

To: Sites participating in NSABP B-39 and B-40

From: Norman Wolmark, MD, NRG Group Chair
Joseph Costantino, DrPH, Director, NRG Statistics and Data Management Center

Date: January 28, 2019

RE: **Study Closure Notice - NSABP B-39 and B-40**

*This information is being provided to NRG Oncology ("NRG") Member Institutions.
Please distribute this information to the appropriate personnel throughout your network.*

For scientific, logistic, and administrative reasons, NRG Oncology decided to discontinue required follow-up data submission for NSABP B-39 and B-40. The closure of these studies will be effective January 31, 2019, at 5:00 PM EDT. Please note the following important information related to the closure.

Final Study Closure

Sites can close the NSABP B-39 and B-40 studies with their IRBs. This memorandum serves as an official protocol amendment for these trials, superseding any protocol text requiring the continued follow-up of patients and submission of data outlined in the protocol.

For sites that use the NCI CIRB as their IRB of record for these studies, NRG Oncology has submitted this memorandum and the patient letters to the NCI CIRB on your behalf.

We are most appreciative of the efforts and sacrifices made by the patients who have participated in these trials over the years. To recognize this, we have provided a letter applicable to each specific study from NRG Oncology to the patients thanking them for their participation. We ask that you consider sending the letter to the patients at your institution; however, we leave this decision up to you. Alternatively, you may want to send a similar letter from your own institution. A Word version of the patient letter can be downloaded from the protocol-specific page the CTSU website and in the NRG Oncology website.

US Institutions

For NCI-sponsored trials, US institutions are required to maintain their research records for at least 3 years after the official completion of each trial. However, any local record retention requirements longer than 3 years will supersede this requirement. To ensure consistency within our clinical records, we ask that you maintain the research records of these trials until January 28, 2022.

Canadian Institutions

For NSABP B-40 – Investigators in Canada are required to retain the research records for a period of 25 years (until January 28, 2044) because a CTA was involved and because of records retention requirements in Canada. Check with your institution's REB regarding any local records retention requirements for your institution.

For NSABP B-39 – Investigators in Canada will be required to retain the research records for a period of 10 years (until January 28, 2029). NSABP B-39 did not involve a CTA. There are no defined regulations or standards for non-regulated research studies so NRG Oncology will only require record retention for 10 years. Check with your institution's REB regarding any local records retention requirements for your institution.

FOR QUESTIONS REGARDING:	CONTACT INFORMATION:
Data Submission	NRG Oncology Statistics and Data Management Center 412-624-2666
Study Closure	NRG Oncology – Pittsburgh Department of Regulatory Affairs 412-339-5300 regulatory@nsabp.org

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