Renewal for Approved Studies

Please complete form, print for signature by Principal Investigator, and e-mail to cancer@hreba.ca or mail to the HREBA Ethics Office. Incomplete forms will be returned, leading to delays which could jeopardize the continuation of the study.

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| --- |
| 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.
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| **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.
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|        |
| 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?
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|        |
| 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.
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|        |
| 1. Do you have any preliminary results? If yes, attach copies.
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|        |
| 1. Will there be publications or presentations?
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|        |
| 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:        |