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| **UNIVERSITY OF HAWAII COOPERATIVE IRB****Continuing Review Report / Final Report Form** |
|  |
| Protocol CHS#: |       | Date: |       |  |
|  |  |
| Title of Project: |       |  |
|  |  |
| Principal Investigator: |       |  |
|  |  |
| Check one: |  | Continuing Review |  |  | Final Report |
|  |  |
|  |  | with changes |  | without changes |  |  | Study Completion Date: |       |  |
|  |  |
|  | Current Expiration Date:  |       |  |  |
|  |  |
|  | Renewal for data analysis: | Yes: |  | No: |  |  |  |
|  |
| # 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:       |  |
|  |
| No: |     |  |
|  | If there were no subject enrollment since last approval, please explain why: |  |
|  |       |  |
|  |
| # of subjects that have withdrawn: Reason(s):  | QMC |     | HPH |     | UH |     | Other |     |  |
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|  |       |  |
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| # of unanticipated events or SAEs that occurred & brief description: | QMC |     | HPH |     | UH |     | Other |     |  |
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|  |       |  |
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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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|  |       |  |
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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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|  |       |  |
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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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|  |       |  |
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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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|  |       |  |
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| What is the proposed length of time remaining in your research project? |
|  |       |  |
| 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 |  |