Site Closure Form

Please complete form, print for signature by Principal Investigator, and upload to section 11.0 of the Documentation Page.

Use this form when your IRISS file is associated with multiple sites in Alberta, and not all sites are closing. “Closing” means that contact with research participants and data collection have ended, and the sponsor has conducted closeout procedures.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| General Study Information | | | | | |
| Ethics #: | | | | | |
| Study Title: | | | | | |
| Protocol #: | | | Date of Original Approval: | | |
| Sponsor: | | | | | |
| Site Specific Information | | | | | |
|  | **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 (Do NOT complete for sites which are still open) | | | | | |
| 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| Terminated | Withdrawn | | Terminated | Withdrawn |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: | | | |