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Gynecologic Oncology Group
Data Sharing Policy

1. Introduction

The Gynecologic Oncology Group (GOG) is a National Cancer Institute (NCI) funded cancer Cooperative Group, and follows NCI policies and guidelines applicable to sharing data from NCI supported studies. This document describes the GOG Data Sharing Policy.

The procedures outlined in this Policy do not apply to data requests from the NCI, FDA or other federal agencies. Those requests are handled administratively and as expeditiously as possible.

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

2. Request Procedure

Most analyses of clinical data collected as part of a GOG study are performed at the GOG Statistical and Data Center (SDC), the repository of GOG data. The GOG also has procedures for making either summary data and/or individual patient data available to other investigators under certain circumstances. An investigator who wishes to use data from one or more GOG studies must make a formal request to the GOG. The request is reviewed on the basis of scientific merit and feasibility. Requests for data will be considered only after the primary study analyses have been published.

An investigator may request data by submitting a brief (1 to 2 pages) proposal to GOG for review. The proposal must specify the research objectives and provide a rationale and a description of how the project will be conducted. 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. Finally, it should include a summary of the analysis plan, if appropriate. The proposal should be submitted with a completed GOG Ancillary Study Concept Form. The Form and instructions for completing it can be found on the GOG webpage (https://gogmember.gog.org). Non-GOG investigators can request the Form from GOG at the address below.

Completed data requests should be e-mailed to: protocol_concepts@gog.org. Questions should be addressed to Kia Neff, Director of Clinical Trials Development, Gynecologic Oncology Group. Telephone: 215-854-0770, FAX: 215-854-0716.

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The GOG Ancillary Data Subcommittee will review each request for data. The Subcommittee will review the merit and feasibility of the proposal submitted, including the availability of the required data, whether there are sufficient data to provide adequate information for analysis, and whether there are sufficient data to meet the goals of the study. The Subcommittee does not evaluate requests which require additional data to be retrieved from GOG participating institutions. The Subcommittee then submits a recommendation to the GOG Protocol Development Committee, which votes on approval of the request. Both committees meet to conduct their business during the GOG Semi-annual Group Meeting.

Investigators will be notified of the decision in writing. When a request for data is denied, the written decision will state the reasons for denial and inform the investigator(s) of the appeal process (see Section 6). Release of the data is subject to the conditions stated in Section 5.

3. Data Abstraction

Occasionally, all of the requested data will not be in the GOG's electronic database but may be available on paper forms maintained at the SDC. In this case, it may be necessary to abstract data. Data abstraction may be performed if there is adequate funding to support this effort. If funding is not available or the GOG does not have sufficient staff available to perform the abstraction, the GOG may permit the investigators to travel to the SDC at their own expense to perform the abstraction. In this case, some funding for clerical support may still be required.

4. Regulatory Considerations

All data collected for research purposes on human subjects involved in GOG studies are subject to the applicable regulations of the Office of Human Research Protections regulations and the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). Generally, patients have only consented to have their health information used for the objectives of the clinical trial in which they participated and certain other limited purposes. Use of the data for other research projects is allowed only if the initial informed consent permits it, 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" www.hhs.gov/ohrp/humansubjects/guidance-/cdebiol.pdf, and at privacyruleandresearch.nih.gov/clin_research.asp, the NIH HIPAA Privacy Information for Researchers site. The criteria for de-identification of data under HIPAA are in the

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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. It should be noted that every patient enrolled in a GOG trial has signed a HIPAA authorization prior to enrollment.

The GOG Human Research Committee is responsible for assuring that that data released pursuant to this policy is done so in a manner consistent with these Federal regulatory requirements.

5. Release Conditions

Release of data for research purposes is subject to the following conditions:

a. A written data use agreement will be required.

b. 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, reviewed and approved.

c. Investigators must agree to keep all of the individual patient data confidential. The data may only be shared within the team conducting the analysis for the approved project. Requests from other individuals for access to the data should be referred to GOG.

d. The regulatory requirements discussed in Section 4 must be met.

e. In situations where a complex data set is required a fee may be charged.

f. Copies of all manuscripts arising from the project must be submitted to the GOG for review prior to publication. Approval of the manuscript is not a condition for use of the data, however.

g. If the data are being provided for a project being conducted by GOG, then all other relevant GOG policies apply, particularly those relating to authorship, manuscript development and approval contained in the GOG Publications Policy. The Publications Policy can be found at https://gogmember.gog.org. If the data are being provided for an independent project, then there is no expectation for the

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GOG to have authorship unless GOG investigators have made substantial contributions to the project.

h. 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 GOG and other entities which cover any of the requested data.

i. In releasing the data, the GOG 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

When a request for data is denied, the applicant may appeal the decision. The appeal will be reviewed by the Group Chair, the NCI Program Officer, and an outside statistician. The statistician will be named jointly by the Group Chair and the Program Officer.