

## SWOG CANCER RESEARCH NETWORK

<http://swog.org>

**Policy Memorandum No. 43**

**Subject:** Requests for Participant Data

**Departments Affected:** All

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### REQUESTS FOR PATIENT DATA FROM SWOG STUDIES

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#### 1. Introduction

This document describes SWOG's policy on providing individual patient data to investigators and pharmaceutical companies and sets forth the procedures for processing such data requests.

SWOG Cancer Research Network (SWOG) is a member of the National Clinical Trials Network(NCTN) funded by the NCI to conduct adult clinical trials in cancer research. Each SWOG study has a formal NCI-approved protocol document that includes a statement of the objectives of the study. Participant consent and HIPAA authorization are obtained to collect individual patient data. Participants registered to SWOG trials are assigned a SWOG participant identification number which is used on all study forms and communicated back to the enrolling institution. Most data are entered electronically (either via RAVE, or directly to the Statistics and Data Management Center (SDMC) database. Data from some sources (e.g. pathology reports) are directly faxed to the SDMC, where they are reviewed, processed and entered into the database maintained at the SDMC, which is co-located at the Fred Hutchinson Cancer Research Center and Cancer Research and Biostatistics, both in Seattle, Washington. Data from the various forms are merged using the SWOG patient identifier as the linking variable. While integrated, analytic data sets may be created for specific purposes, the primary source data remain in separate data files that correspond to the data collection form or central patient demographic files. The electronic database is used as the basis for the analysis of SWOG studies, with the analyses performed by staff at the SDMC.

The procedures described in this policy do not cover requests from the NCI, FDA or other federal agencies for information required by federal regulations or by the terms of the SWOG grant awards. Such requests do not require internal review or approval, but are honored as expeditiously as possible.

This document also does not cover requests for collection of additional data not otherwise available or contained in the files of the SDMC. Retrospective collection of data is expensive and time consuming. Requests for such additional data usually require IRB review at each participating site and may require obtaining additional patient consent and/or authorization. SWOG may consider such requests in special circumstances, if adequate funding support will be provided both at the SDMC and at the participating institutions. The

procedures for the collection of such additional data are more complex and are not described herein.

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. Further information is available from the SWOG Website at <http://www.swog.org/>.

## **2. Data Sharing**

While most analyses of SWOG studies are performed at the SDMC, SWOG also makes research data available to investigators and pharmaceutical companies, as required by the policies of the National Institutes of Health (NIH). An investigator who wishes to use a SWOG dataset must make a formal request which is evaluated by SWOG, as discussed in the following section. Requests may be made by investigators who are not members of SWOG (external) or by SWOG investigators (internal). Any SWOG research data may be requested, but requests for data including study endpoints will only be considered once the primary study analyses are published. In rare cases, study endpoint data may be provided prior to publication with approval of the Group Chair's Office, SDMC, and the applicable Disease Committee Chair. Use of data from a Phase III study, prior to general release of the data by the SWOG Data and Safety Monitoring Committee (DSMC), requires approval of the DSMC.

Most data requests involve the analytic files created by the SDMC. Issues relating to requests for additional data not contained in such existing files but which may be available at the SDMC are discussed in Section 4.

It should also be noted that further analyses of SWOG data could also be conducted at the SDMC, in which case the data stays at the SDMC and the analysis is performed by SWOG statisticians. Both SWOG members and external investigators can propose data analysis projects. Such analysis requests would follow the same review process as the data requests and the request should clearly note that the analyses will be performed in the SDMC.

## **3. Genomic Data Sharing**

In accordance with NIH data sharing policies, genomics data generated from SWOG studies are deposited into the database on Genotypes and Phenotypes (dbGaP) to be shared for broad research purposes. The SDMC is responsible for overseeing this process. SWOG genomics studies are typically conducted as companions to SWOG clinical trials and the genomic data are not generated by SWOG. In these instances, the institution generating the genomic data is responsible for reporting to the appropriate database. To facilitate this process, SWOG includes reference to these requirements in its Data Use and Material Use Agreements.

### Timing

Some outcomes measured within clinical trials are available relatively early in the trial, while some of the key outcomes, are not available until the primary endpoint(s) of the trial are met, and because high-throughput genomic data can be generated very rapidly and may be appropriately applied to outcomes available early in the trial, the desire to facilitate data sharing and fully comply with NIH data sharing policies must be balanced against long-standing practices in clinical trials research that have traditionally precluded sharing of data from a study until it is completed and at the time of acceptance of the first publication.

### Institutional Certification

Studies led by SWOG that involve genomic research data will submit Institutional Certification. The Fred Hutchinson Institutional Review Board (IRB) will review the genomic data sharing aspects of projects to assure that the proposal for data submission and sharing is appropriately consented.

#### **4. Guidelines for Availability of Datasets**

As a member of the NCTN program, SWOG will make study data available within the following timing guidelines. For Phase III studies, it is anticipated that individual-level de-identified datasets that include variables sufficient to reproduce results provided in a publication (i.e., published manuscript) containing the primary study analysis would be available to individuals within 6 months of publication of the manuscript. The process for requesting data is described in Section 4.

For non-Phase III studies, a patient dataset containing the variables analyzed in the primary results paper would similarly be expected to be available (subject to the restrictions stated in Section 7). Since these studies could be quite small, the release of data may be constrained by the ability to de-identify data.

Ancillary data not used in the primary analysis will also be made available. The timing for release will be subject to availability of staff time to address the request.

For publications that do not contain the primary analysis of the trial, patient datasets containing the variables analyzed in the paper should be available as above (subject to the restrictions stated in Section 6).

#### **5. Request Procedures**

An investigator who wishes to use individual patient data from one or more of the SWOG's studies (see section 3) must make a formal request to the SWOG Network Group Operations Center. SWOG 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 (approximately 2 pages) of the project. The Network Group Operations Center may also require IRB approval or exemption from the IRB associated with the SDMC.

The SWOG Network Group Operations Center will also 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 of the scope of the project.

There should be no scientific review of the request for data; however availability and regulatory issues will be evaluated. If SWOG is unable to fulfill a request, the SWOG Network Group Operations Center will inform the investigators of the reasons the request cannot be fulfilled. If SWOG believes the request will not be amendable, the SWOG Network Group Operations Center will inform the investigator of the appeal process outlined in Section 9 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.

#### **6. Data Abstractions**

On occasion, data requested for analysis will not all be coded into the SWOG data base but may still be available at the SDMC. Such requests for data abstractions will only be performed if both adequate funding to support the abstraction is provided and SWOG staff support is available to perform the abstraction.

As an alternative to the SDMC conducting the data abstraction, investigators, their representatives or contractors may perform the abstraction at the SDMC. In this situation, funding for clerical support at the SDMC may still be required. As the records to be reviewed by non-SWOG personnel necessarily contain potentially identifiable patient data, a considerably higher risk to patient confidentiality is created. Therefore, more stringent regulatory approvals and data use agreements will be required in this situation.

## 7. Regulatory Considerations

All research use of data collected on human subjects from studies led by SWOG 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 (HIPAA). Generally, participants 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, that the use of the data in the project is exempt from consent requirements, or if the project does not constitute human subjects research. The level of review or approval will generally depend on if the data required for the project can be fully rendered anonymous, coded, or de-identified. 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](http://privacyruleandresearch.nih.gov/clin_research.asp)). The criteria for de-identification of data under HIPAA are given in the Code of Federal Regulations (CFR) Title 45, 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 45 CFR, Section 164.512 and in the NIH HIPAA guidance documents), without obtaining additional patient consent or authorization.

The SDMC is overseen by an IRB at both the Fred Hutchinson Cancer Research Center and Cancer Research And Biostatistics in Seattle, Washington. These IRBs require that documentation be provided that the investigator's local requirements for conducting the research have been met prior to releasing the data. Usually this consists of one of the following:

- A. An approval or waiver from the local IRB for conducting the research without obtaining the patients' consent.
- B. Documentation of an exemption issued by their local IRB (note: it is up to IRB officials, not individual investigators, to determine if research is exempt).
- C. A statement from a local IRB official that the project does not constitute human subjects research (for example, because of anonymization or de-identification), and therefore does not require review.

Subject to the policies of the local IRB, for research projects using only data from existing databases (that is, with no additional patient contact or data collection), it is usually possible to obtain a waiver through an expedited review. Generally, b) and c) above are only appropriate if the data set to be provided can be fully de-identified.

## 8. Release Conditions and Disclaimer

It is anticipated that most data requests can be provided as non-complex data sets in electronic form. SWOG will release data for research purposes, subject to the following conditions:

- A. SWOG will require a signed data use agreement covering the specific use of the data provided.
- B. Investigators must agree to keep the individual participant data confidential. The data may only be shared within the team conducting the analysis project. Any additional use of the data or requests from other individuals for access to the data should be referred to SWOG.

- C. The regulatory requirements discussed in Section 6 must be met.
- D. Applicable fees for complex non-coded data or additional abstraction must be paid (see section 8).
- E. Copies of all publications arising from the project should be sent to the SWOG Network Group Operations Center at [pubs@swog.org](mailto:pubs@swog.org) ; however, approval of the manuscript is not a condition for use of the data. If the purpose of releasing the data is for a SWOG project, then all other relevant SWOG policies apply, particularly those relating to authorship and review of abstracts and manuscripts. If the data are being provided for an external independent project, there is no expectation of SWOG representation in authorship, unless members of SWOG are active collaborators or have otherwise made substantial contributions to the project. Publications resulting from access to standard SWOG datasets for independent projects that do not include active SWOG collaboration and authorship must carry the following disclaimer: "SWOG is a member of the National Clinical Trials Network supported by the National Cancer institute (NCI). This manuscript was prepared using a limited access data set obtained from SWOG and does not necessarily reflect the opinions or views of SWOG or the NCI".
- F. Data are released only to extent that the release does not breach other contractual and legal obligations of the Group.
- G. 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. Copies of all publications for such trials must be sent to the NCI's Regulatory Affairs Branch ([NCICTEPpubs@mail.nih.gov](mailto:NCICTEPpubs@mail.nih.gov)) for review as soon as they are received. NCI will review proposed manuscripts and abstract to assure that confidential information is protected.
- H. 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.

## **9. Fees**

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

## **10. Appeals Process**

If a request for data is denied, the applicant may appeal the decision. The appeal will be reviewed by the SWOG 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 SWOG Group Chair and the Lead NCTN Program Director.