NATIONAL CANCER INSTITUTE

NATIONAL CLINICAL TRIALS NETWORK PROGRAM GUIDELINES

DIVISION OF CANCER TREATMENT AND DIAGNOSIS

NATIONAL CANCER INSTITUTE

NATIONAL INSTITUTES OF HEALTH

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Version 1.1

This is an Update to Version 1.0 which was dated July 23, 2012.
Please see pages 239-241 for a summary of the updates.

VII. Model for NCTN Program Data Sharing Policy for Network Group Ops Centers & SDMCs

1. Introduction

This document describes general policies of the NCI National Clinical Trials Network (NCTN) Program for funded Network Groups (defined as Network Group Operations Center and its associated Network Group Statistics and Data Management Center) on providing individual patient data to investigators for use in research projects. Each Network Group may have a more detailed set of procedures implementing the general policy but those procedures should be consistent with all provisions of the general policy.

The Network Groups conduct clinical trials in cancer research. Each Network Group or NCTN study has a formal protocol document, which includes a statement of the objectives of the study. Patient consent and authorization are obtained to collect the individual patient data required for addressing the study objectives. These data are sent from the treating or enrolling institution to the Network Group's Statistics and Data Management Center, where the data are reviewed, processed and entered on an electronic database. The data may be submitted on paper or electronically. Not all information submitted on paper becomes part of the electronic database. The electronic database is used as the basis for the analysis of the Network Group's studies, with the analyses performed by the staff at the Network Group's Statistics and Data Management Center.

The procedures described here do not cover requests from the NCI, FDA or other federal agencies for information required by federal regulations or by the terms of the Network Group's grant awards. Such requests will be honored as expeditiously as possible.

This document only covers requests for existing data, not requests for use of biospecimens (which are covered under a different evaluation and review process) or for collection of additional data. Requests for individual-level genomic or other high-dimensional data not used in the primary publication may be subject to other NCI and NIH regulations.

The data requested by an investigator may include data generated from laboratory correlative studies. However, this document only covers requests for existing data, not requests for use of tissue or for collection of additional data.

2. Guidelines for Availability of Datasets

For phase 3 studies, it is anticipated that individual-level de-identified datasets that would be sufficient to reproduce results provided in a publication (i.e., published manuscript) containing the primary study analysis would be available to individuals via the requesting procedure described in Section 3 generally within 6 months of publication of the manuscript. It is anticipated that datasets containing patient-level entry data of all baseline variables summarized in the publication would be available within 12 to 15 months after the publication of the primary analysis.

For non-phase 3 studies, a patient dataset containing the variables analyzed in the primary results paper would be expected to be available upon request (subject to restrictions stated in Section 4). This process could take several months. Since these studies could be quite small, the release of data may be constrained by the ability to de-identify data.

For publications that are not presenting the primary analysis of the trial, patient datasets containing the variables analyzed in the paper should be available upon request (subject to restrictions stated in Section 4). This process could take several months.

Release of data collected in a clinical trial conducted under a binding collaborative agreement between the NCI Cancer Therapy Evaluation Program (CTEP) and a pharmaceutical/biotechnology company must be in compliance with the terms of the binding collaborative agreement and must be approved by CTEP. Release of the data is also subject to the terms of any contracts between the Network Group and other entities, which cover any of the requested data. These two considerations could, in some instances, delay the release of data to requesting investigators.

3. Request Procedure

While most analyses of the Network Group's studies are performed at the Network Group Statistics and Data Management Center, the Network Group also makes research data available to other investigators, as required by the policies of the National Institutes of Health. An investigator who wishes to use individual patient data from one or more of the Network Group's studies must make a formal request to the Network Group Operations Center.

The Network Group Operations Center will typically require documentation of Institutional Review Board (IRB) approval (or exemption) from the institution of the requesting investigator which should include a brief description of the project; see Section 4 below. The Network Group Operations Center may also require IRB approval or exemption from the IRB associated with the Network Group Statistics and Data Management Center. The Network Group Operations Center will also typically require the investigator to sign a data use agreement specifying who will have access to the individual patient data and specifying that it will not be shared with others outside this specified set of individuals.

The Network Group Operations Center website should contain a list of the available collections of datasets from their clinical trials, the request procedure, and who to contact to obtain these collections.

There should be no scientific review of requests for data. If a Network Group is unable to fulfill a request, the Network Group Operations Center must inform the investigators of the reasons the request cannot be fulfilled. In most cases it is likely the investigators will be able to amend the request to comply with the procedures. If the Network Group believes the request will not be amendable, the Network Group Operations Center will inform the investigator of the appeal process outlined in Section 6 and also notify the Chief, Clinical Investigations Branch (CIB), Cancer Therapy Evaluation Program (CTEP) in the Division of Cancer Treatment and Diagnosis (DCTD) at the NCI who is also the Lead NCTN Program Director. Release of the data is subject to the disclaimer in Section 5.

4. Regulatory Considerations

All research use of data collected on human subjects from NCTN studies led by the Network Group Operations Center with its associated Network Group Statistics and Data Management Center is subject to applicable Office of Human Research Protections (OHRP) regulations and to applicable regulations of the Privacy Rule of the Health Insurance Portability and Accountability Act. Generally, patients have only consented to have their health information used for the objectives of the clinical trial in which they participated. Use of the data for other research projects is allowed only if an IRB has determined that use of the data in the project meets the minimal risk criteria for conducting the research without the patients' consent, if the use of the data in the project is exempt from consent requirements, or if the project does not constitute human subjects research. The required level of review or approval will generally depend on the degree to which the data have been rendered fully anonymous, de-identified, or coded.

Guidance on these matters can be found in the OHRP document "Guidance on Research Involving Coded Private Information or Biological Specimens" (http://www.hhs.gov/ohrp/policy/cdebiol.html) and at the NIH HIPAA Privacy Rule Information for Researchers site (http://privacyruleandresearch.nih.gov/clin_research.asp). The criteria for de-identification of data under HIPAA are given in the Code of Federal Regulations, Part 46, Section 164.514. It should be possible to conduct most projects using coded data (as described in the OHRP Guidance) that meet the criteria for a limited data set that can be released under a data use agreement (as described in Part 46 of the CFR, Section 164.512 and in the NIH HIPAA guidance documents), without obtaining additional patient consent or authorization.

(**NOTE:** Each Network Group Operations Center and/or Network Group Statistics and Data Management Center may need to add extra requirements imposed by the IRB's covering their Centers.)

5. Release Conditions & Disclaimer

A simple, formal data use agreement specifying who will have access to the individual patient data (and specifying that it will not be shared with others outside this specified set of individuals) as well as covering the release conditions described below and the regulatory considerations described in Section 4 above will usually be required.

It is anticipated that most data requests can be provided as non-complex data sets in electronic form. If possible, data sets from Network Group trials may be provided to the public via a website to facilitate access in the future.

It will sometimes be the case that the data requested for analysis will not all be coded on the Network Group's database but will be available in the paper charts at the Network Group Statistics and Data Management Center. In this case, the data will need to be abstracted from the charts. Data abstractions can only be performed if adequate funding to support the abstraction is available. Even if funding is available, the Network Group may not have staff available to perform the abstraction. In this case, the Group may be willing to have the investigators or their representatives or contractors come to the Network Group Statistics and Data Management Center to perform the abstraction. Some funding for clerical support may still be required. Likewise, in cases in which data requested require data sets not available in easily obtained electronic format, especially older trials, the Network Group may require some funding for support to create the dataset in a simplified electronic format.

In releasing the data, the Network Group makes no representations and extends no warranties of any kind, either expressed or implied. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of the data will not infringe any patent, copyright, trademark, or other proprietary rights. No indemnification for any loss, claim, damage, or liability will be intended or provided.

Copies of any manuscript arising from the project associated with the data request should be sent to the Network Group Operations Center; however, approval of the manuscript is not a condition for use of the data.

6. Appeals Process

If a request for data is denied, the applicant may appeal the decision. The appeal will be reviewed by the designated Network Group Chair, the Lead NCTN Program Director, CTEP Associate Director or his/her designee, and an outside statistician (i.e., a statistician that does not work for the Network Group). The outside statistician will be named jointly by the designated Network Group Chair and the Lead NCTN Program Director.

7. Fees

Routine costs associated with preparing standard data sets are viewed by NCI as covered by the grants for the Network Group Operations Centers and Network Group Statistics and Data Management Centers funded under the NCTN Program and fees should not be charged for release of non-complex electronic data sets. For complex data sets where substantial work is involved, fees may be charged for preparing and documenting the data set. Any fees will be limited to the actual time, effort and materials required for preparing and documenting the data set.