NORTH MISSISSIPPI HEALTH SERVICES
INSTITUTIONAL REVIEW BOARD
Progress Report and Re-approval Application

Listing number on ClinicalTrials.gov (please put N/A if not listed):

Study Title:

Protocol Number: **NMHS IRB code:**

Sponsor:

Principal Investigator:

Study Overview:

Initial approval date: **Initial IRB-approved # of subjects:**

Most recent approval date: **Current IRB-approved # of subjects: (date:_____)**

Total anticipated, worldwide subject enrollment:

Current total subject enrollment: worldwide: **NMHS: overall total enrolled at this site (sum total):**
currently enrolled:
completed enrollment:
total withdrawn:
*If any have withdrawn, please provide reason:

total expired:

Subject enrollment since last approval: **worldwide:** **NMHS:**

Total initial adverse events for this protocol: **worldwide[a]:** **NMHS:**
* Do not count follow-up events
* Include only the AEs on this protocol

Adverse events since last approval: **worldwide[a]:** **NMHS:**
* Do not count follow-ups and include only AEs on this protocol
* Attach summary of adverse events

[a]Please record the number of worldwide **serious** adverse events if available. If only the total number of adverse events is available from the sponsor, this number may be used and this should be noted. Please include below in the "Comments" section the most commonly reported worldwide adverse events.

Protocol deviations/violations since last approval (attach summary): **NMHS:**

Provide brief summaries and dates of review of the following changes since last approval

Protocol changes:

Informed consent form and/or process changes:

Subject recruitment changes (e.g. adding recruitment/retention inducements**):**

Other changes:

Does study have a Data Safety Monitoring Board (DSMB): ☐ yes or ☐ no
If yes, please attach a copy of the most recent report.

Have there been any complaints about the research from subjects enrolled since last approval? If yes, please explain.

Study status (check one): **Biomedical Studies**

___Actively enrolling subjects
___No longer enrolling, but subjects actively receiving study treatment
___No active study treatment, but subjects are being monitored
***If this option is selected, please briefly explain what is happening during follow-up visits (study required procedures, phone calls only, etc.).**

_____

_____

___Data cleanup only

Non-Biomedical Studies
___Actively procuring subject information (e.g. PHI review or surveys)
___Data cleanup only

Comments:

Principal Investigator:_____ Date:_____

*Please attach a copy of the completed self audit report.