Annual/Final Report (REC paper files only)

*Please complete and submit this report document to the CTC. Promptly notify the CTC when the project concludes. The information provided in this form must be current to the time of submission and received by the CTC for the deadline of the meeting one month prior to the anniversary of your study approval date.*

**PRIMARY INVESTIGATOR NAME (**Please Print**):**  **REC FILE #:**

1. **COMPLETE TITLE OF PROJECT INCLUDING PROTOCOL NUMBER:**

1. **STATUS OF STUDY** *(Please* ***complete only one*** *of the following sections - Annual* ***or*** *Final)***:**

*I am requesting renewal of the HREBA – Clinical Trials Committee (formerly RERC) approval:*

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| --- |
| **Annual Report: Please only include data from your site.** [ ]  **Attach review fee** Open to Recruitment: - No. of subjects consented to date:      - No. of subjects enrolled to date:      Closed to Recruitment: - Date recruitment ended:      - No. of subjects consented:     - No. of subjects enrolled:    Please give the date of the currently approved Informed Consent Form:      Safety Update Reports Enclosed:[ ]  Safety Update Reports Previously Submitted : [ ]  |

**OR**

*The study is complete, please close the file:*

|  |
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| **Final Report: Please only include data from your site.** [ ]  **Attach review fee** Date Site Closed:      No. of subjects consented:     No. of subjects enrolled:     Safety Update Reports Enclosed:[ ]  Safety Update Reports Previously Submitted: [ ]  |

1. **NUMBER OF SUBJECT WITHDRAWALS:** **WITHDRAWAL REASONS SUMMARY:**
2. **SERIOUS ADVERSE EFFECTS OR EVENTS THAT OCCURRED AT YOUR SITE within the last year:** *Please identify whether or not the event(s) is study related (attach a separate sheet if necessary).*

**PRIMARY INVESTIGATOR’S SIGNATURE DATE**