PROTOCOL DEVIATION/VIOLATION REPORTING GUIDANCE FOR CTEP TRIALS

The 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

The NCI does not allow for protocol deviations or waivers. Please read associated information at the following link: http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm
All protocol deviations/violations must be reported by the site to the following departments:
• The protocol specific Data Management Team
• The Regulatory Compliance Department

Please note reporting the deviation/violation does not negate any consequences at audit time.

Data Management (DM) will notify the study chair as appropriate and provide guidance on how to proceed with the patient case. Data Management internal procedures will provide a special alert to the QA Auditors when the deviation/violation results in making the patient ineligible.

Regulatory Compliance will require **the submission of the name of the DM to whom you reported the deviation/violation, a memo identifying ways in which this type of deviation/violation will be avoided in the future, along with the dated local IRB acknowledgement of the deviation/violation**. **Please identify the submission with the affected study and case number as well as your CTEP institution Number. Please note, HQ may ask for a corrective action plan if warranted.**

Please follow your institutional IRB notification policies related to protocol deviations. The IRB notification can be achieved by using your institution's specific reporting form, creating a note to file or providing some written documentation from the PI detailing the events of the deviation/violation. Regulatory Compliance internal procedures will assure the QA Auditors are informed of all deviations/violations

All documentation relating to the deviation/violation should remain available in the study file. Please send all information noted as required (bolded) above to the Regulatory Compliance Department at rtogreg@acr.org Please provide the following information in the subject line of the email: ***Protocol Deviation/Site Name/Site CTEP code/Study #/Case#***

Disclaimer: The information represented here while current is subject to change due to modifications within internal processes or federal regulatory guidelines