

Data Management FAQs

Can I send identified data to IROC RI?

- Research personnel at participating sites in all clinical trials supported by QARC are instructed to remove any information that directly identifies a subject, for example, patient name, address, or medical record number.
- IROC RI's standard practice is to adhere to good clinical practice procedures that include maintaining patient records with strict confidentiality and protecting all identified data from any unauthorized use.
- Only de-identified summary data and evaluations are sent to the National Clinical Trials Network (NCTN) group statistical centers for study analysis.
- Please make sure submitted data, are clearly labeled with the NCTN Group patient identifier (case number) and protocol and that information such as the date of a diagnostic study has not been removed in the de-identification process.

When will IROC RI destroy my patient's data?

- IROC RI's record retention SOP maintains that decisions regarding record retention and destruction are done under the lead NCTN Group's direction. All records archived at IROC RI are maintained securely with controls and limited access.

Can you send me a copy of the protocol or a specific section of the study?

- Protocols are the NCTN Group's confidential documents. Access to these documents is through your institution's participation in the respective NCTN Group or through the CTSU. IROC RI does not have the authority to provide copies of protocol documents or protocol sections. If you need a copy of the study, please contact the CRA (clinical research associate) responsible for your institution's participation in the NCTN Group.

Does IROC RI pay for shipping?

- No, IROC RI does not have funding from any of the NCTN Groups or the NCI to cover courier expenses. These costs must be borne by the member institution.
- Radiation therapy plan data and diagnostic imaging should be submitted electronically.
 - TRIAD is the preferred method for submitting DICOM, DICOM RT and Non-DICOM files in most NCTN protocols.
 - Screen shots saved in non-dicom files such as PDFs, jpegs, etc can be submitted via TRIAD along with the DICOM/DICOM RT files.
 - Older protocols that do not include TRIAD allow submission of DICOM/DICOM RT and Non-DICOM files via sFTP.
 - For more on sending RT data via a sFTP account, please refer to the [Digital Data Submission FAQ](#)
 - For more information on TRIAD, please go to: <https://www.irocqa.org/Resources/TRIAD>.

Can I send patient data to IROC RI using a secure email?

- Data submitted to IROC-RI via secure email is no longer be accepted. All data should be sent using Secure File Transfer Protocol (sFTP) or TRIAD.

What forms should I submit to IROC RI?

- A copy of the checklist should be submitted with patient data. The checklist is available on our website www.irocri.qarc.org. A copy can be retained as a record of what was submitted.
- Checklists for the adult Groups are found under the lead NCTN Group for the study.
- COG checklists are under COG and then organized by disease category.
- If you need to send data for a study and you do not see the checklist on our website, please contact IROC RI at 401-753-7600.
- If required by the study, please submit the completed IROC RI radiation therapy forms. Many studies require the RT-1 Dosimetry Summary Form and RT2 Radiotherapy Total Dose Record to be submitted. Other studies may require the submission of a more specialized IROC RI radiation therapy form. These forms are located on the IROC RI website at www.irocri.qarc.org under Forms.
- Some diagnostic imaging studies have staging and response worksheets and requests for review that must be submitted with the imaging. These are available on our website www.irocri.qarc.org. You should retain a copy of these for your records.
- Some protocols will require copies of CRFs that are sent to the NCTN Group also be submitted to IROC RI. These forms are not located on the IROC RI website and we cannot provide copies of them. IROC RI does not get copies of these forms from the NCTN Group, so if required by the study, please submit a copy to IROC RI per the protocol.

When will my case be reviewed?

- Interventional RT reviews are performed as soon as possible after receipt of all required data. Reviews generally occur within 3 business days.
- Real-time imaging reviews vary based on the protocol and availability of the central reviewer.
- Questions about a review for a specific case should be directed to the CRA who manages the study at IROC RI. Information on whom to contact for a particular study can be found on our website at www.irocri.qarc.org.
- There are many steps involved in preparing a case for dosimetry and physician review and if data are received late in the day or incomplete the review may be delayed.

What happens to my RT data when it goes to IROC RI?

- When data arrives at IROC RI the date of receipt is noted in the patient's electronic record at IROC RI.
- The data is distributed for processing to ensure that the materials required for the review are complete and that the imaging received is for the correct time-points and is complete and viewable.
- Cases that will be presented for an interventional radiation therapy review also undergo a dosimetry review.
- After the data has been processed and had a dosimetry review, a case is reviewed by an IROC RI Radiation Oncologist. The review results are communicated to the treating Radiation Oncologist via email.

What do I send to IROC RI?

- A complete list of the materials that should be submitted to IROC RI can be found in the appropriate section or sections in the protocol document.
- If a protocol asks for copies of diagnostic imaging, this means a copy of the scan should be submitted to IROC RI, not just the report.
- The checklist that is on our website can be a quick reference guide. The checklist can be used as a transmittal form with the submitted data.

- Radiation Therapy Data:

The submission of radiation therapy treatment plans digitally in DicomRT is required by most protocols and is critical for patients being treated using advanced technologies. Guidelines for submitting the RT treatment plans digitally in DicomRT format are available in the [Digital Data Submission FAQs](#).

 - Radiation therapy data can be submitted via a number of different methods
 - sFTP (notify IROC RI of submission by emailing sFTP@qarc.org)
 - TRIAD (use only for TRIAD enabled protocols)
 - If data are submitted via one method, duplicate data does not need to be sent in another way. For example, if the RT-1 form is sent via TRIAD, a duplicate of it does not need to be sent via sFTP.

- Diagnostic Imaging Data:

The submission of diagnostic imaging in DICOM format is mandatory in many protocols and the preferred method for all studies. Many central imaging reviews are done by remote review; therefore the imaging must be in DICOM format.

 - Copies of the scans must be submitted for review, not just the reports.
 - Submitting Diagnostic Imaging Dicom Files:
 - TRIAD is the preferred method for submitting imaging on NCTN protocols.
 - Some of the older protocols may not include TRIAD. In those cases sFTP (notify IROC RI of submission by emailing sFTP@qarc.org) or Dicommunicator, if you have that set-up at your site, are the preferred methods.
 - When electronic submission is absolutely not available, DICOM files may be submitted on a CD or DVD.
 - Dicommunicator email (must have Dicommunicator set-up at your site). See IROC RI website www.irocri.qarc.org – Digital Data- for further instructions.
 - Efforts should be made to submit the data electronically using sFTP or TRIAD. CD and/or DVDs will be accepted under certain circumstances.
 - PET/CT, PET, CT and MR must be in DICOM format. Do not send PET/CT, CT or MR imaging as .jpg or .bmp or as PowerPoint. These are not acceptable alternatives.

- Other imaging modalities may not be available in DICOM format. If available as DICOM format, this is the required format for submission. If not available in DICOM format, IROC RI does accept these types of scans in other formats. Please contact IROC RI about what would be an acceptable format.
- Do not send imaging on a CD in a proprietary format, the actual digital DICOM files must be on the CD and able to be extracted from the CD and imported into our PACS.
- Identification of study by protocol defined event, (i.e., post 2 cycles, end-of-treatment, pre-radiation, relapse, etc.), is very helpful especially when the date of the imaging study is different from what would be expected, for example an unexpected delay in treatment administration.
Ensure critical information is included in the image header, including series information, study date, slice thickness, details of acquisition, and some trace of patient identification. This information must be transferred to IROC RI and must not be obscured or removed by any effort to de-identify image data.
- IROC RI can accept data with PHI (Patient Health Identifiers such as study date) as long as proper consent and authorization have been obtained.

Why do I get multiple queries from different sources for the same patient on a protocol?

- IROC RI works with the NCTN Groups and is similar in function to a Core Lab.
- IROC RI works with the NCTN Groups to ensure that the required radiation therapy data and diagnostic imaging is complete and evaluable for analysis.
- Data extracted from radiation therapy plans and results from central imaging reviews are forwarded to NCTN Groups to be included in the study analysis.
- IROC RI sends queries for the radiation therapy data and/or diagnostic imaging that are needed to complete a review. Requests from the NCTN Groups will usually be asking for CRFs or copies of reports, while we are requesting detailed treatment data and/or imaging studies and reports. Under some circumstances, such as final analysis for a study, an NCTN Group may send queries requesting that missing data be submitted to IROC RI.
- If there are questions or concerns about the data that has been requested, please contact us.