DATA MANAGEMENT AND SHARING PLAN

**IROC Data Management & Sharing Plan – Template Example**

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on [sharing.nih.gov](https://sharing.nih.gov/). The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no “form page” for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

# Element 1: Data Type

## Types and amount of scientific data expected to be generated in the project:

The **NCTN Network Radiotherapy and Imaging Core Services Center** is funded by NCI under a U24 (Resource-Related Research Projects) cooperative agreement to provide scientific and technical expertise for incorporation of appropriate, integrated quality assurance/control (QA/QC) for radiation therapy (RT) and image data management for applicable NCTN clinical trials that require specialized QA/QC or imaging data management and/or assessment for radiotherapy and imaging interventions. In addition, the Center may also provide similar services for other approved NCI-supported clinical trials network programs (e.g., NCI/DCTD/CTEP early phase clinical trial network program (ETCTN) and the NCI Division of Cancer Prevention (NCI/DCP) NCI Community Oncology Research Program (NCORP). IROC provides electronic exchange of digital planning data, images, and software tools for data review and image review by study chairs for specific NCTN trials or trials by other applicable trials.

The NCTN trials and others that IROC provides services for are anticipated to enroll thousands of patients over the 6-year project period in multi-site cancer treatment and advanced primary imaging clinical trials/studies led by one of the U.S. NCTN Network Groups, NCTN Canadian Collaborating Clinical Trials Network, and/or other approved NCI-supported clinical trials network programs.

Imaging and/or radiotherapy data (including for patients enrolled on specific NCTN multi-site trials (and other non-NCTN trials) include information on site credentialling data for both radiotherapy (RT) and imaging required for specific trials and patient data including, but not limited to the following:

* anthropomorphic phantoms for complex treatment delivery of RT
* RT treatment delivery data including remote review of 3D and 4D images
* RT objects with data on dosimetry, rapid volumetric treatment data, physical dose assurance).
* Storing/archiving of imaging data for applicable NCTN and other trials for assessment of primary and secondary trial endpoint or other trial-specific imaging aims.

Each user who is involved with the NCTN and other NCI-supported clinical trials network programs will be given role specific access to the NCTN Group’s EDC (common electronic data management system such as Medidata Rave) where patient clinical metadata related to the patient’s radiotherapy treatment and/or imaging scans will be stored, and access will be controlled by NCI Clinical Trials Support Unit (CTSU). If imaging scans are required to be sent to IROC, the scans will be transmitted to the appropriate IROC offices using the Triad platform in a secure manner with appropriate de-identification of PHI but with an appropriate trial ID/# generated for the patient on a specific trial.

Imaging scans and RT data will also be stored by the IROC for use by the NCTN Groups and other clinical trial network programs to support appropriate QC/QA for RT therapy, imaging, and/or storage of imaging scans (digital format as well) for assessment by the organization leading the clinical trial of protocol-defined aims (e.g., QA/QC RT therapy, central review of imaging scans for the trial’s primary endpoint or important secondary endpoint).

Data elements will be collected at protocol-specified frequencies, typically for up to five years for trials or longer if long-term follow-up is intended in accordance with the informed consent and protocol specifications and/or there are regulatory requirements necessitating longer retention per Regulatory Agencies (e.g., FDA, EMA) policies.

## Scientific data that will be preserved and shared, and the rationale for doing so:

The scientific and clinical data/metadata on patients enrolled on NCTN and other multi-site studies/trials will **not** be shared by the IROC as the data is collected **only** for use and interpretation as an integrated whole study by the NCTN Group or other trial organization leading the trial. Data that IROC collects for protocol specific RT treatment or imaging scan assessment will be preserved by IROC for use by the NCTN Group or other trial organization leading the multi-site trial/study and shared (protocol-specified collected data, including but not limited to the data elements described above) only by the NCTN Group or other trial organization at appropriate time points per the NCTN Group’s Data Management and Sharing Policy or other trial organization’s policy.

In addition, the NCTN Group (or other trial organization) leading the multi-site trial/studies for which IROC provides services will make primary and secondary study data results made available in the National Library of Medicine (NLM) Protocol Registration and Results System (PRS), with results publicly available on clinicatrials.gov per the DMS plan of the NCTN Group or other trial organization.

## Metadata, other relevant data, and associated documentation:

The protocol and sample informed consent will be made available in the NLM PRS when primary study results are reported per the Data Management and Sharing Policy of the NCTN Groups (or other trial organizations’ DMS plans) that are leading multi-site trials/studies for which IROC provides services.

# Element 2: Related Tools, Software and/or Code:

**Not Applicable - The scientific and clinical data and metadata generated for the trials/studies that IROC provides services for will be transferred to the NCTN Groups (or other trial organizations) leading those trials. IROC does not share this data as the data are collected and overseen only as an integrated whole by the NCTN Group or other trial organization leading the individual multi-site trial/study. The NCTN Group leading the trial/study provides/uses related tools, software, and/or code under its Data Management & Sharing Policy to share trial data.**

# Element 3: Standards

**Not Applicable - The scientific and clinical data and metadata generated for the trials/studies that IROC provides services for will be transferred to the NCTN Groups (or other trial organizations) leading those trials. IROC does not share this data as the data are collected and overseen only as an integrated whole by the NCTN Group or other organization leading the individual multi-site trial/study. The NCTN Group leading the trial/study provides/uses related tools, software, and/or code under its Data Management & Sharing Policy to share trial data.**

# Element 4: Data Preservation, Access, and Associated Timelines

## Repository where scientific data and metadata will be archived:

**Not Applicable - The scientific and clinical data and metadata generated for the trials/studies that IROC provides services for will be transferred to the NCTN Groups (or other trial organizations) leading those trials. IROC does not share this data as the data are collected and overseen only as an integrated whole by the NCTN Group leading the individual multi-site trial/study. The NCTN Group leading the trial/study specifies repositories where data and materials will be archived, how data will be findable & identifiable, and when & how long data will be made available under its Data Management & Sharing Policy. In the special situation in which the NCTN Group or other trial organization requests IROC load imaging data and metadata to an Archive (e.g., Cancer Imaging Archive (TCIA) overseen by the NCI/DCTD Cancer Imaging Program) so the images for trial patients can be linked to patient clinical data, this is done only under the NCTN Group or other trial organization DMS Plan and NCTN Group’s or other trial organization’s direction.**

## How scientific data will be findable and identifiable:

**Not Applicable – Please see explanation under Element 4 A. above.**

## When and how long the scientific data will be made available:

**Not Applicable – Please see explanation under Element 4 A. above.**

# Element 5: Access, Distribution, or Reuse Considerations

## Factors affecting subsequent access, distribution, or reuse of scientific data:

**Not Applicable - The scientific and clinical data and metadata generated for the trials/studies that IROC provides services for will be transferred to the NCTN Groups (or other trial organizations) leading those trials. IROC does not share this data as the data are collected and overseen only as an integrated whole by the NCTN Group leading the individual multi-site trial/study. The NCTN Group or other organization leading the trial/study provides access, distribution, and/or reuse of data with appropriate control and protection for privacy, rights and confidentiality of human research participants under its Data Management & Sharing Plan. IROC may, however, make the data available at the direction of the NCTN Group or other trial organization per the Group’s/organization’s DMS Plan.**

## Whether access to scientific data will be controlled:

**Not Applicable – Please see explanation under Element 5 A. above**

## Protections for privacy, rights, and confidentiality of human research participants:

**Not Applicable – Please see explanation under Element 5 A. above**

# Element 6: Oversight of Data Management and Sharing:

**Not Applicable - The scientific and clinical data and metadata generated for the trials/studies that IROC provides services for will be transferred to the NCTN Groups or organizations leading those trials. IROC does not share this data as the data are collected and overseen only as an integrated whole by the NCTN Group or other trial organization leading the individual multi-site trial/study. The NCTN Group or other trial organization leading the trial/study provides oversight under its Data Management & Sharing Policy/DMS Plan.**