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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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| Terminated | Withdrawn | | Terminated | Withdrawn |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. |  | | |  | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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: | | | |