Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: ALL SOUTHWEST ONCOLOGY GROUP MEMBER, CCOP, UCOP AND AFFILIATE INVESTIGATORS AND CLINICAL RESEARCH ASSOCIATES

FROM: SWOG Operations Office

DATE: September 15, 2007

SUBJECT: Investigator's Brochures (IBs)

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 commercially available drugs. Rather, information about these drugs is publicly available in the Physician's Desk Reference (PDR), prescribing information and other resources.

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 at 301/496-5725.

Please do not hesitate to contact any Protocol Coordinator in the Operations Office at 210/450-8808 if you have further questions.

PC/dbs

cc: Headquarters Office staff
Statistical Center staff