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| **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **Continuing Review Report / Final Report Form** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Protocol CHS#: | | | | |  | | | | | | | | | Date: | | | | | | | | | | | | | | | |  | | | | | | | | | | | |  |
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| Title of Project: | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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| Principal Investigator: | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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| Check one: | | |  | | Continuing Review | | | | | | | | | | | | | | | |  | | |  | | Final Report | | | | | | | | | | | | | | | | |
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|  | | |  | | | with changes | |  | without changes | | | | | | | | | | |  |  | | Study Completion Date: | | | | | | | | | |  | | | | | | | | |  |
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|  | | | Current Expiration Date: | | | | | |  | | | | | | | | | | |  |  | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | Renewal for data analysis: | | | | | Yes: | |  | | No: | | |  | | | |  |  | | | | | | | | | | | | | | | | | | | | | |
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| # of subjects enrolled since study initiation: | | | | | | | | | | QMC | |  | | | HPH | | | | | | | | | |  | | UH | | | | |  | | | Other | | | | |  |  | |
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| # of subjects enrolled since last report: | | | | | | | | | | QMC | |  | | | HPH | | | | | | | | | |  | | UH | | | | |  | | | Other | | | | |  |  | |
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| # of subjects in follow-up status: | | | | | | | | | | QMC | |  | | | HPH | | | | | | | | | |  | | UH | | | | |  | | | Other | | | | |  |  | |
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| # of subjects completing study: | | | | | | | | | | QMC | |  | | | HPH | | | | | | | | | |  | | UH | | | | |  | | | Other | | | | |  |  | |
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| Is the protocol closed to accrual? | | | | | | | | | | Yes: | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
|  | | | | | | | | | | No: | |  | | | Date Closed: | | | | | | | | | | | | |  | | | | | | | | | | | | | |  |
| Are there participants still on treatment/intervention? | | | | | | | | | | Yes: | |  | | | Number of Participants: | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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| No: | | | | | | | | | | | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | If there were no subject enrollment since last approval, please explain why: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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| # of subjects that have withdrawn:  Reason(s): | | | | | | | | | | QMC | |  | | | HPH | | | | | | | | | |  | | UH | | | | |  | | | Other | | | | |  |  | |
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| # of unanticipated events or SAEs  that occurred & brief description: | | | | | | | | | | QMC | |  | | | HPH | | | | | | | | | |  | | UH | | | | |  | | | Other | | | | |  |  | |
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| # of deaths and reasons: | | | | | | | | | | QMC | |  | | | HPH | | | | | | | | | |  | | UH | | | | |  | | | Other | | | | |  |  | |
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| **Submit a report if not previously submitted.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Are patients in any treatment group of your study doing so well that it is inadvisable to withhold this treatment from other members of this study? If yes, Explain: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes: | |  | | |  | | No: |  | |  | | | |
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| Have there been any significant new findings which may relate to the subjects’ willingness to continue participation in this study? If yes, Explain: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes: | |  | | |  | | No: |  | |  | | | |
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| Have there been any administrative changes to the project, such as change in Investigators, research site, status of enrollment, etc.? If yes, describe: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes: | |  | | |  | | No: |  | |  | | | |
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| Have there been any changes to the protocol, consent form, or HIPAA Authorization form that have not been reviewed /approved by the IRB)? If yes, describe and submit revised documents | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes: | |  | | |  | | No: |  | |  | | | |
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| What is the proposed length of time remaining in your research project? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Other comments: | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
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|  | In the space below, provide a brief summary of the progress and results obtained to date. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
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|  | | Signature of Principal Investigator | | | | | | | | | | | | | | |  | | | | | Date signed | | | | | | | | | | | | | | | |  | | | | |