

CLINICAL STUDY STATUS REPORT
Renewal/Continuing Review Request

Principal Investigator:

Study Title:

HAC Number:

Current Approval Date:

Approval Terminates:

Performance Site: MCGHI MCG Charlie Norwood VAMC Other: _____

Indicate the current status of the study:

_____ Not yet started

_____ Active, no human subjects (samples and tissues only)

_____ Active, no human subjects (chart review only)

_____ Active, enrolling subjects*

_____ Active, treating subjects only

_____ Active, follow-up only

_____ Completed ** *A report must be completed. If subjects are in follow-up, or if data analysis is incomplete, the study must remain active.*

**Per the federal regulations, all studies that are currently enrolling subjects must submit a clean copy of the informed consent document (s) and/or children's assent document(s) for review and approval.*

*** If the study is in the follow-up phase, then the ICD and/or CAD are not required for approval. Advertisements must also be submitted.*

SECTION 2. SUBJECT INFORMATION

Cumulative Number of Subjects from the Beginning of the Protocol Approval:

Do not write in the shaded areas. If this form was completed before, then the numbers in the shaded areas below are the numbers that were previously reported to the HAC. Complete the "Subject Changes Since the Last Review" and the "New" columns.

NOTE: The sum of the numbers in "Withdrawn/Screen Failures", "Completed", and "Continuing" must equal the number "Consented".

	Prior	Subject Changes Since the Last Review	New Total
Specified by the Protocol/Contract			
Screened			
Consented			
Withdrawn/Screen Failures			
Completed			
Continuing			

If subjects were withdrawn during the time since the last review, please provide the following information (if additional space is needed, please attach an additional report). You are not required to report on screen failures.

Subject Study Identifier	Withdrawal Date	Reason for Withdrawal

SECTION 3

Equitable Selection of Subjects: Provide subject information since the last review.

1.	Number of male subjects	
2.	Number of female subjects	
3.	Number of African-American subjects	
4.	Number of Asian subjects	
5.	Number of Caucasian subjects	
6.	Number of Hispanic subjects	
7.	Number of subjects from other ethnic groups	
8.	Number of subjects considered as members of a vulnerable population as defined by HAC Policies and Procedures.	
9.	Number of non-veterans enrolled at VA, if applicable	

SECTION 4 - RISKS, BENEFITS, CONFLICTS OF INTEREST AND REQUIRED REPORTING

Please answer these questions as they pertain to the period from the last continuation approval (or the initial HAC approval, as applicable) of the study: If this question does not apply to your study, check "No".

<p>Have any unanticipated problems (UAP) involving risks to subjects or others occurred? <i>(If yes, and not already submitted to the HAC, submit the UAP with the HAC Form 113)</i></p>	<input type="checkbox"/> Yes *	<input type="checkbox"/> No
<p>Has the investigator reported all unexpected and related adverse events involving risks to subjects or others? <i>(If yes, and not already submitted to the HAC, submit the URAE with the HAC Form 110)</i></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Has the investigator reported all unexpected and related serious adverse events involving risks to subjects or others? <i>(If yes, and not already submitted to the HAC, submit the URSAE with the HAC Form 110)</i></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Has any subject sought compensation for injury or complained about their participation in the study? <i>(If yes, and not already submitted to the HAC, submit pertinent information with the HAC Form 113.)</i></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Has any recent relevant literature been published that relates to the study? <i>(If yes, please submit a summary and/or a copy of the report (s))</i></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Have there been any interim findings? <i>(If yes, and not already submitted to the HAC, submit pertinent information with the HAC Form 113.)</i></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Are there any changes in the nature and/or degree of the risks or benefits, which may result from this research study? <i>(If yes, explain in section 6. Attach additional pages as needed.)</i></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Have any issues of non-compliance occurred? <i>(If yes and not submitted to the HAC, notify the HAC immediately via email at HAC@mcg.edu. NOTE: All issues of non-compliance must be reported to the HAC upon occurrence.)</i></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Have there been any changes in the conduct of the protocol that result in a conflict of interest for the investigator or research team members?</p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Has there been any change in the risk to benefit ratio for the subjects enrolled in the protocol? <i>(If yes, include this information in Section 6 Report of Study Progress.)</i></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Version Date
10/22/2008

Clinical Study Status Report

HAC Number: _____
Principal Investigator: _____

Principal Investigator (Required)

_____ Signature: _____ Date: _____

Version Date
10/22/2008

Clinical Study Status Report

HAC Number: _____
Principal Investigator: _____

Version Date
10/22/2008

Clinical Study Status Report

HAC Number: _____
Principal Investigator: _____