

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.

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

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| --- | --- | --- | --- | --- | --- |
| Principal Investigator: | | | | | |
| **Address** | | **City** | | State MI | 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](mailto:IRBadmin@maryfreebed.com) for instructions. | | | | | | | | | | | | | | | | | |
| MFB FCOI form *(required annually for all research study staff)* | | | | | | | | | | | | | | | | | |
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| Signature of Principal Investigator | | | | | | | | | |  | | Date | | | | | |
|  | | | | | | | | | |  | |  | | | | | |
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| Signature of Person Completing this Form | | | | | | | | | |  | | Date | | | | | |

**Return a completed and signed copy of this form via email to** [**IRBadmin@maryfreebed.com**](mailto:IRBadmin@maryfreebed.com)**.**