

Tulane University Health Sciences Center
Institutional Review Board
Committee on Use of Human Subjects

Progress Report for Continuing Review of Research

Title of Study «Protocol_Number__Title»	Name and Mailing Address of Principal Investigator «AddressTo» «Street_Address_1» «Street_Address_2»			
Phone	Fax	Other	E-Mail	
Name of Co-Investigators				
Name of Funding Source (Sponsor)				
A. Renew - continuing enrollment of new subjects <i>Submit 10 copies of this form, 10 copies of updated consent, 2 copies of updated project summary and 2 copies of most recent DSMB report.</i>				
B. Renew - enrollment closed; however subjects are still receiving study treatment/intervention subjects have completed study treatment/intervention but continue in follow-up observation subject involvement completed but renewal is requested for data analysis <i>Submit 1 copy of this form and 1 copy of the most recent DSMB report.</i>				
C. Terminate because research completed lack of funding other reason (specify) <i>Submit 1 copy of this form.</i>				
ANSWER QUESTIONS 1 - 6 BASED ON INFORMATION SINCE LAST REVIEW			YES	NO
<i>Attach a succinct memo explaining any "yes" answers.</i>				
Have any subjects withdrawn from the study either voluntarily or otherwise?				
Have there been unanticipated problems or serious adverse events <i>at this site</i> involving risk to subjects since the last renewal which have not been previously reported to the IRB?				
Has the risk/benefit ratio changed unfavorably as a result of any new information?				
Is this a multi-center study with a Data Safety Monitoring Board? If yes, provide a report from the board.				
Have there been any amendments since the last review not previously submitted to the IRB?				
Have there been changes in subject population, recruitment, study procedures or consent procedures that <i>were not</i> submitted as amendments?				
Are you requesting any changes in subject population, recruitment, study procedures or consent procedures as part of this renewal?				
Are there any protocol deviations not previously reported or covered otherwise on this form?				
ENROLLMENT	TMC	VA	MCLNO	Remote Sites
1. Total projected enrollment				
2. Total number of subjects enrolled to date				
3. Number of subjects enrolled since last renewal				

I certify that each of the above named co-investigators has accepted his/her role in this study. I agree to a continuing exchange of information with the Committee on Use of Human Subjects (IRB). I agree to obtain IRB approval before making any changes or additions to the project. I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects.

Signature of Principal Investigator

Date

Signature of Primary Reviewer
Approved / Disapproved / Provisional

Meeting Date

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Project Summary
Description of Proposed Research Activity
Generally Not to Exceed 3 Single-Spaced Pages Using a 12-Point Font

Title of Study	Name of Principal Investigator
1. Purpose and Rationale: Provide a brief summary of the background information, state the research question(s), and tell why the study is needed. Avoid an extensive literature review. Example: The purpose of the study is to determine the . . .	
2. Subjects: Specify number, age range, gender, ethnicity, and whether healthy volunteers or patients. If patients, specify the disease or condition and indicate how potential subjects will be identified. If pregnant women are excluded, or if women who become pregnant are withdrawn, specific justification must be provided. NIH application requires that women, minorities, and children be included or that their exclusion be justified.	
3. Inclusion/Exclusion Criteria: List required characteristics of potential subjects, and those that preclude enrollment.	
4. Full Description of the Study Design, Methods and Procedures: Include the type of experimental design; study procedures; sequential description of what will be asked of/done to subjects; assignment of subjects to various arms of the study if applicable; doses; frequency and route of administration of medication and other treatment if applicable; kinds of data to be collected; primary outcome measurements; and follow-up procedures. If the study is a clinical trial involving patients as subjects and the use of a placebo control is involved, provide justification for the use of the placebo controls. This section (4) should generally not exceed 1 since-spaced page using 12-point font type.	
5. Duration of Entire Study and Duration of an Individual Subject's Participation, Including Follow-up Evaluation If Applicable: Include the number of required visits and approximate duration of each visit.	
6. Where Will the Subject Be Studied: List locations such as Tulane, MCLNO, GCRC, VA.	
7. Full Description of Risks and Measures to Minimize Risks: Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality, etc.) economic harm (e.g., loss of insurability) and legal jeopardy (e.g., disclosure of illegal activity) as well as known side effects of study medication, if applicable, and risk of pain and physical injury, risk of progression of disease, if applicable.	
8. Benefits to Subjects and/or Society: The possibility of benefit to society should be clearly distinguished from the possibility of benefit to the subject, if any. If there is no direct benefit to the individual subject, say so. Do not list monetary payment as a benefit.	
9. Inducements for Participation: If monetary, specify the amount and how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it.	
10. Costs to Be Borne by Subjects: Include clinic fees, diagnostic and laboratory studies, drugs, devices, transportation, all professional fees, etc. If there are no costs to subjects, indicate this.	
11. Statistical Analysis: If this is a single-center clinical trial, provide evidence that the sample size is sufficient to achieve the study aims and tell how the data will be analyzed. If a multi-center trial, indicate where and by whom statistical analysis will be performed.	
12. Methods of Recruiting: Tell how prospective subjects are contacted. If they are patients, initial contact should be made by their treating physician, or by someone whom the patients know to have legitimate access to their medical records.	
13. How Will Informed Consent Be Obtained: Describe the process. When the consent of a legally authorized representative is substituted for consent of the adult subject, explain why this is necessary. If non-English-speaking subjects will be enrolled, a consent form should be prepared in the foreign language. Someone who is fluent in the subject's language must be available to interpret.	
14. Describe Plans for Data and Safety Monitoring: Describe how data and safety monitoring will occur.	