

CCTG Early Centre Closure Request Form - Non-NCTN Trials

This form is required to document CCTG’s review and approval of early/premature study closure. **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.

This form should be completed by the site for sites participating directly through CCTG or by the responsible group if the site is participating through a cooperative group or other international partner.

Once completed, save a copy of the form and submit directly to 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 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.

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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Centre Name:	CCTG Centre Code:		
CCTG Protocol Number (e.g. CA.XX):			
Rationale for Early Closure of Study:			
1) No participants were accrued at the institution and no future accruals are anticipated.	Yes	No	
OR			
2) All participants accrued at the institution have completed protocol treatment and protocol required follow-up, or have been transferred or are deceased and no future accruals are anticipated;	Yes	No	
All enrolled participants' data submitted; all data queries are resolved.	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	
3) For either scenarios #1 or #2 above – was study drug 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: _____