

ACNS0831 FAQs

Central Radiology Review:

We sent the initial pre-operative and post-operative MRIs and reports to IROC RI for rapid central review. When will these scans be reviewed?

- There is no rapid central review of scans done at study entry. While all patients enrolled on ACNS0831 will have a central imaging review, only a subset of patients will have a rapid central review of scans.
- The subset of patients who will have a rapid or real-time central imaging review are those that enrolled on the study with a subtotal resection (STR). The initial pre-op and post-op MRIs are used in the rapid central review as a baseline to evaluate the response to induction chemotherapy. Patients, who enroll as a STR, will have rapid central imaging reviews done at 2 time-points: after the completion of induction cycle B to determine response and after second surgery to determine extent of resection.

When will the rapid imaging review be completed for my STR patient?

- Rapid review materials for this protocol are processed as soon as they are received at IROC RI. Cases are assigned for review after the receipt of all of the required imaging and other pertinent data. Per protocol guidelines, rapid reviews are completed within 1 week after cases are assigned to the study reviewers. Please note these reviews are not done on site at IROC RI, but are completed by Study Committee members via remote review. The results of the rapid central imaging review are entered by the study radiologist directly into the COG eRDES. Your site should receive an email notification with the rapid review results.

If you have questions about the rapid review or are urgently waiting for the results to move forward with the patient's treatment, please contact IROC RI to let the responsible CRA know.

Our patient has not had a pre-operative brain MRI, but has had a pre-operative head CT scan. Is our patient eligible for the study?

- The neuroimaging (MRI) examination is the basis for determining eligibility, the extent of resection and/or induction chemotherapy response, and subsequent therapy. At this time, a pre-operative brain MRI is not an eligibility requirement for the study, but sites should make every effort to have a pre-operative brain MRI done and available to be submitted to IROC RI.

Why am I being asked to submit operative and pathology reports when these were already sent to COG?

- These reports are essential to determine the extent of resection at study entry and after second surgery. On the COG website, there are shuttle sheets for the submission of the Operative reports, so please make sure to submit copies of all relevant reports to COG via the eRDE, so that we may retrieve copies of the reports. If an operative report is not submitted to COG via the eRDE, we must ask the site for a copy. Please note that pathology reports are not submitted via shuttle sheet to COG, so we need copies submitted.

- The rapid central imaging review done post second surgery requires a copy of the operative report for the second surgery. If a finalized version of this report is not available to enter into the COG eRDE, please submit a preliminary copy to IROC RI with the imaging and radiology reports, so that the rapid central review may be completed.

Radiation Therapy Review:

Does my patient require a boost or cone down after 5400 cGy?

- Patients who go to Observation only do not get radiation therapy.
- All other patients on ACNS0831 should receive radiation therapy to 5940 cGy. Radiation is delivered in two parts. The initial phase is for 30 treatments (fractions) to 5400 cGy followed by a 3 fraction boost to bring the total dose to 5940 cGy. The 3 fraction boost after 5400 cGy is a mandatory field reduction to spare normal tissue. Please refer to section 18.5.9 of the protocol for details on the boost.

- However, patients who are less than 18 months at the start of irradiation and have a gross-total resection do not get this mandatory field reduction. This group of patients is done with radiation at 5400 cGy.

Why am I being asked to send scans for the radiation therapy plan review?

- Copies of the pre-op, post-op and any additional brain MRIs done prior to the start of radiation therapy are required to determine the protocol target volumes. The reviewers must be able to assess the extent of disease prior to ALL surgeries and after all surgeries to accurately review the target volumes. If these scans are not available at the time of the interventional RT review, the plan cannot be evaluated. Reviews will be delayed pending receipt of the required imaging.

Do I need to resubmit scans for if they were already sent for the central imaging review?

- If a scan was sent for the radiology review (rapid and/or retrospective) it does not need to be resubmitted. COG data is permanently stored at IROC RI, so you do not need to resubmit the same studies again. However, copies of any MRIs that are relevant to the RT and/or imaging reviews that have not been previously submitted should be sent to IROC RI with their corresponding reports at the appropriate time points.