

Request for LPO Approval of Early Closure Form – Instructions

This form is required to document the Lead Protocol Organization’s (LPO) review and approval of early study closure regardless of the accrual status of the site. **Approval is not guaranteed (e.g., registration trials).**

1. For trials with a registration intent, it is recommended you contact the LPO prior to form submission to confirm that early closure is an option.
2. Submit the form to the LPO for all studies without registration intent, until the LPO has indicated that follow-up is complete. If follow-up is complete with the LPO submit the form with the LPO’s follow-up complete memo to the NCI CIRB or the CTSU, as applicable, rather than to the LPO.
3. If multiple studies are being closed, a separate form should be used for each study. If the request to close the study applies to multiple sites, the additional sites should be included on the Supplemental Site List. If a form that can accommodate more than 19 sites is required, please contact the CTSU at CTSUContact@westat.com.
4. Once completed, save a copy of the form and submit it to the applicable LPO at the email address provided below.
 - a. NCTN
 - i. ALLIANCE* – regulatory@alliancenctn.org
 - ii. CCTG – CCTGStudyClosureRequest@ctg.queensu.ca
 - iii. COG – cogqa@childrensoncologygroup.org
 - iv. ECOG-ACRIN – EASudyClosureRequest@ecog-acrin.org
 - v. NRG* – regulatory-phl@NRGOncology.org
 - vi. SWOG – SWOGStudyClosureRequest@crab.org
 - b. ETCTN
 - i. Theradex – CTMS-DM@theradex.com; and
 - ii. LAO Leading the study (see protocol contact table)
 - c. Other networks
 - i. CITN – citn.core.reg@hvtn.org
 - ii. PBTC – Submit to PBTC Protocol Coordinator listed on contact page of protocol.
 - iii. URCC – URCC_Regulatory@urmc.rochester.edu
 - iv. WAKE – NCORP@wakehealth.edu
 - v. All others – Submit to the statistician/data manager per the protocol contact table.
5. After receiving an approved form back from the LPO, submit it to the NCI CIRB via IRBManager if you are closing the study at all of the participating sites under your CIRB Signatory Institution or to CTSU Regulatory Office via the Regulatory Submission Portal with the CTSU if you are closing the study at some, but not all, of the participating sites under your CIRB Signatory Institution, or if you are closing the study through your local IRB.

*This process supersedes the previous Alliance and NRG early closure processes.

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.

Request for LPO Approval of Early Closure Form

Submit to LPO, as appropriate, per instructions on the previous page.

| | |
|--|-------------------------------|
| Institution Name*: | NCI Institution Code*: |
| | |
| *Please check this box if Supplemental Pages are needed for additional sites <input type="checkbox"/> | |
| Protocol Title (Shortened version acceptable): | Protocol Number: |
| | |
| Rationale for Early Closure of Study | |
| 1) No subjects were accrued at or transferred to the institution and no future accruals are anticipated. | <input type="checkbox"/> |
| 2) All subjects enrolled or transferred to the institution have completed treatment and follow-up, are off-study, or have been transferred; all patient data queries are completed; no future data queries or enrollments/transfers are anticipated. | <input type="checkbox"/> |
| 3) Other (please provide rationale): | <input type="checkbox"/> |
| Typed name of the person completing the form: | Email Address: |
| Date form completed: | |

LPO/Theradex Use Only – To be Completed by LPO*

| | |
|---|--------------------------|
| No patients enrolled. No data submitted and no data queries outstanding; or | <input type="checkbox"/> |
| All data for all enrolled patients has been submitted; and | <input type="checkbox"/> |
| All data queries have been resolved with no anticipation of future queries for all patients enrolled. | <input type="checkbox"/> |
| Early closure is Approved | <input type="checkbox"/> |
| Early closure is Disapproved | <input type="checkbox"/> |

**For the ETCTN, both Theradex and the LAO leading the protocol are required to approve.*

Typed Name and Title of LAO/LPO Approver: _____

Signature: _____ Date: _____

Typed Name and Title of Theradex Approver for ETCTN/CITN studies: _____

Signature: _____ Date: _____

