

SOUTHWEST ONCOLOGY GROUP

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Policy Memorandum No. 15

Subject: Applicability of IND Applications and Investigator
Brochures/Support from Pharmaceutical
Companies

Departments Affected: All

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APPLICABILITY OF IND APPLICATIONS AND INVESTIGATOR BROCHURES/ SUPPORT FROM PHARMACEUTICAL COMPANIES

Investigational New Drug Applications

Authorization from the Food and Drug Administration (FDA) must be secured prior to the interstate shipment and administration of investigational new drug (IND) to human subjects (Title 21, Code of Federal Regulations, Parts 312 and 314). The FDA requires an application from an individual, pharmaceutical firm or research organization to sponsor clinical studies on a new drug for investigational use or a previously approved drug used for new indications.

The Southwest Oncology Group Investigational New Drug Program was implemented in September 1992, in response to an increasing number of Group clinical trials with investigational new agents for which the National Cancer Institute (NCI) did not hold the IND application. In cases where the NCI does not hold the IND, the Group IND Program is responsible for the submission of IND applications to the FDA for all Group-sponsored studies in which a new drug will be used or an established drug will be prescribed for a new indication.

Group investigators interested in conducting clinical trials with a new application of an investigational drug should contact the specific disease committee chair or protocol coordinator in the Operations Office.

A Drug Master File (DMF) was originally submitted by the Operations Office to the FDA in January 1993 and is updated annually. This DMF is intended to support the cancer research activities of the Group. IND applications will be primarily cross-referenced INDs.

Investigator's Brochures

The FDA Guidance web site includes the following language regarding Investigator's Brochures (IB) (<http://www.fda.gov/oc/ohrt/irbs/toc4.html> - under 2. "Charging for Investigational Drugs and Biologics," (ii) "Treatment Protocol or Treatment IND", 2nd paragraph): "There is no specific regulatory requirement that the Investigator's Brochure be submitted to the IRB. There are regulatory requirements for submission of information which normally is included in the Investigator's Brochure. It is common that the Investigator's Brochure is submitted to the IRB, and the IRB may establish written procedures which require its submission."

Submission of the IB is an institutional issue and the Southwest Oncology Group has not required submission of the IB to the IRB as part of its institutional audits. It is commonly held that an IB is not needed at all for studies using only commercially available drugs. Rather, information about these drugs is publicly available in the Physician's Desk Reference (PDR), prescribing information and other resources.

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For protocols that are performed under an Investigational New Drug application (IND) that is held by the Southwest Oncology Group, the Group's application to the FDA specifically states that the protocol serves as the IB for the purposes of the study. As the protocol is required to include all relevant drug safety information, the relevant information from the IB is therefore made available to the IRB. This further ensures that additional company proprietary information contained in the IB is not needlessly disclosed.

In such instances involving a Group held IND, submission of the protocol to the IRB should suffice for the purpose of providing an IRB with information about a drug. The Group, however, does maintain contacts with the pharmaceutical companies providing drug for Group studies when the Group holds the IND. If necessary, company contact information can be provided to institutions on a drug and protocol-specific basis to allow an institution to request an IB directly from the company. For such company information, please contact the Group Protocol Coordinator for the relevant study in the Operations Office.

For protocols that are performed under an IND that is held by the National Cancer Institute (NCI), the NCI is able to provide copies of the IB upon request if the institution is participating in an NCI protocol using the drug. These can be requested from the NCI Pharmaceutical Management Branch.

Contract Negotiations for Protocol Support

The Southwest Oncology Group and the pharmaceutical industry may enter into scientific liaisons for the purpose of conducting clinical investigations of new anticancer agents or other cancer therapies, or for the collection of additional data management and statistical analyses. These activities are pursued after the Southwest Oncology Group and pharmaceutical company enter into a mutually acceptable contract for the conduct of the trial. Such collaborations represent an opportunity by which scientific questions of interest to the Group and a pharmaceutical company may be answered by making maximum use of the resources of each organization.

Pharmaceutical companies may provide financial support for equipment, data management, statistical analysis, investigational or non-investigational drug supply and distribution, quality of life assessment, pharmacologic specimen analysis, collection of financial disclosure forms, and/or data monitoring visits. Financial reimbursement to the Group from pharmaceutical companies must be arranged by contract to cover costs and overhead incurred by the Group. Examples of resources provided by the Group include: patient accrual to the study; data management and/or statistical analysis; pharmacologic specimen collection; financial disclosure information; and evaluation and publication of the results.

In order to provide the necessary non-grant funding for the costs of contract performance and scientific/administrative services related to pharmaceutical industry collaborations, a 25% administrative handling fee will be assessed to the total dollar budget. These fees will be delegated but not limited to the following costs which are directly associated with pharmaceutical contracts:

- Contract: negotiation, preparation, execution, government interaction, retention, modification, tracking
- Protocol: modification to accommodate pharmaceutical interaction, review, discussion, revision, coordination
- Administrative: Copying, supplies, computers, phones, mailing, study activation, website updates, communication with sites for initiation
- SAEs: reporting, database maintenance, communications
- Activation: communication with government, study review/discussion/triage, study specific conference calls

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- Accounting costs - includes invoicing/tracking sponsor payments and creating of reports

There will be no pharmaceutical representative on the Data and Safety Monitoring Committee. The data base will be maintained at the Group Statistical Center, and publications will be the sole responsibility of the Group, without pharmaceutical co-authors or involvement.

As negotiated and contained in the contract and following contract execution, pharmaceutical firm representatives may accompany Group representatives on audits of the institutions participating on a Study to check that investigators are in regulatory compliance. This review may include items such as informed consent, institutional assurance, and validation of individual patient eligibility but will not include review of individual patient data generated while on Study. This monitoring may also include the review of safety data on file in the Group Operations Office.

At no time prior to contract execution and study activation may the potential pharmaceutical collaborator advertise, publish or otherwise disclose information concerning the proposed trial to the public absent the review and approval of the Group's authorized officials.

Written documentation of all aspects of the collaboration between the Group and pharmaceutical company must be assured and agreed upon by all parties. This is handled by the Group Operations Office in collaboration with the Headquarters Office. Please see Policy #34 (Industrial Interaction) for further information.