

ANNUAL RENEWAL/CLOSURE FORM

Renewal Form

Annual IRC review is required for ongoing human subject research. Researchers continuing with recruitment of human subjects and/or data analysis must apply for renewal using this form. If a researcher does not file for renewal by the project's one year deadline, the project will be closed and the researcher will be required to resubmit the project through the entire IRC process as a new project.

Closure Form

Once the project is complete, with no further recruitment, data collection, or analysis, researchers must fill out the closure form.

Title of Study:

Principal Investigator:

What is the status of this study? (If recruitment, data collection, or data analysis is ongoing, the study is not yet complete. If data analysis is complete, then the project is considered completed.)

- Recruiting Subjects
 - Recruitment Complete; Following Subjects
 - Data Collection Complete; Data Analysis Only
 - Study Not Begun
 - Study Completed/Closed
 - Humanitarian Use Device
-

Renewal Form:

**If you have made changes to any supporting documents such as your informed consent, recruiting materials, or survey/interview questions, submit copies of the new documents with your renewal form.*

Number of participants enrolled:

Mercy: _____

St. Luke's: _____

Other: _____

Any local adverse events? Yes No

If yes, please describe:

Any subject complaints, early withdrawals, or problems with the study? Yes No

If yes, please describe: _____

Have there been any changes to the research study, principal investigator or research staff, or informed consent since the last IRC approval? Yes No

If yes, please describe: _____

Closure Form:

Please attach a summary of (or describe below) study results, including number of subjects recruited and summarizing any subject complaints, early withdrawals, adverse events, injuries or problems with the research study.

Primary Investigator Signature: _____

Date: _____

Please complete and return to:

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