

## **SOUTHWEST ONCOLOGY GROUP**

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**Policy Memorandum No. 34**  
**Subject:** Industrial Interaction  
**Departments Affected:** All

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### **INDUSTRIAL INTERACTION**

As a clinical trials network funded by the National Institutes of Health, the primary mission of the Group is to make progress in the prevention and cure of cancer through clinical research. A major factor in meeting this mission is the commitment to generate and disseminate knowledge in the public interest. The Group has for many years enjoyed a close relationship with industry. This relationship has, in large measure, flourished because it is based on the conviction that new knowledge and discoveries occur throughout society and that the movement of knowledge is never unidirectional.

To ensure the free flow of information and generation of public knowledge, the Group will not enter into or renew any contract that would restrain its freedom to disclose the existence of the document, the identity of any collaborator of the proposed research, or the purpose and scope of the proposed research. Further, the Group does not accept grants, contracts, or agreements for research which restrict its members from publishing or otherwise disseminating the results of the research, consistent with Group Policy #24 and related policies.

In order to better ensure patient safety in Group clinical trials, at no time prior to contract execution and study activation may the industrial 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. Further, assuming contract execution and trial activation occur, prior to issuing a press release that references the Study or its results, or that uses the other party's name or trademarks, the parties agree to provide reasonable prior review and comment by the other party. Both parties agree to comply with the request of the other party for the removal of confidential information, previously identified as such, from the press release prior to publication. Neither party shall reference the Study or its results or use the other party's name or trademarks for promotional or advertising purposes absent the other party's prior written consent.

When working with industry collaborators, it is important for the Group's status as a consortium of academic institutions, hospitals, community hospitals, community-based physician cooperatives, and individual physician offices to be expressed and preserved. Thus, individual investigators are not authorized to commit Group resources to any collaborative studies with industry without the formal notification and approval by Southwest Oncology Group Headquarters. The development of any contract will be handled through the Southwest Oncology Group Operations Office with assistance by the Headquarters Office.

There is the potential that any Southwest Oncology Group Investigator, Committee Chair, Study Coordinator or Statistician may approach (or be approached) by an industrial sponsor for one of the following reasons:

- possible collaboration of any sort
- gain access to Group data, serum specimen or tumor bank specimens
- potential supply/distribution of a drug for a study

- provide financial support for a clinical trial or any ancillary study
- provide funds to the Group as a whole or to any subset, committee, or office of the Group

Should any of the above situations occur the following steps must be taken:

1. The applicable Executive Officer of the Southwest Oncology Group must be notified immediately in writing by email or otherwise by the Group Investigator, Committee Chair, Study Coordinator or Statistician/Operations Office who has had contact with an industrial collaborator.
2. The individual having the initial communications with industry must inform his/her industry contact that all negotiations must take place through the Group's appropriate administrative personnel.
3. This free flow of information will allow for prompt action to conclude negotiations with the industrial collaborator and to keep all relevant Group members informed.
4. All negotiations leading up to a final contract will be performed by the Operations Office with assistance from the Headquarters Office. Such negotiations must result in a contract which is consistent with the Clinical Trials Cooperative Group Guidelines, grant award restrictions, awarding agency requirements, federal regulations, and Group policies and procedures.
5. All final contracts must be approved and signed by the Group Chair.