

Data Sharing Policy

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1 Introduction

This document describes general policies of the NCI funded cancer Cooperative Groups on providing individual patient data to investigators for use in research projects. Each group will have a more detailed set of procedures implementing the general policy.

The NCI funded Cooperative Groups conduct clinical trials in cancer research. Each Cooperative Group 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 Group's Statistical 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 Group's studies, with the analyses performed by the staff at the Group's Statistical 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 Group's grant awards. Such requests will be honored as expeditiously as possible.

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 Request Procedure

While most analyses of the Group's studies are performed at the Group's Statistical Center, the 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 Group's studies must make a formal request to the Group. The Group will review the scientific merits and feasibility of the request, as discussed in the following section. Requests for data will only be considered once the primary study analyses have been published.

A brief proposal (1 to 2 pages) must be submitted for review. The proposal must indicate the objectives of the project and briefly describe how the project will be conducted, including a summary of the analysis plan, if appropriate. The proposal must state which cases are to be included in the data set, e.g. list the study numbers and describe any exclusion restrictions, and state what data items are required.

(Note: Each Group should add instructions on how and where proposals should be submitted.)

The Group will conduct an internal review of the merit and feasibility of the proposal, including whether there is sufficient data to provide adequate information for analysis and the availability of the required data. Investigators will be notified of the Group's decisions in writing. If a request is denied, the Group must, in the written decision, state the reasons the request was denied and inform the investigators that a denied request may be appealed as outlined in Section 6. Release of the data is subject to the conditions stated in Section 5.

3 Data Abstractions

It will sometimes be the case that the data requested for analysis will not all be coded on the Group's database but will be available in the paper charts at the Statistical 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 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 statistical center to perform the abstraction. Some funding for clerical support may still be required.

4 Regulatory Considerations

All research use of data collected on human subjects from Cooperative Group studies is subject to applicable Office of Human Research Protections 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/humansubjects/guidance/cdebiol.pdf>) 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 group will need to add extra requirements imposed by the IRB's covering their central office)

5 Release Conditions

Release of data for research purposes is subject to the following conditions. A formal data use agreement covering the relevant conditions will usually be required.

- 1) Investigators must agree to use the data only for the approved research project. If the investigator later wishes to use the data in a new project, a new proposal must be submitted.
- 2) Investigators must agree to keep the individual patient data confidential. The data may only be shared within the team conducting the analysis project. Requests from other individuals for access to the data should be referred to the Group.
- 3) The regulatory requirements discussed in Section 4 must be met.
- 4) In situations where a complex data set is required a fee may be charged.
- 5) Copies of all manuscripts arising from the project must be sent to the Group. Approval of the manuscript is not a condition for use of the data, however.
- 6) If the data is being provided for a project being conducted by the Group, then all other relevant Group policies apply, particularly those relating to authorship and review of abstracts and manuscripts. If the data is being provided for an independent project, then there is no expectation for the Group to have representation on the authorship, unless members of the Group have made substantial contributions to the project.
- 7) 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 and the company. Release of the data is also subject to the terms of any contracts between the Group and other entities, which cover any of the requested data.
- 8) In releasing the data, the 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.

6 Appeals Process

If a request for data is denied the applicant may appeal the decision. The appeal will be reviewed by the Group Chair, the NCI's program officer and an outside statistician. The statistician will be named jointly by the Group Chair and the program officer.

7 Fees

Routine costs associated with preparing standard data sets are viewed by NCI as covered by the Cooperative Group grants. 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.