FAQs Related to Site Request for Study Closure with Site IRB or Transfer of IRB Responsibility

Q - Will I need to respond to any future RTOG queries related to this study?
A - Yes, a response to all RTOG data management & statistical queries arising prior to RTOG study termination will still be required.

Q - Do I need to submit this form if the study has already been terminated by RTOG?
A – No, to save yourself the extra paperwork; please check the terminated studies list at http://www.rtog.org/LinkClick.aspx?fileticket=IXVnFvY6amU%3d&tabid=345 to determine if a study has already been terminated.

Q – What if I have to list more institutions than the lines on the form will accommodate?
A – Add a separate page listing the same information in table format.

Q – Can I submit multiple study requests via the same e-mail?
A – No each study request must be in a separate e-mail as they are circulated to various individuals and departments according to disease site team.

Q - Can I request IRB closure if an affiliate site is still actively accruing or has cases enrolled whom have not withdrawn consent, completed treatment and follow up or are deceased?
A – No, the criteria selected on the form must have been met for all institutions operating under the IRB approval.

Q – Can RTOG approve IRB closure for a study for which they are not the lead group?
A – No, the request for IRB closure must be submitted to the lead group.

Q – Does RTOG verify that I have provided accurate RTOG Institution Numbers and NCI Codes during the processing of my request?
A – No, the request is processed for the numbers and codes as you have listed them on the form. The accuracy of this information is the submitter’s responsibility.

Q – Can I close out the study with the IRB as soon as I submit the form to RTOG?
A – No, the form is not merely informational; it requires RTOG approval, which will be sent via e-mail to the submitter of the form.

Q – Is this form required to be submitted to report the transfer of IRB responsibility associated with a patient transfer?
A – No the Transfer of IRB Responsibility portion of the form is intended for use when the entire study is being transferred to another IRB (e.g., when the original IRB is disbanded or ceases to exist).

Q – How do I resolve unmet criteria related discrepancies (e.g., Form disapproved noting live patients when all patients are deceased)?

Q – What is the anticipated response time for a submitted form?
A – If the form is completed properly with the appropriately formatted subject line “Request for IRB Closure study #/Institution #/ NCI Institution Code” (e.g., Request for IRB Closure 0525/0601/PA1221) a response can be expected within 10-14 business days. The response time will be significantly delayed and runs the risk of being lost during circulation if not submitted as required (as noted in italics above).

Q – Why do I have to format the subject line with “Request for IRB Closure study #/Institution #/ NCI Institution Code” (e.g., Request for IRB Closure 0525/0601/PA1221)?
A – The form is circulated via e-mail to multiple team members in multiple departments within RTOG HQ to confirm the selected criterion is met prior to approval. A properly formatted subject line will facilitate recognition by reviewing staff and quicker turn around internally. Improperly formatted subject lines run the risk of being lost during circulation.

Q – What is the difference between a study that “closed to accrual” and a study that has been “terminated”?
A – A study that has been “closed to accrual” means that no additional subjects will be enrolled in the study. Study activity will continue which may include interaction with subjects, continued use of a drug/device, and/or data analysis. A study that is “terminated” means that all study activity is complete. This may occur because the sponsor has decided to stop the study or the study activity and data analysis are complete.

Q- What is the Transfer of IRB Responsibility?
A- The Transfer of IRB Responsibility is intended for use when the entire study is being transferred to another IRB (e.g., when the original IRB is disbanded or ceases to exist) not to report the transfer of IRB responsibility associated with a patient transfer. The RTOG patient transfer form at the following link http://www.rtog.org/LinkClick.aspx?fileticket=1Ue75SArheg%3d&tabid=164 should be used to report patient transfers.