RTOG®
RADIATION THERAPY
ONCOLOGY GROUP

PROTOCOL DEVIATION/VIOLATION (Rev 10-2010):

The NCI does not allow for protocol deviations. 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 at RTOG HQ:
• 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. RTOG DM internal procedures will provide a special alert to the RTOG QA Auditors when the deviation/violation results in making the patient ineligible.

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

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 RTOG 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 RTOG Regulatory Compliance Department at HQ:

ACR/RTOG
Attention Regulatory Compliance Manager
1818 Market Street, Suite 1600
Philadelphia, PA 19103
Fax: 215-574-0300
E-mail: mdamico@acr.org

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