DATA MANAGEMENT AND SHARING PLAN

**LAPS 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**

1. **Types and amount of scientific data expected to be generated in the project:**

The **[*Name of Lead Academic Institution/Organization for the Application*]** NCTN Network Lead Academic Participating Site (LAPS) is anticipated to enroll hundreds 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 or the NCTN Canadian Collaborating Clinical Trials Network.

Clinical data for patients enrolled on NCTN multi-site studies will be obtained from the LAPS electronic (or paper-based) patient health records, or directly from patients, and will be entered into the electronic data-capture (EDC) system of the NCTN Group leading the trial/study by site or study-specific research staff using study-specific case-report forms (CRFs). The clinical data will include demographic data, medical history, medications, physical exams, lab tests performed by sites and/or central laboratories, results of biological analyses or immunoassays from biospecimens, genomic data, treatment history, protocol adherence, adverse events, patient reported outcomes (PROs), quality of life data, clinical response to treatment, longer-term follow-up, and other data pertinent to the trial/study.

Each LAPS user will be given role specific access to the NCTN Group’s EDC (common data management system such as Medidata Rave) where the data will be stored, and access will be controlled by NCI Clinical Trials Support Unit (CTSU). The demographic clinical data submitted on patients will also be stored by the NCI CTSU long-term on an NCI database for Inclusion Reporting.

Data elements will be collected at protocol-specified frequencies, typically for up to five years in accordance with the informed consent and protocol specifications.

1. **Scientific data that will be preserved and shared, and the rationale for doing so:**

The scientific and clinical data on patients enrolled by the LAPS on multi-site studies/trials will **not** be shared by the LAPS as the data in collected only for use and interpretation as an integrated whole study by the NCTN Group leading the trial. Clinical data that will be preserved by the NCTN Group 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 at an appropriate time points per the NCTN Group’s Data Management and Sharing Policy. In addition, the NCTN Group leading the multi-site trial/studies the LAPS participates in 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 NCTN Group’s policy. The NCTN Group leading a trial/study generating human genomic data that fall within the scope of the National Institute of Health (NIH) Genomic Data Sharing (GDS) policy will be responsible under its NCTN Group policy for appropriate registration and deposit of data in accordance with NIH Policy.

1. **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 leading the multi-site trials/studies in which the LAPS participates.

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

**Not Applicable - The scientific and clinical data generated for the trials/studies the LAPS participates in will be transferred to the NCTN Groups leading those trials. LAPS do 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 provides/uses related tools, software, and/or code under its Data Management & Sharing Policy.**

**Element 3: Standards:**

**Not Applicable - The scientific and clinical data generated for the trials/studies the LAPS participates in will be transferred to the NCTN Groups leading those trials. LAPS do 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 employs appropriate standards under its Data Management & Sharing Policy.**

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

1. **Repository where scientific data and metadata will be archived:**

**Not Applicable - The scientific and clinical data generated for the trials/studies the LAPS participates in will be transferred to the NCTN Groups leading those trials. LAPS do 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.**

1. **How scientific data will be findable and identifiable:**

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

1. **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**

1. **Factors affecting subsequent access, distribution, or reuse of scientific data:**

**Not Applicable - The scientific and clinical data generated for the trials/studies the LAPS participates in will be transferred to the NCTN Groups leading those trials. LAPS do 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 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 Policy.**

1. **Whether access to scientific data will be controlled:** **Not Applicable – Please see explanation under Element 5 A. above.**
2. **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 generated for the trials/studies the LAPS participates in will be transferred to the NCTN Groups leading those trials. LAPS do 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 provides oversight under its Data Management & Sharing Policy.**