

**Quincy College Institutional Review Board
Study Renewal Form**

Answer the following questions based on information since the initial approval or last renewal. Only include subjects covered by this IRB.

1. Have there been any modifications approved since the last review?
YES ____ NO ____

If there have been changes that were not previously submitted to the IRB, please attach an updated protocol and any revised documents, including any consent documents.

2. Have any subjects withdrawn voluntarily or been withdrawn from the study?
YES ____ NO ____

If yes, explain; give number and reasons for withdrawals

3. Have there been any complaints about the research from subjects or others?
YES ____ NO ____

If yes, explain

4. Have there been any findings (e.g., publications, new information) that alter the risk/benefit ratio or otherwise impact the study?
YES ____ NO ____

If yes, explain, including whether these new findings are relevant to participants' willingness to continue in the study.

5. Have there been any unanticipated problems or serious adverse events since the last renewal?
YES ____ NO ____

If yes, include copies of all adverse event reports with this submission.

6. Are you requesting any changes to the study or consent documents?
YES ____ NO ____

If yes, include a description of the changes and revised documents.

7. Will you be enrolling, consenting, or re-consenting subjects in the upcoming approval period?
YES ____ NO ____

If yes, include any new recruitment materials.

ACTION REQUESTED BY THE INVESTIGATOR (CHOOSE ONLY ONE):

Renew approval:

_____ Study has always involved only analysis of existing data or specimens. Continue as approved.

Study involves direct interaction/intervention or contact with subjects:

_____ Continue as approved: Enrollment of new subjects continues.

_____ Enrollment of new subjects closed; interaction/intervention with previously enrolled subjects continues.

_____ Direct interaction with subjects completed but subsequent monitoring or follow-up continues.

_____ Subjects' involvement completed but renewal is requested for data analysis.

Closure of Study:

_____ Research completed: Identifiable data or human biological specimens are stored according to plan already approved by the IRB.

_____ Research completed: All data or human biological specimens are deidentified.

_____ Other reason (*specify*):

Signature of Principal Investigator

Date