



Project Renewal Application

PRINCIPAL INVESTIGATOR:

PROJECT TITLE:

Original IRB Approval #:

BRIEFLY DESCRIBE THE PURPOSE OF THE PROJECT/STUDY (2-3 sentences in non-technical language)
Provide a copy of the original application

STARTING DATE OF PROJECT:

DATE OF LAST IRB APPROVAL:

INDIVIDUALS SCREENED AND ENTERED:

- (a) Number of individuals **screened** for entry into study since the start of the project:
- (b) Number of individuals **entered** into the study since the start of the project:
- (c) Number of individuals **entered** into the study since the last IRB review:
- (d) If known, complete the grid below relating to (a) and (b) above:

Individuals Entered (should reflect # in (b) above)				
Racial/Ethnic Composition	Male		Female	
	Age Range	Number Entered	Age Range	Number Entered
Caucasian				
African American				
Native American				
Asian				
Hispanic				
Other				

DID ANY ADVERSE EVENTS/REACTIONS OCCUR WITH THIS PROJECT? Yes No *If Yes, briefly explain:*

PROVIDE A DESCRIPTION OF:

(a) Any withdrawal(s) of participants from the research. Give the reason(s) the participants withdrew:

(b) Any complaint(s) about the research:

HAVE YOU MADE MODIFICATIONS TO THE PROTOCOL THAT AFFECT THE PARTICIPANTS? Yes No

If Yes, have the modifications been approved by the IRB? Yes No

WHAT ARE YOUR PLANS FOR FUTURE PARTICIPANT ENROLLMENT?

Open to Accrual? Yes No

If Yes, give narrative for plans for future enrollment:

If No, date closed to Accrual:

NOTE: Provide copies of all cover memos from all amendments approved by the IRB during the renewal period.

LIST ANY CHANGES TO THE PROTOCOL BEING REQUESTED AT THIS TIME: