Annual Renewal for Approved Studies

Please complete form, print for signature by Principal Investigator, and mail to HREBA – CC. Incomplete forms will be returned, leading to delays which could jeopardize continuation of the study.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| General Study Information | | | | | | | | | | |
| Ethics #: | | | | | | | | | | |
| Study Title: | | | | | | | | | | |
| Protocol #: | | | | | | | | Sponsor: | | |
| Current Approval Expiry Date: | | | | | | | | Is this is multisite study? Yes No | | |
| Current Consent Form Version Date: | | | | | | | | Current Protocol Version Date: | | |
| Study Originally Approved by: Delegated Review Full Board Review | | | | | | | | | | |
| Site Specific Information (if this is NOT a multi-site study, disregard the columns for Participating Site) | | | | | | | | | | |
|  | | | | | **Lead Site (LS)** | | | | **Participating Site (PS)** | |
| Principal Investigator: | | | | |  | | | |  | |
| PI E-mail Address: | | | | |  | | | |  | |
| PI Telephone Number: | | | | |  | | | |  | |
| Status of Study | | | | | | | | | | |
| For clinical trials, please provide the following information: | | | | | | | | | | |
| **LS** | **PS** | |  | | | | | | | |
| FB A |  |  | | No accrual to date (if no enrollment, please provide reason): | | | | | | | |
|  |  | | Currently accruing participants | | | | | | | |
|  |  |  | | Accrual complete (please check all that apply): | | | | | | | |
| FB B |  |  | | *Participants receiving study treatment* | | | | | | | |
|  |  | | *Participants undergoing protocol mandated interventions that are not part of standard care* | | | | | | | |
| Exp B |  |  | | *Post-intervention follow-up and data collection only* | | | | | | | |
|  |  | | *Intervention and follow-up complete – analysis, data clarification, data transfer ongoing* | | | | | | | |
|  |  |  | | *Date accrual completed* | | | | | | | |
| For chart or image reviews or lab-based studies, please provide the following information: | | | | | | | | | | |
| **LS** | **PS** | |  | | | | | | | |
| Exp A |  |  | | No charts, images, or biological samples accessed (please provide reason): | | | | | | | |
|  |  | | Continue to access charts, images or biological samples | | | | | | | |
|  |  |  | | Access to charts, images, biological samples complete (please check all that apply): | | | | | | | |
| EXP B |  |  | | *Analysis of already collected data or biological samples continuing* | | | | | | | |
|  |  | | *Abstracts and/or publications in preparation* | | | | | | | |
|  |  |  | | *Date access to charts, images or biological samples was completed* | | | | | | | |
| Accrual Information | | | | | | | | | | |
| For clinical trials: | | | | | | | | | | |
| **LS** | | **PS** | |  | | | | | | |
|  | |  | | Number of subjects required for study | | | | | | |
|  | |  | | Number of subjects consented locally | | | | | | |
|  | |  | | Number of subjects consented but did not meet inclusion criteria | | | | | | |
|  | |  | | Number of subjects withdrawn from study | | | | | | |
|  | |  | | Number of subjects in follow-up | | | | | | |
|  | |  | | Number of subjects who have completed follow-up | | | | | | |
|  | | | | | | | | | | |
| For chart or image reviews or lab-based studies: | | | | | | | | | | |
| **LS** | | **PS** | |  | | | | | | |
|  | |  | | Number of charts/images/biological samples required | | | | | | |
|  | |  | | Number of charts/images/biological samples accessed | | | | | | |
| Comments: | | | | | | | | | | |
| Study Summary | | | | | | | | | | |
| 1. Please provide a brief summary of the progress of the study over the last year. | | | | | | | | | | |
| **Lead Site (LS):** | | | | | | | | | | |
| **Participating Site (PS):** | | | | | | | | | | |
| 1. Is there any new information in the literature or from any other recent studies that would change the rationale or risk/benefit ratio for this research (e.g. changes in the standard of care, new information regarding side effects, approval of another drug for this indication)? If yes, please describe. | | | | | | | | | | |
|  | | | | | | | | | | |
| 1. If any patients have been withdrawn from the study prematurely or have withdrawn consent, provide the reasons for the patient withdrawal. | | | | | | | | | | |
| **LS:** | | | | | | | | | | |
| **PS:** | | | | | | | | | | |
| 1. Have there been any subject complaints or feedback about the research? If yes, please describe. | | | | | | | | | | |
| **LS:** | | | | | | | | | | |
| **PS:** | | | | | | | | | | |
| 1. a) Have all local serious adverse events (SAEs) which meet HREBA reporting requirements been   reported to the HREBA-Cancer Committee? If no, please explain. | | | | | | | | | | |
| **LS:** | | | | | | | | | | |
| **PS:** | | | | | | | | | | |
| b) Please describe any action taken in response to Local SAEs and/or and procedural changes to detect such SAEs. | | | | | | | | | | |
| **LS:** | | | | | | | | | | |
| **PS:** | | | | | | | | | | |
| c) In the opinion of the Principal Investigator, is there a trend in the Local SAEs? If so, please identify. | | | | | | | | | | |
| **LS:** | | | | | | | | | | |
| **PS:** | | | | | | | | | | |
| d) Have there been any deaths at your site related to or not related to the study intervention (while patient on study or within 30 days of treatment)? | | | | | | | | | | |
| **LS:** | | | | | | | | | | |
| **PS:** | | | | | | | | | | |
| e) Have all important safety notifications or updates from the sponsor been submitted to the HREBA   –Cancer Committee? | | | | | | | | | | |
| **LS:** | | | | | | | | | | |
| **PS:** | | | | | | | | | | |
| f) Has there been a change in the frequency and/or severity of any serious adverse events that would result in a change to the protocol or consent form? If yes, was a protocol amendment or revised consent form submitted for HREBA-Cancer Committee approval? | | | | | | | | | | |
| **LS:** | | | | | | | | | | |
| **PS:** | | | | | | | | | | |
| Reviews/Audits | | | | | | | | | | |
| DSMB Review  Yes No Date: | | | | | | | | Sponsor DSMB Review  Yes No Date: | | |
| Sponsor Audit (e.g. NCIC CTG, RTOG)  Yes No Date:       Site: | | | | | | | | Regulatory Audit (e.g. CRU Audit, Health Canada)  Yes No Date:       Site: | | |
| If you answered “yes” to audits, has a summary of any relevant findings been submitted to the HREBA-Cancer Committee?  Yes No Notes: | | | | | | | | | | |
| Other Information | | | | | | | | | | |
| 1. Has the study now changed to include collection or banking of tissue or other specimens (blood, saliva, urine, etc.)? If yes, was a banking consent form submitted to the HREBA-Cancer Committee for approval? | | | | | | | | | | |
|  | | | | | | | | | | |
| 1. Is the contact information on the consent form current? | | | | | | | | | | |
| **LS:** | | | | | | | | | | |
| **PS:** | | | | | | | | | | |
| 1. Do you consider the most recently approved consent form to still be appropriate? If not, please explain and submit a revised consent form to the HREBA-Cancer Committee for review. | | | | | | | | | | |
|  | | | | | | | | | | |
| 1. Do you have any preliminary results? If yes, attach copies. | | | | | | | | | | |
|  | | | | | | | | | | |
| 1. Will there be publications or presentations? | | | | | | | | | | |
|  | | | | | | | | | | |
| 1. Are there any future analyses or projects planned from the results of this research? | | | | | | | | | | |
|  | | | | | | | | | | |
| 1. Please attach any other related information pertaining to this study. | | | | | | | | | | |
|  | | | | | | | | | | |
| Sign-off | | | | | | | | | | |
| Person Completing Form | | | | | | | | | | |
| Name: | | | | | | E-mail: | | | | Date: |
| Principal Investigator Lead Site | | | | | | | | | | |
| Signature: | | | | | | | Name (printed): | | | |
| Date: | | | |
| Principal Investigator Participating Site (if applicable) | | | | | | | | | | |
| Signature: | | | | | | | Name (printed): | | | |
| Date: | | | |