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| **A. SUBMISSION INFORMATION** | |
| IRB Project #: | Date of Expiration of Existing IRB Approval: |
| Review Type:  Expedited Review Eligible  Full Board Review Required | |

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| --- | --- |
| **B. GENERAL STUDY INFORMATION** | |
| Study Title: | |
| Principal Investigator : | E-mail address: |
| Clinical Coordinator: | E-mail address: |

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| **C. DETAILS PERTAINING TO THE CURRENT CONTINUATION REQUEST:** |

**1. Please provide a brief progress report to the originally approved proposal.**

**2. Is the project being carried out as described in the original submission to QBRI-IRB?**

Yes No

If no, please explain the discrepancies in the space below.

**3. Have any of the research subjects suffered any serious or unexpected harms, toxicities or side effects?**

Yes No

If yes, please describe.

**4. Have there been any internal or external audits of the research, preliminary (stopping rule) analyses, reports of data and safety monitoring boards... etc.?**

Yes No

If yes, please describe

**5. Has there been any significant change in the information on which the QBRI-IRB provided ethical approval, e.g., new knowledge from the literature, from the present project or from other related sources?**

Yes No

If yes, please describe the new information, and indicate how it differs from that in the previous or original ethics approval, and its impact on the ethics of the research underway.

**6. Have any amendments been made to the Research Protocol since its original approval?**

Yes No

If yes, please explain.

**7. Were these amendments approved by the QBRI-IRB?**

Yes No

If yes, when? If no, reasons why?

**8. Are you now requesting any amendment(s) to the original application?**

Yes No

If yes, please describe and justify the proposed amendment(s).

**9. When do you expect the project to be completed? (Please provide month and year)**

**Important:**

If the project and/or the previously approved consent form have changed since the original submission was approved, or are requested at this time, please provide the current or proposed versions and indicate where the changes were made.

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**Principal Investigator** **Date**

***Please do not write below this line. This part is for QBRI-IRB use only:***

Renewal Request received on:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Renewal Issued for Period: \_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (One Year)

Next Renewal Due by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_