Site Closure/Study Completion Form

Please complete form, print for signature by Principal Investigator, and mail to HREBA – CC. Incomplete forms will be returned.

Use this form when contact with research participants and data collection have ended and the sponsor has conducted closeout procedures.

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| General Study Information |
| Ethics #:        |
| Study Title:        |
| Protocol #:        | Sponsor:        |
| Date of Original Approval:       | Is this is multisite study? [ ] Yes [ ] No |
| Site Specific Information (if this is NOT a multi-site study, disregard the columns for Participating Site (PS)) |
|  | **Lead Site (LS)** | **Participating Site (PS)** |
| Site Location: |        |        |
| Principal Investigator: |        |        |
| PI E-mail Address: |       |       |
| PI Telephone Number: |        |        |
| Site Study Status: | [ ]  Ongoing | [ ]  Closed | [ ]  Ongoing | [ ]  Closed |
| Closed Site Information |
| Closure Date: |       |       |
| Status:*(Reason for Closure)* | [ ]  Complete | [ ]  Abandoned | [ ]  Complete | [ ]  Abandoned |
| [ ]  Terminated | [ ]  Withdrawn | [ ]  Terminated | [ ]  Withdrawn |
| Is this closure expected? If no please explain. |        |        |

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| Study Recruitment Information |
| Total # of Subjects Required World Wide:        | Total # of Subjects Enrolled World Wide:        |
| Site Specific Information (Do NOT complete for sites which are still open) |
|  | **Lead Site (LS)** | **Participating Site (PS)** |
| 1. Total # Signed Consent Forms:
 |       |        |
| 1. Total # Screen Failures:
 |       |       |
| 1. Total # Withdrawals:
 |       |       |
| 1. Total # Completed:
 |       |       |
| 1. Sponsor final close out visit:
 | [ ] Yes [ ] No [ ] N/A | [ ] Yes [ ] No [ ] N/A |
| * 1. Actual/Expected Visit Date:
 |       |       |
| 1. Have all Local Serious Adverse Events (SAEs) which meet HREBA reporting requirements been reported to the Committee? If not, please explain.
 |
| **LS:**        |
| **PS:**        |
| 1. Have all amendments been reported to the Committee? If no please explain.
 |
|        |
| 1. Have the results been published or presented at a meeting?
	1. If yes attach an abstract or reference where material can be located.
	2. If no, when is a publication or presentation expected?
 |
|  |        |
| Sign-off |
| Person Completing Form |
| Name:        | E-mail:        | Date:        |
| Principal Investigator Lead Site (as applicable) |
| Signature: | Name (Printed):        |
| Date:        |
| Principal Investigator Participating Site (as applicable) |
| Signature: | Name (Printed):        |
| Date:        |