Progress Report / Brief Project Summary

Date ______________________

Study # ____________________

Title _____________________________________________________________________________________

1. Brief description of the study:

2. Number of subjects accrued: Study-wide ___________  L+M ___________

3. Brief summary of any amendments since last review:

4. New or relevant information since last review:

5. Summary of any unanticipated problems:

6. Results of data monitoring committee reports, if any:

7. Results of regulatory agencies’ actions, if any:

8. Summary of any subject withdrawals, and reasons for withdrawal, if known:

9. Summary of any subject complaints:

10. Anticipated study completion date: ____________________
Dear Lawrence + Memorial Hospital Institutional Review Board:

The study # ____________________, title _________________________________________________
_______________________________________ is due for annual reapproval on ____________________.

Please consider this application for annual reapproval.

As part of the reapplication process, I have included with this letter the following information:

A. A written progress report / brief project summary that includes the following:
   1. A brief description of the study
   2. Number of subjects accrued study-wide and at L+M.
   3. A brief summary of any amendments since the last review
   4. Any new or relevant information since last review
   5. A summary of any unanticipated problems
   6. Results of data monitoring committee reports, if any
   7. Results of regulatory agencies’ actions, if any
   8. A summary of any subject withdrawals, and reasons for withdrawal, if known
   9. A summary of any subject complaints
   10. Anticipated study completion date

B. Any proposed modifications to the protocol or consent form

C. The latest version of the protocol and consent form

D. The current Investigator’s Brochure, if any

Thank you.

Sincerely,

________________________________________ Title: ________________________________

Email: ______________________________________________________________