Meritus Medical Center Institutional Review Board

11110 Medical Campus Road, Robinwood Suite 229, Room 2224

Hagerstown, MD 21742

P 301-790-8825

**Progress Report**

(must be typed)

**INSTRUCTIONS: Please forward 1 hard copy to the address above.**

**1 electronic copy to** [**Christine.Fornwalt@meritushealth.com**](mailto:Christine.Fornwalt@meritushealth.com)

**The packet needs to include: Progress Report, latest protocol (electronically only), redacted consent form, updated signed CV, current medical license, and updated human subjects training (only if expired).**

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| MMC IRB # | Click here to enter text. | | IRB Approval Expiration Date: | | | Click here to enter a date. | |
| Study Title | Click here to enter text. | | | | | |
| Principal Investigator | | Click here to enter text. | | Email | Click here to enter text. | |
| Address | | Click here to enter text. | | Phone | Click here to enter text. | |
| Study Coordinator | | Click here to enter text. | | Email | Click here to enter text. | |

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| **SECTION A: STUDY STATUS SINCE LAST IRB REVIEW AND APPROVAL *(Check one category only)*** |
| Enrollment has not begun  Actively enrolling participants: *If you have enrolled subjects using a written consent form since the last approval,*  *submit a COPY of a signed and dated consent form (please redact the name) so we*  *may verify you are using the correct version of the document.*  Enrollment closed on ***insert date****;* participants are receiving treatment/intervention or are in follow-up.  Accessing records/charts/analyzing identifiable data. Please confirm by checking the appropriate box(s)  *PI will not retain any HIPAA identifiers*  *PI will destroy link or code between data and subject identifiers at end of analysis*  *PI is unable to re-link data with individual participants*  *No consent forms were signed by participants; the PI has no record of participant names or other identifiers*  Accessing/analyzing de-identified data.  Repository *(provide listing of associated research studies in Section F below)*  Data coordinating center activities only  Humanitarian Use Device (HUD) – (complete sections B, D, and E only) |

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| **SECTION B: PARTICIPANT RECRUITMENT** | |
| Number of participants **enrolled in the past year** (for the first year of the study or since the last progress report). | Click here to enter text. |
| Number of male participants.  Not applicable for this study. | Click here to enter text. |
| Number of female participants.  Not applicable for this study. | Click here to enter text. |
| Number of screen fails/not eligible for participation? | Click here to enter text. |
| Total number of participants **enrolled since this study was initially approved**. | Click here to enter text. |
| Total number of male participants.  Not applicable for this study. | Click here to enter text. |
| Total number of female participants.  Not applicable for this study. | Click here to enter text. |
| Number of records reviewed or samples studied **ONLY** if waiver of consent was granted. | Click here to enter text. |
| **SECTION C: PARTICIPANT WITHDRAWAL** | |
| How many participants voluntarily withdrew from the study at their own request? | Click here to enter text. |
| If participants voluntarily withdrew please state the reason(s). Click here to enter text. | |
| How many participants were withdrawn from the study at the request of the PI? | Click here to enter text. |
| If participants were withdrawn from the study at the request of the PI, please state the reason(s). Click here to enter text. | |
| Please indicate if there have been any complaints about the research or research staff. Click here to enter text. | |
| If applicable, please provide a brief summary of any difficulty retaining participants. Click here to enter text. | |
| **SECTION D: HUMANITARIN USE DEVICE** | |
| Is The HUD use necessary to prevent death or serious harm to a patient?  Yes  No | |
| Is the HUD to be used for HDE-approved indication(s) only?  Yes  No | |
| Was safety or effectiveness data collected?  Yes  No | |
| Is HUD being used as part of a clinical investigation?  Yes  NO | |
| What material was given to the subject before and after using the HUD? | |
| **SECTION E: ADVERSE EVENT REPORTING, UNANTICIPATED PROBLEMS POSING RISKS AND DEVIATIONS** | |
| Have all serious related and **unexpected** adverse events to date been submitted to the IRB?  Yes  No  *If no, please attach the events that have not been submitted.* | |
| In the past year, have there been any unanticipated adverse events or problems that were related to the study intervention that posed risks to the subjects?  Yes  No  *If yes, provide explanation.* | |
| In the past year, has there been any **anticipated** adverse events not yet reported to the IRB?  Yes  No  *If yes, list them here or attach a summary of the events.* | |
| During the last approval period, have there been any protocol deviations?  Yes  No  *If yes, attach a copy of the IRB letter of acknowledgement..* | |
| **SECTION F: ACTIVITIES DURING THIS APPROVAL PERIOD** | |
| Are there any amendments to the protocol?  Yes  No  If yes, please list: Click here to enter text. | |
| Are study drugs still being administered?  Yes  No | |
| Has the latest Data Safety Monitoring report been submitted?  Yes  No NA  *If no, please attach.* | |
| **SECTION G: Please complete a PROGRESS REPORT SUMMARY FOR THIS APPROVAL PERIOD** | |
| The progress report should provide the IRB with a description of the progress of the study over the past approval period, and the study’s current status.  • Progress towards achieving research objectives;  • Barriers to meeting research objectives, and strategies to overcome barriers;  • Your analysis of the study’s adverse events and unanticipated problems and any effect on the research;  • Any scientific developments affecting the equipoise, safety, efficacy or other fundamental aspect of the study;  • Your opinion as to whether the risk/benefit ratio for the study remains reasonable;  • For community based studies, have any findings have been shared with the local community?  **Begin your progress report summary addressing the issues above here:** Click here to enter text. | |
| **SECTION G: SIGNATURE** | |
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