NRG ONCOLOGY

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**NRG Oncology Records Retention Guidance for NCTN & NCORP Trials Version: May 8, 2024**

## I. RECORD RETENTION FOR IND STUDIES

Per section 10.3 of the Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP (Cancer Therapy Evaluation Program) ) and DCTD Division of Cancer Treatment and Diagnosis, NCI (National Cancer Institute):

> *FDA regulations require investigator to keep all research records (including patient charts, case report forms, x-rays and scans that document response, IRB approvals, signed informed consent documents and all agent accountability records) for at least 2 years after an NDA or BLA has been approved for that indication, or the CTEP, DCTD Investigational New Drug (IND) application has been withdrawn from the FDA. CTEP will notify investigators when these events occur. This requirement is an explicit part of the FDA Form 1572.*

## II. RECORD RETENTION FOR NON-IND STUDIES

The point of reference used to determine the length of time required for record retention for non-IND studies is the study's termination date, which is when the study is terminated to any data collection after analysis and follow-up is complete. The study meets the FDAAA 801 rule for NCI Central Investigational Review Board (CIRB) and the ClinicalTrials.gov website status is "Completed". Institutions will be notified via broadcast of study termination/completion. Sites should follow their institutional guidelines.

## III. RECORD RETENTION FOR SITES IN CANADA

All institutions in Canada must conduct NCTN and NCORP trials in accordance with International Conference on Harmonization-Good Clinical Practice (ICH-GCP) Guidelines [per section 6.2.5 of ICH E6(R2)]. Clinical trial records for drugs, biologics and natural health products must be retained for 15 years following the completion of the trial at the participating site (15 years post final analysis, last data collected, or closure notification to the Institutional Review Board (IRB)/Research Ethics Board (REB), whichever is later), or until notified by the sponsor that documents no longer need to be retained [per C.05.012 (4) of the FDR].