VALPARAISO UNIVERSITY
Institutional Review Board
Request for Changes and Continuing Review

GENERAL INFORMATION

PI Name

PI Dept

PI E-mail

PI Phone

Faculty Supervisor Name

Faculty Supervisor Dept

Faculty Supervisor E-mail

Faculty Supervisor Phone

Study Title

Most Recent IRB Approval Date

REASON FOR REQUEST

Required Annual Review ☐ This project will continue past the IRB approval date with no changes. The project was originally planned to last longer then 1 year and initially underwent a Full IRB review.

Change in Project Duration ☐ This project will last longer than originally approved by the IRB. Other than duration, there are no changes to the previously approved protocol. This form is required for all changes in duration, regardless of the type of IRB review.

Change(s) in Protocol ☐ Changes to the protocol are requested, including procedure, risk, and/or class of human subjects. This form is required regardless of the type of IRB review.

PROJECT ENROLLMENT (Enter Number of Subjects)

Subjects Enrolled to Date

Subjects Enrolled Since Last IRB Approval

Subjects in IRB-Approved Protocol

Subjects to be Enrolled in the Future

Subjects Withdrawn Since Last IRB Approval

Reason(s) for Withdrawal(s) (Attach additional sheet(s) if necessary)

PROTOCOL DEVIATIONS/VIOLATIONS OR ADVERSE EVENTS (Check only if applicable)

Protocol Deviation(s) or Violation(s) ☐ One or more deviations or violations of the IRB-approved protocol have occurred since the study began. How many? Describe the nature of the deviation(s)/violation(s) on attached sheet.

Serious Adverse Event(s) ☐ One or more serious adverse events have occurred as a result of the IRB-approved protocol. How many? Describe the nature of the serious adverse event(s) on attached sheet.

ATTACHMENTS

Progress Report	☐	List and explanation of requested changes	☐
Explanation of Protocol Deviation(s) or Violation(s)	☐	Explanation of Serious Adverse Event(s)	☐

Required only if changes are requested:

Consent/Assent Documents if Subjects are Still being Enrolled	☐	Current IRB-Approved Protocol	☐

PI CERTIFICATION

I certify that the approved protocol, including the method for obtaining informed consent, have been followed during the conduct of this project and that this research protocol is being conducted in accordance with regulations and requirements governing the protection of human subjects. I also certify that the information provided for the requested changes/continuing review is complete and accurate to the best my knowledge.

PI Signature		Date	
Faculty Supervisor Signature		Date	

REVIEW SIGNATURES

Expedited Review	☐	Limited Review	☐	Full Review	☐

IRB Chair Signature		Date	

IRB Decision/Notes: