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Record Retention of Records for RTOG Legacy Trials under the NRG Oncology Program

The record retention guidelines apply to legacy RTOG studies and current NRG Oncology studies for the following disease sites and the listed breast studies:

- Brain/CNS
- Head and Neck
- Lung
- Noncolorectal GI
- GU
- Sarcoma
- NRG-BR001
- NRG-BR002

FOR CTEP HELD IND STUDIES

Per section 10.3 of the Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI

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records) for at least 2 years after an NDA or BLA has been approved for that indication, or the CTEP, DCTD IND has been withdrawn from the FDA.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, <http://ctep.cancer.gov/forms/>

FOR RTOG LEGACY NON IND STUDIES

The point of reference used to determine the length of time required for record retention for non IND studies would be the study's termination date, which is when the database is locked and no further information would be required. Institutions will be notified via broadcast of all study terminations. Sites should follow their institutional guidelines.