**Instructions and guidance for requesting early IRB closure:**

* This form applies to NRG Oncology studies. Sites should contact the lead group (e.g., Alliance, SWOG, ECOG-ACRIN, CCTG or COG) for Non-NRG led studies.
* **Please Note: NRG reserves the right to ask for *resolution of all data management & statistical queries arising prior to study closure at your site until the study is terminated by NRG.***
* **DO NOT** complete this form for studies that have been terminated by NRG.
* Sites must refer to record retention policies for each study.
* All items marked with a red asterisk (**\***) must be completed by the site electronically for legibility and submitted as a Word document.
* A separate form and e-mail must be submitted for each study. Submit this form to [*regulatory-phl@NRGOncology.org*](mailto:regulatory-phl@NRGOncology.org)**with Request for IRB Closure/Study Number/NCI Institution Code** in the subject line (e.g., Request for IRB Closure NRG-BN001/PA100).
* The individual from the site who submitted the e-mail will receive notification of approval/disapproval to close the study with the IRB. No action can be taken at the site until formal approval has been received from NRG. The site will be responsible for notifying their IRB of the study closure. Sites will also be responsible for submitting a copy of their local documentation closing the study at their institution along with the approved *NRG Oncology Request for Early IRB Closure Form* to the CTSU via the Regulatory Submission Portal.
* Allow 10-14 business days for initial processing of this form. Please contact the study data manager or dosimetrist to resolve perceived discrepancies. A new form must be submitted if the matter requires re-review once discrepancies have been resolved.

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| **Request for Early IRB Study Closure Form**  **\*** Initial Submission  Resubmission | | **A copy of the completed form must be sent as an e-mail attachment to:**  [regulatory-phl@NRGOncology.org](mailto:regulatory-phl@NRGOncology.org) | | | |
| |  | | --- | | **\* Site Contact Information** Name:       Title: | | Phone:       E-mail: | | | | | | |
| **Institution Name: (List all Institutions for this request)** | | | **NCI Institution Code: (i.e. PAXXX)** | | |
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| **Protocol Title** | | | **Protocol Number: (Lead Group Number)** | | |
| **\*** | | | **\*** | | |
| **\* Rationale for Study Closure (select one)** | | | **\*** | | **Comments** |
| 1. No subjects were accrued or transferred to the institution(s) listed above  **OR** all patients have been transferred to a different institution(s). | | |  | |  |
| 1. All subjects accrued at or transferred to the institution listed on the request form are: 1) deceased or 2) transferred out or 3) have withdrawn consent or 4) completed required follow up and are no longer receiving protocol treatment or 5) declared lost to follow up by NRG and all required data forms have been submitted, data have been sufficiently reviewed and all open queries have been resolved. | | |  | |  |
| **\***  The IRB of record for this study agrees to allow NRG to query data after closure. The only data allowed to be queried will be for the period of IRB approval at the site | | | | | |
| **\* Typed name of person completing the form:** | **\*Phone:** | | | **\* Email:** | |
| **\*Typed name of study principal investigator:** | | | | **\* Date:     /     /** (mm/dd/yyyy) | |
| ***The Institutional and NRG Staff listed below certify that the information provided above is correct*** | | | | | |
| **NRG Statistics and Data Management Reviewer Name:** | | | | **Date:     /     /** (mm/dd/yyyy) | |
| Criteria for early closure confirmed Yes  No | | | | | |
| **NRG Regulatory Staff Name:** | | | | **Date      /     /** (mm/dd/yyyy) | |
| Approval  Disapproval | | | |  | |