)

1. Approximately on what date did data collection begin?_____
2. Please indicate the statement that best describes the status of this protocol:

___ a) I have completed work on this protocol. I will answer the remaining questions on this form to enable the IRB office to officially close the protocol.
___ b) I have not begun data collection. I plan to start on _____.
___ c) Human participants are currently being recruited. I have attached 3 clean copies of the current informed consent.
___ d) No further recruiting will occur after the expiration date. However, the data collected during the research shall be analyzed.
___ e) No further recruiting of participants will occur, but data collection will continue on at least one participant.
___ f) No further recruiting will occur. All interventions are completed on all participants, but follow-up is being conducted as described in the informed consent. These follow-up activities are described as follows:

3. If there have been any additions or deletions to the list of researchers involved with this protocol, I have described the reason for each change below and have updated the informed consent form to include only the current researcher(s):

4. If the protocol is externally funded, and the information about sponsorship is not correct in the protocol, the revised IRB form identifies the following sponsor(s):

5. Please indicate the following:

___ a) The total number of participants recruited during the past year:_____
___ b) The total number of participants to be recruited during the next year:_____
___ c) I have recruited, or plan to recruit, more participants than originally estimated because:

___d) I have recruited no participants because:

6. Was written informed consent required by the IRB and obtained from each participant? __Yes __No
If the answer is YES, attach to this form a photocopy of the last signed consent that you obtained.
If the answer is NO, please explain the circumstances under which written informed consent was not obtained:

7. Were any changes, however minor, made to your protocol last year? ___Yes ___No
If YES, were those changes reviewed and approved by the IRB prior to their implementation? ___Yes ___No
If changes were made to the protocol that were not submitted to and approved by the IRB, please describe the revision and explain why it was not sent to the IRB for review:

8. Did any unanticipated outcomes or adverse events occur the past year? __Yes __No
If YES, please indicate which ones were previously reported to the IRB:

9. Did any participant withdraw from this research project during the past year? __Yes __No
If YES, please indicate the reason for EACH participant's withdrawal:

10. The research participants in this protocol include the following that are checked:
___Children (under age 19)
___Adults ___Prisoners ___Pregnant women
___Mentally or emotionally challenged individuals

11. The IRB, Troy University, and the Federal regulatory agencies consider continuing reviews to be extremely important. Research studies are approved based on an estimated ratio of potential benefits to possible risks.
• Comment on how your participants responded to the study and tolerated your interventions. (This item may be omitted only if no data were collected on research participants in the last year.)

• Give your opinion about any changes in the risk-benefit ratio. Is there any new information (e.g. alternative procedures, new information published in the literature) that might affect the risk benefit ratio?

• If data from your study have been reported, list all publications:

Principal Investigator:_____ Date _____

Faculty Advisor (if student-only project)_____ Date _____

Supervisor (if faculty or staff project) _____ Date _____