



Elm & Carlton Streets
Buffalo, New York 14263

Institutional Review Board

Approval Notice

This institution has an approved assurance of compliance on file with HHS which covers this activity FWA 00006731 Federal Wide Assurance identification number

September 27, 2018

[Anurag Singh, MD](#)

Anurag.Singh@RoswellPark.org

Dear [Dr. Singh](#):

On 9/25/2018, the IRB reviewed the following submission:

Type of Submission:	Continuing Review
Type of Review:	<input type="checkbox"/> Full Board <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Exempt <input type="checkbox"/> Non-Human Research
Special Determinations:	Waiver of HIPAA authorization; Waiver/alteration of the consent process
Title of Study:	Evaluation of Various Types of Radiation Therapy in the Treatment of Lung Cancer
Investigator:	Anurag Singh, MD
IRB ID:	CR00001288 / EDR 171710
Funding:	None
Grant ID:	None
IND, IDE, or HDE:	None
Documents Reviewed:	None

The IRB approved the study from 9/25/2018 to 10/23/2019 inclusive. Before 10/23/2019 or within 30 days of study close, whichever is earlier, you are to submit a completed continuing review and required attachments to request continuing approval or closure. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

If continuing review approval is not granted before the expiration date of 10/23/2019, approval of this study expires on that date.

Please be advised that only the IRB approved and stamped consent form can be used to enroll subjects.

The principal investigator is responsible for ensuring that the research complies with all applicable regulations. Any modifications in the research project are subject to approval by the Board prior to initiation by the investigator. The Board reserves the right to stop the research for violations of regulatory or IRB requirements.

A progress report must be submitted to the IRB at least one month prior to the expiration date noted above for continuing review as required by federal regulations and/or institutional requirements.

Please be advised that your research study may be audited periodically by the IRB for compliance.

This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This protocol fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device.

The study documents have been submitted to Clinical Research Services (CRS) Compliance Office for processing prior to release and protocol implementation. Please contact CRS Compliance for information regarding the protocol implementation release date.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103), including the reporting of Unanticipated Problems and any other Reportable New Information.

Sincerely,
Donald Handley MSc, MBA