

	<i>Policy</i>	7.7	<i>Section</i>	7.0	Study Monitoring & Data Collection	<i>Completion Date</i>	July 2006
	<i>Subject</i>	COG Data Sharing Policy				<i>Pages</i>	8
						<i>Approved by</i>	EC9/02 Rev7/06 Approved by Leadership

PURPOSE

In accordance with NCI guidelines for funded Cooperative Groups, this policy describes the release and use of COG individual patient data for investigator-initiated research projects. (http://grants1.nih.gov/grants/policy/data_sharing/index.htm). This document refers to requests for existing data, including data generated by laboratory investigators. It does not cover the following requests:

- Access to banked tissue. The process for requesting COG tissue for laboratory use is described in COG policy 7.7.1, below.
- Information that may be available at COG member institutions for patients treated on COG research protocols, but not previously provided to the COG SDC.
- From NCI, FDA or other federal agencies for information required by federal regulations or by the terms of the Group's Grant Awards.

SCOPE

The COG Statistics and Data Center (SDC) is responsible for the design, data collection, data storage, data quality control and statistical analysis of all COG studies under its purview. This responsibility does not preclude data sharing: such data sharing may be highly desirable and is to be encouraged.

Only data expressly released from the oversight of the relevant COG data and Safety Monitoring Committee (DSMC) are available to be shared. Data sharing will ordinarily be considered only after the primary study manuscript is accepted for publication. Exceptions may be requested through the Group Chair's Office.

DEFINITIONS AND DATA AVAILABILITY

COG Data: COG data are defined to be information generated as a result of research conducted through COG approved protocols; these data include, but are not limited to, clinical trial information, laboratory research data and quality control data collected per protocol specifications, and other research conducted using COG-approved protocols.

Non-COG Data: When research is conducted by non-COG investigators or COG investigators using COG research material that does not require the use of COG data beyond the annotated material provided (as would be the case for laboratory-based research on anonymous banked tissue samples), the data generated belongs to the researchers, although an acknowledgement that the research material was obtained from the COG is expected.

Archived Datasets: Any dataset used in a peer-reviewed publication must be archived at the COG Statistics Data Center. Once a peer reviewed manuscript had been accepted for journal publication, the Group considers the data used to support this communication to be in the public domain and will release its dataset for public use.

DESCRIPTION

Types of data requests

Requests for data from cases registered by a participating Cooperative Group to a COG-coordinated study: Such requests will be automatically honored without review provided the study has been previously released from DSMC monitoring or the DSMC has approved the release of the information

Requests for health-related research projects to illustrate statistical methods or for the use in grant submissions or protocols: Such requests should be made following the request procedure outlined below

Requests for data from pharmaceutical companies or other health related companies: Such requests, in addition to following the request procedure outlined below, must execute a specific contract with the COG which covers the use of the information requested, except in cases where such an agreement was entered into prior to the activation of the protocol.

Requests for archived datasets: Investigators wishing to use the dataset must submit a formal request that describes the purpose of the request as well as the funding for the processing of the request. This should be submitted to the Group Chair's Office (see request procedures, below). The requestor must agree to credit COG in any subsequent publication of the data.

REQUEST PROCEDURE

Consistent with the policies of the National Institutes of Health, COG is prepared to consider requests from investigators who are not members of COG and to make its research data available to them. Investigators who wish to use individual patient data from one or more COG studies must make a formal request to the Group. COG will then review the scientific merits and feasibility of the request, as discussed in the following section. Requests for data will ordinarily be considered once the primary study analyses have been published. Nevertheless, consideration of requests for data will be entertained in the event that there are long delays in the publication of the primary study data.

A brief proposal (no more than 5 pages) must be submitted for review. The proposal must indicate:

1. The objectives of the project
2. Briefly describe how the project will be conducted
3. Summary of the analysis plan, if appropriate.
4. 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.

See Appendix I for outline of information to be provided to the COG prior to its review.

Requests for access to COG protocol research data should be sent to:

Gregory Reaman, MD
COG Group Chair
4600 East West Highway, Suite 600
Bethesda, MD 20814-3457

The Group will conduct an internal review of the merit and feasibility of the proposal, including whether there are sufficient data to provide adequate information for analysis and if the required data are available. Investigators will be notified of the Group's decisions in writing within 6 weeks of receipt. If a request is denied, COG, in the written decision, will provide the reasons the request was denied and inform the investigators that a denied request may be appealed as outlined in the appeals process section below. Release of the data is subject to the conditions outlined in release conditions below.

Data Abstractions

There may be times when the data requested for analysis will not be in the COG database but will be available in the paper charts at the SDC. In such cases, the data will have to be abstracted from the charts. However, data abstraction can be performed only if adequate funding to support the abstraction is available. Even if adequate funding is provided, the Group's SDC may not have staff time available to perform the abstraction. In such cases, and exclusively at the discretion of the COG, investigators or their representatives or contractors,

after signing confidentiality agreements, may be allowed access to patient records at the SDC to perform the abstraction. Some funding for SDC clerical support to facilitate the abstraction may still be required.

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, and 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.

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. Use of data for purposes not expressly authorized by the approved research project constitute a breach of the agreement.
- 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 must be refused and referred to the COG.
- 3) The regulatory requirements discussed in the above section 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 COG. However, approval of the manuscript is not a condition for use of the data.

- 6) If the data are being provided for a project being conducted by a COG investigator, then all other relevant COG Group policies apply, particularly those relating to authorship and review of abstracts and manuscripts. If the data are being provided for an independent (non-COG) project, there is no expectation that members of COG have authorship, unless COG members 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 COG and other entities, which cover any of the requested data.
- 8) In releasing the data, COG 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.
- 9) Under no circumstances will any of the 18 identifiers delineated in the HIPAA privacy rule be provided (the complete list can be found at http://privacyruleandresearch.nih.gov/pr_08.asp). Dates, including dates of birth, diagnosis, registration, enrollment, treatment failure, death, etc. are considered identifiers and will not be provided. Instead time intervals required for analysis will be provided.
- 10) For all data sharing with investigators who are not members of COG, a project-specific identifier which is not the patient's COG identifier will be provided which identifies the research subject. The COG Statistics and Data Center will maintain the record of the patient's COG identifier and the project-specific identifier.

Appeals Process

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

Appendix 1

Process of requesting access to COG data from completed COG protocol research

Provide the following information regarding the request for data from completed COG protocol research. Please keep the proposal to no more than 5 pages. Proposals longer than 5 pages will be returned un-reviewed.

- Title of research proposal
- Project Principal investigator(s), and contact information: address, phone number, e-mail address
- COG protocol(s) from which project data is being requested
- Project primary and secondary aims
- A description of the project's importance: what is to be learned from the research proposed to be performed using the data requested
- A description of the data elements requested and how these data will be used to address the primary and secondary aims of the research
- Description of funding plan for the project to include time and effort allocations for the SDO and SDC

Policy 7.7.1

Requests for Use of Tissue (Please refer to COG policy on Tissue Banking and Research)

The leadership of the COG recognized that the use of tissue collected for Group research is a valuable resource. As such, the material may be requested with a formal collaboration between COG investigators and external investigators (if appropriate)

The procedures outlined below are the methods whereby tissue may be requested

Letter of Intent

Any investigator wishing to develop a collaboration to use COG banked tissue will send a two page letter of intent describing the project to the COG Group Chair's Office and a copy to the CHTN or the appropriate reference laboratory. The criteria employed for review will be:

1. The project must be feasible given the resources of the COG tissue bank
2. The project should have the approval of the appropriate Disease/Discipline committee(s)
3. The project must be of substantial scientific interest
4. The project must not be currently proposed or have overlap with another project by the COG

5. IF over 100 specimens are to be utilized a formal protocol must be submitted and reviewed through the Scientific Council
6. Adequate funding must be obtained prior to the start of the project

The project will be considered in conflict with an existing proposal if an investigator has submitted a written proposal through the disease committee and subsequently to the Scientific Council.

LOI review will take 4-6 weeks. The review will be returned either as accept or reject. Rejected proposals can be resubmitted with justification of the comments provided in the rejection notice. If an LOI is accepted it will proceed through the review of the Scientific Council.

Proposal

The proposal's format should be similar to an NIH grant proposal and contain the following sections:

1. Specific Aims
2. Background and Significance
3. Preliminary Studies
4. Methods

The proposal should be no more than 10 pages in length. The proposal is to be submitted to the COG Group Chair's Office, referencing the LOI number assigned at the time of the acceptance. The proposal must be approved by the Scientific Council after appropriate consultation with COG committees and the SDC.

There are additional considerations that need to be addressed in these proposals. Analysis of genetic susceptibility to disease is associated with complex ethical considerations. A full discussion of the ethical implications of these analyses must be a part of the proposal. The Scientific Council may seek the advice of the COG Bioethics Committee or the COG IRB during the review process of such proposals. A proposal may be summarily rejected based on the review of either of these two bodies.

Proposals that require analyses of specimens in COG resource laboratories will also require affirmative review of the Chair of the COG Translational Research Committee. The methodology proposed must be considered accurate and reproducible. Details of the assay's variability provided must be recently done and attributed to the technicians who will perform the analyses for the proposal. The collaborative agreement will specify how the samples will be disposed of at the conclusion of the proposal.

The proposal will include a timeline for completion. Upon acceptance of the proposal the timeline will be updated according to the availability of staff resources.

Appendix 1 - Letter of Intent Outline

Objectives:

The major study objective, or at most, a limited number of major study objectives (the one or two major scientific questions to be posed by the study).

Background:

A brief sketch, with a few references, outlining the rationale for the objectives. The reason for using COG, rather than another data source, must be clearly described. Although COG is a unique resource, it is heavily used and added demands on investigators must be clearly justified. In addition, proposals to evaluate highly speculative hypotheses are not considered appropriate and will not be approved by the External Review Committee.

Study Design

Describe the data required and the methods that will be used to achieve the stated objectives.

Statistical Section

Describe the primary outcome measures used to assess the study goals. Statistical design must include the target differences (if the study is comparative) or the target parameter (if the study uses historical controls or a fixed parameter).

If accepted, then a full proposal should be developed and submitted to the Group Chair for consideration of the scientific leadership of the Group. The second review will focus on details of proposal and whether there are sufficient resources to accomplish its goals.