Restoring Hope and Freedom
Mary Free Bed Rehabilitation Hospital

Mary Free Bed Rehabilitation Hospital
Research Institutional Review Board
235 Wealthy SE
Grand Rapids, MI 49503

CONTINUING REVIEW REPORT/ RENEWAL REQUEST

Federal regulations require a protocol review within one year of previous approval/review (unless a more frequent review has been designated by our IRB). This report is essential to permit continued human subject involvement. ***This form must be returned by the due date noted below to ensure compliance with the regulations.*** If the report is not complete or is not returned, the IRB approval will expire and your study will be closed.

Study Title:	**IRB #**
	Current Expiration Date:
Protocol #	**Progress Due Date:**

Principal Investigator:			
Address	**City**	**State**	**Zip Code**
Phone:	**Fax:**	**E-mail:**	

Sub-Investigators (Please list):	**Study Coordinator:**
	Phone:
	Fax:
	E-mail:

Please **provide a brief summary** of project progress/results, including any significant findings to date.

Protocol Consent *(check one):*	
☐	Study is closed to enrollment effective _____ *(consent document no longer necessary)*
☐	Waiver of Informed Consent was approved for this study
☐	Protocol and informed consent form use continues as last approved. ***(Attach a copy of the currently used informed consent form that does <u>not</u> have the IRB stamp of approval)***
☐	If any *new changes* in the informed consent form, please complete Amendment Request to Approved Protocol form and return with a copy of the revised document.

Retrospective Record Review *(Complete this section only if it applies to your study)*		
☐ Record review is complete	# records reviewed to date:	
☐ Record review continues	# additional records requiring review:	

Study Enrollment *(This section does not need to be completed if your study is a retrospective record review)*			
# patients screened		# screen failures	
Total # of subjects currently enrolled by this PI:			
# enrolled since last review:		# discontinued since last review:	
Please explain any discrepancies:			

Confidentiality of Data				
Are study files kept in a locked, secure location?	☐ Yes	☐ No *(Please explain)*		
Adverse Events / Unanticipated Problems				
How many have occurred at this site since study inception:		How many since last review:		
Have there been any previously <u>unreported</u> events at this site or from the sponsor?	☐ Yes	☐ No		
If yes, please attach a SAE Report Form and indicate the reason for the communication delay and the corrective action being taken:				
Have all reports from your Data Safety Monitoring Board been submitted to the IRB?	☐ Yes	☐ No	☐ N/A	
If no, please attach a copy of the report(s) and indicate the reason for the communication delay:				
Regulatory Binder				
Is your regulatory binder current?	☐ Yes	☐ No *(Please explain)*		
Risk/Benefit Ratio				
Does new knowledge or do adverse events change the risk/benefit ratio?	☐ Yes	☐ No	☐ N/A	
Is/was there a corresponding change in the consent form needed?	☐ Yes	☐ No		
Investigational New Drug/Device				
If this study involves an IND, has an annual report been submitted to the FDA?	☐ Yes	☐ No	☐ N/A	

Please attach: ☐ Copy of CV for principal investigator **-OR-**	☐ Copy of CV for principal investigator on file with IRB *(within past 3 yrs.)*
☐ **CITI** Certificate of Completion for **<u>all research study staff</u>** **-OR-**	☐ **CITI** Certificate of Completion for **<u>all research study staff</u>** on file with IRB *(current within past 3 yrs)*

Signature of Principal Investigator	Date
Signature of Person Completing this Form	Date

Return a <u>completed and signed</u> copy of this form via email to research.irb@maryfreebed.com