

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:**  |  |

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

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

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

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| 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 unreported 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-** *(external researchers only)* | [ ]  Copy of CV for principal investigator on file with IRB *(within past 3 yrs. – external researchers only)* |
| [ ]  Responsible Conduct of Research, Human Subjects Protection, and FCOI training Certificates *(required for all research study staff)****\**** **\*NOTE:** Mary Free Bed Rehabilitation Hospital requires all individuals conducting research within Mary Free Bed to be **trained in Responsible Conduct of Research, Human Subject Protection and Financial Conflict of Interest** prior to their participation in a research project. If you do not have access to this training, or if you have completed training through another organization, please contact IRBadmin@maryfreebed.com for instructions. |
| [ ]  MFB FCOI form *(required annually for all research study staff)* |
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|  |  |       |
| Signature of Principal Investigator |  | Date |
|  |  |  |
|  |  |       |
| Signature of Person Completing this Form |  | Date |

**Return a completed and signed copy of this form via email to** **IRBadmin@maryfreebed.com****.**