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**REQUESTS FOR PATIENT DATA
FROM INVESTIGATORS AND PHARMACEUTICAL COMPANIES**

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1. Introduction

This document describes the Southwest Oncology Group’s (SWOG) policies on providing individual patient data to investigators and pharmaceutical companies and sets forth the procedures for processing such data requests.

SWOG is a National Cancer Institute funded Cooperative Group conducting clinical trials in cancer research. Each SWOG study has a formal protocol document that includes a statement of the objectives of the study. Patient consent and HIPAA authorization are obtained to collect individual patient data. Patients registered to SWOG trials are assigned a SWOG patient identification number, which is used on all study forms and communicated back to the enrolling institution. The data are entered onto study forms (electronic or paper) and transmitted to the SWOG Statistical Center by the treating or enrolling institution.

The data from the paper study forms are reviewed, processed and entered into the SWOG database maintained at the SWOG Statistical Center, co-located at the Fred Hutchinson Cancer Center and Cancer Research and Biostatistics both in Seattle, Washington. However, not all information submitted on the forms becomes part of the electronic database, e.g., some free text fields may not be captured. Data from the various forms are merged using the SWOG patient identifier as the linking variable. While integrated, analytic datasets 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 SWOG Statistical Center.

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 SWOG Statistical Center. 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 Statistical Center and at the participating institutions. The procedures for the collection of such additional data are more complex, though, and are not described herein.

Requests for data may include data generated from SWOG correlative studies. However, only requests for existing data are covered by this document. Requests for use of tissue are covered by separate review procedures. Further information is available from the SWOG Operations Office.

2. Data Sharing

While most analyses of SWOG studies are performed at the SWOG Statistical Center, SWOG also makes research data available to pharmaceutical companies and investigators, as required by the policies of the National Institutes of Health. An investigator who wishes to use a SWOG data set must make a formal request which is reviewed 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). Internal requests can be either directly related to evaluating study objectives (in cases where analyses cannot be performed at the Statistical Center) or for projects unrelated to study objectives. 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 SWOG Statistical Center 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 SWOG Statistical Center. Issues relating to requests for additional data not contained in such existing files but which may be available at the SWOG Statistical Center are discussed in Section 4.

It should also be noted that further analyses of SWOG data could also be conducted at the SWOG Statistical Center, in which case the data stays at the Statistical Center and the analysis is performed by SWOG statisticians. Both SWOG members and external investigators can propose database 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 SWOG Statistical Center.

3. Review Procedures

There are several different types of data requests that can arise. The review procedures vary based on the type of request submitted and who the submitter is. In all cases, a written response to the data request will be provided by SWOG. If a request is denied, SWOG's written response must include the reasons for the denial. Denied applicants must be informed of the ability to utilize the appeal process set forth in Section 8.

3.1 Requests from statistical centers of other cooperative groups

Requests for data only on cases registered by the requesting group on SWOG coordinated intergroup studies. These requests are automatically honored, and no review is required, although a brief proposal (approximately 2 pages) indicating the project objectives and analysis plan must be submitted. SWOG does reserve the

right to limit the frequency of such requests, and release of data from phase III studies is subject to review and approval by the SWOG DSMC. The requesting Statistical Center's IRB approval is assumed to cover the use of the data. No fees will be assessed as long as the requesting group has a reciprocal policy, otherwise a fee per Section 7 below may be assessed.

Requests for data on cases entered from groups other than the requesting group. These requests are processed as in Section 3.2 below.

3.2 Requests for data for use in health related research projects

To request existing data for use in health related research projects, a brief proposal (approximately 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, i.e., describe inclusion and exclusion criteria, and state what data items are required. The SWOG Statistical Center will perform the initial review of the application and may suggest changes based on data actually available. Either the original request following SWOG Statistical Center review or a revised proposal, if required, will be reviewed by the SWOG Executive Committee. The Executive Committee will consider the scientific merits of the project, whether there is sufficient data to provide adequate information for analysis, the availability of the required data, and the potential costs. For internal requests, the feasibility of performing the analysis at the SWOG Statistical Center versus providing a data set for outside analysis will also be considered. Finally, the Executive Committee will decide whether a SWOG co-author is needed. This decision will depend upon the intended audience for the resultant publication, the expertise of the submitting group, and the likelihood of correct clinical interpretation of the data.

Investigators will be notified of the Executive Committee's decision, and provided with an estimate of potential fees, if appropriate. Release of the data is subject to the conditions stated in Section 6.

3.3 Requests for data to illustrate statistical methodology

Requests for data sets to use for illustration of statistical methods (both design and analysis) in papers intended for publication in the statistical literature should be submitted in writing to the SWOG Statistical Center as well. A brief proposal describing the nature of the project and the data required should be included. If the data set has previously been used for illustrative analysis in statistical papers, and the data set appears to be appropriate for the project, then the SWOG Statistical Center can approve the request without further review. Release of the data is subject to the conditions stated in Section 6. Typically no fees will be assessed for use of an existing data set. If the data have not previously been used in a statistical paper, then the request will be reviewed by the SWOG Executive Committee, as described in Section 3.2.

3.4 Grants and protocols

Special projects, especially but not limited to laboratory correlative projects, sometimes involve submission of grant applications for separate funding. Grants submitted with requests to use data or tissue from SWOG cases must be reviewed by SWOG or the Intergroup (when intergroup data are involved) prior to submission and may only be submitted with SWOG's approval. Such projects may involve sending clinical data to other locations, such as to the institution performing the lab

work, for analysis. If the specific data required and a summary of the analysis plans were clearly described in the grant at the time of SWOG review, and SWOG and the funding agency have approved the grant, then data requests for these projects will be approved without further review. The release conditions in Section 6 still apply. If the data requested or the planned analyses go beyond what SWOG had agreed to at the time the grant was reviewed, then the request must be reviewed by the SWOG Executive Committee, as described in Section 3.2 above.

Similar considerations apply to specialized analyses written into SWOG protocols. It may sometimes be necessary to send data outside the Statistical Center for these analyses. As long as the details, including the location where the work is to be performed, the data needed for analysis, and a summary of the analysis plan, have been given in the protocol, and provided the protocol has received all required approvals, then further review of the data request is not needed. The release conditions in Section 6 still apply however.

3.5 Pharmaceutical companies

Data provided to pharmaceutical companies is generally for regulatory rather than research purposes. Provided that a contract has been executed with SWOG covering the request, further review is not required. For Phase I and II studies conducted under a CTEP IND, all data provided to the government through the Clinical Data Update System (CDUS), will be made available to the pharmaceutical sponsor for information purposes only and that this disclosure shall not impact or circumvent the investigator's right to publish or present. For Phase III studies, only CDUS abbreviated data and AdEERS reports will be provided to the company sponsor. For studies, regardless of phase, with multiple pharmaceutical sponsors involving combination drugs/therapies, additional language may be contained in the contract which requires disclosure of the multi-party study data to both sponsors. In such instances, the applicable sponsor contracts will be reviewed to ensure consistency but disclosure of the data is still subject to the policies of the DSMC. For further access to additional data, the company sponsor must negotiate with SWOG, receiving the approval of both the Executive Committee, as set forth in Section 3.2. and DSMC, pay any additional applicable costs, and be subject to the release conditions included in Section 6 below.

4. Data Abstractions

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

An alternative to the SWOG Statistical Center conducting the data abstraction is for the investigators, their representatives or contractors to perform the abstraction at the SWOG Statistical Center. In this situation, funding for clerical support at the SWOG Statistical Center 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.

5. Regulatory Considerations

All research use of data collected on human subjects from SWOG 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, that the use of the data in the project is exempt from consent requirements, or that 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, as described in the Code of Federal Regulations, Part 46, Section 164.514. Please note, though, that if patient specific dates or geographic locators are needed, then the data may not qualify as de-identified and some form of waiver of consent will be required.

The SWOG Statistical Office is overseen by an IRB at both the Cancer Research and Biostatistics offices and Fred Hutchinson Cancer Research Center 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 generally 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. Data sets that contain no facially identifiable information and no patient specific dates may qualify as de-identified.

6. Release Conditions

Release of data for research purposes is subject to the following conditions. SWOG may require a signed letter of agreement or a formal data use agreement covering the relevant conditions.

- 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 SWOG.
- 3) The regulatory requirements discussed in Section 5 must be met.
- 4) Applicable fees must be paid.
- 5) Copies of all manuscripts arising from the project must be sent to the SWOG Statistical Center.
- 6) 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 independent project, there is still a general expectation of SWOG representation on the authorship, although this will be assessed on a project-by-project basis.

- 7) Any applicable contracts relating to the provision or use of the data must have been executed.
- 8) 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.
- 9) 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.

7. Fees

SWOG will charge recipients for the costs of preparing and documenting data sets, unless otherwise stated herein. For academic researchers, charges will be limited to personnel time at regular salary and fringe rates and the actual costs of any materials, plus administrative fees. For other requesters, additional fees in addition to these charges may apply. The estimated costs will be provided to the requesting investigator in advance of commencing work as payment is required upfront. These charges can be waived at SWOG's sole discretion.

8. Appeals Process

If a request for data is denied, the applicant may appeal the decision. The appeal will be reviewed by the Group Chair or his/her designee. The decision of the Chair or designee is final.