

September 2003

Submission of Group-Specific 1572 and CV

The FDA form 1572 and additional supporting documentation (in our system a copy of the investigator's CV) serve as statements of investigator qualification for performance of NCI-sponsored protocols. In previous years Southwest Oncology Group investigators have been required to submit one set of documents to the NCI's Pharmaceutical Management Branch (for studies using drug supplied under an NCI-sponsored IND) and another set of documents to the Southwest Oncology Group (for studies using drug supplied under a Southwest Oncology Group-sponsored IND).

We have recently received permission from the NCI's Pharmaceutical Management Branch to allow us to use their files of investigator registration and qualification documents for studies using drug supplied under a Southwest Oncology Group-sponsored IND. So, effective November 1, 2003, Southwest Oncology Group investigators will no longer be required to submit a separate set of qualification documents annually to the Southwest Oncology Group. The single submission of these documents to the Pharmaceutical Management Branch will suffice for both NCI-sponsored IND studies and Southwest Oncology Group-sponsored IND studies.

NOTE: Please ensure that your NCI regulatory documents are current. The Statistical Center registration program rejects all registrations by any investigator whose 1572 and CV are not current.