

## **CCTG Early Centre Closure Request Form - Canadian Sites on NCTN CCTG Trials**

This form is required to document CCTG’s review and approval of early/premature study closure of Canadian sites participating in NCTN trials that CCTG leads or has joined (i.e. led by another NCTN Group). **Approval is not guaranteed (e.g., registration trials).**

Prior to completing this form please ensure the following criteria have been met:

- No further accrual is anticipated at the site
- All participants at your site are off protocol treatment and are no longer being followed for purposes of the study
- All data and supporting documentation have been submitted and all queries have been resolved
- If applicable, all correlative samples and/or radiology have been submitted as outlined in the protocol
- If applicable (i.e. drug trial), if study drug was received at the site, final drug reconciliation has occurred
- REB of record for the study allows the lead group to query *existing* data and allows the site to respond and change data as appropriate after closure\*
- REB of record for the study permits auditing and/or regulatory inspections after closure

\*additional queries may be possible until final analysis/primary publication has occurred.

**Once completed, save a copy of this form AND the completed CTSU “Request for LPO Approval of Early Closure Form” (found at <https://www.ctg.queensu.ca/> in the ToolBox under Centre Forms) and submit to [CCTGStudyClosureRequest@ctg.queensu.ca](mailto:CCTGStudyClosureRequest@ctg.queensu.ca).**

Following review by CCTG, the trial study coordinator will return the completed form to you which will document whether the request for early closure is approved. If the request was approved, CCTG will also submit the “Request for LPO Approval of Early Closure Form” to CTSU on behalf of the site. If request is approved, at that time you may initiate local closure processes.

**Please note completion of this form is not required once studies have been permanently closed by CCTG.**

### **Filling out PDF Forms**

This PDF form contains “**roll-over** or **double-click**” help functionality and allows for direct data entry.

To fill out a form:

1. Select the hand tool.
2. Position the pointer inside a field and click to type text.
3. After entering text or selecting a check box, do one of the following:
  - a. Press tab to accept the form field change and go to the next form field.
  - b. Press Shift+Tab to accept the form field change and go to the previous form field.
  - c. Press Enter (Windows) or Return (Mac OS) to accept the form field change and deselect the current form field.

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<b>Centre Name:</b>	<b>CCTG Centre Code:</b>		
<b>CCTG Protocol Number (e.g. XX.XX):</b>	<b>Protocol Number Other Lead Group (if applicable):</b>		
The Request for LPO Approval of Early Closure Form is complete.	Yes	No	
If applicable, all correlative samples have been submitted	Yes	No	NA
If applicable, all central imaging/radiology has been submitted	Yes	No	NA
REB of record for the study allows the lead group to query <i>existing</i> data and allows the site to respond and change data as appropriate after closure	Yes	No	
REB of record for the study permits auditing and/or regulatory inspections after closure	Yes	No	
Was study drug (clinical trials supply) received at the site?	Yes	No	
	NA (no clinical trial supply or study does not include a drug)		
Typed name and Role of the person completing the form:	Phone Number:	Email Address:	
Typed name of the Qualified Investigator:			
Date form completed:			

### CCTG Use Only – To be Completed by CCTG Study Coordinator

Early closure is Approved	
Early closure is Not Approved Reason/s not approved:	

Typed Name and Title of CCTG Approver: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_