ANNUAL RENEWAL / FINAL REPORT FORM

☐ Annual Renewal – study is ongoing
☐ Final Report – no further contact with participants will occur (no copies required)

Protocol IRB# ___________________________  Principal Investigator: ___________________________
Date Submitted: ________________  Date of last IRB approval: ________________
Project Title: ___________________________________________________________

If Annual Renewal, please check the appropriate category below and attach the required copies for each submission:

☐ For expedited review (See Guidelines Part VI for explanation of expedited review):
  Submit two copies of this form, two copies of the most recent version of the IRB approved stamped consent, and two copies
  of the most current protocol and investigator’s brochure (if applicable).

☐ For full board review (See Guidelines Part VI for explanation of full board review):
  Submit thirty copies of this form, thirty copies of the most recent version of the IRB approved stamped consent, and three
  copies of the most current protocol and investigator’s brochure (if applicable).

The IRB is required by the federal government to obtain the following information in order to approve a request for a renewal of
approval and/or conduct a continuing review of a research project.

This research protocol:
☐ remains ongoing (open to additional enrollment)
☐ remains ongoing (permanently closed to additional enrollment; subjects continue to undergo protocol-related treatment(s)/interactions(s) and follow-up)
☐ remains ongoing (permanently closed to additional enrollment; all subjects discontinued from protocol-related treatment(s)/interaction(s); collection of
  follow-up data continues). Renewal may be expedited.
☐ remains ongoing (all protocol-related enrollment, treatment(s)/ interactions(s) and follow-up completed; data analysis continues). Renewal may be
  expedited.
☐ study is terminated (Date of termination: ________________________).

1. Total number of patients enrolled since study opened

2. Number of patients screened and enrolled in past year

   Screened  Enrolled

3. Number of subjects by race screened for entry into study since the start of the project

4. Number of subjects screened by gender since the start of the project

   Male  Female

5. Number of subjects by race entered into the study since last IRB review

6. Number of subjects by gender entered into the study since last IRB review

   Male  Female
7. Has there been any amendments/revisions since the last IRB approved renewal?  □ NO  □ YES
If yes, briefly explain.

8. Have there been any serious adverse event (on-site) reports since the last IRB approved renewal?  □ NO  □ YES
If yes, briefly explain.

9. Have there been any deviations from the last IRB-approved protocol?  □ NO  □ YES
If yes, provide a brief description of the event and a plan for preventing future occurrences.

10. Has this research study been audited by the Office of Research Compliance and Assurance since the last IRB approved renewal?  □ NO  □ YES
    If yes, list the date of review and attach a copy of the audit report.

11. Any changes in key personnel since last IRB approved renewal?  □ NO  □ YES
    If yes, list the individuals, role in research study and date of human subjects protection training.

12. Brief summary to date. What preliminary findings or evaluations of the study have you received?

Revised: 6/2005