STUDY CLOSURE FORM

If this protocol is closed to accrual, but research participants are still on study treatment, an annual renewal report should be submitted.

|  |  |
| --- | --- |
| **1. REPORT DATE:** |  |
| 2a. Protocol Number:  |  |
| 2b. Protocol Title:  |       |
| 3. Local Principal Investigator: |       |
| 4a. Termination Date: |       | [ ] Scheduled or [ ] Premature |
| 4b. If premature, state reason for termination (e.g. no subjects (participants), adverse events, recruitment or funding issues, etc.): |       |
| 5a. Most recent approval ‘expiry date’: |       |
| 5b. Number of research participants who have provided consent AND enrolled into the study locally, since initial approval OR last renewal report date: |       |
| 5c. Total number of research participants enrolled at this site since initial OHSN-REB approval:  |       |
| 5d. Number of local withdrawals since initial OHSN-REB approval OR last renewal report date: |       |
| 5e. Total number of withdrawals at this site since initial OHSN-REB approval: |       |
| 5f. Reason for withdrawals:  |       |
| 5g. Have all the closeout procedures been completed at this site?☐ Yes☐ No, *if ‘no’ is checked*, Please explain: Click here to enter text.***Note****: If your study involved hospital/institution departments/services (i.e. pharmacy, EORLA, Department of Medical Imaging) please inform them of the study termination/completion.* |

### **6. ADVERSE EVENTS**

Have any unexpected side effects, adverse events, or findings been noted since last approval? **[ ]  Yes [ ]  No**

If yes, an adverse event report must be submitted. The report may be found on our website at: <http://www.ohri.ca/ohsn-reb/forms.htm>.

If already submitted to OHSN-REB, indicate the date of submission. **Date:**

**7. RESULTS**

***Note:***  *It is mandatory for all interventional studies to post results to the public registry*

*(i.e. Clinicaltrials.gov)*

Have any results from this research been published, submitted for publication or presented at a meeting or seminar?

**[ ]  Yes** If ‘Yes’ please specify (attach any abstracts, presentations or publications if applicable): Click here to enter text.

**[ ]  No** If ‘No’, do you intend to publish?

**[ ]  Yes** **[ ]  No** If ‘No’, Justify: Click here to enter text.

Have the study participants at this site been informed of the research results?

**[ ]  Yes**  If ‘Yes’, describe how the results have been provided? Click here to enter text.

**[ ]  No** If ‘No’, Describe how study participants will be provided study results or justify why they will not be disseminated? Click here to enter text.

#### 8. SUMMARY OF CONCLUSIONS

PLEASE TYPE OR PRINT CLEARLY

|  |
| --- |
|       |

**Original Signature of Principal Investigator** **Date**

**PLEASE NOTE: You must *keep a copy of this form for your study file.***

Version June 14, 2018