EFFECTIVE JANUARY 6, 2003
NEW REGULATORY SUPPORT SYSTEM (RSS 2.0)

As of January 6, 2003, there will be a new procedure for all NCI-sponsored (Phase I, II, and III) Cooperative Group clinical trial regulatory documents, with the exception of certain prevention trials: STAR, SELECT, BCPT, PCPT, and GOG 0190. All regulatory documents will be submitted to the Central Regulatory Office located in Philadelphia, PA and to the Southwest Oncology Group Operations Office in San Antonio, TX.

There will be two new required submission forms. These forms are the CTSU IRB/Regulatory Approval Transmittal Sheet and the CTSU IRB Certification Form. The CTSU IRB/Regulatory Approval Transmittal Sheet will act as a cover sheet to ensure submitted regulatory document packets are received in their entirety. The CTSU IRB Certification Form will contain all the essential data elements required to ensure proper entering of data into the RSS 2.0 database. More information, including the RSS Quick Facts Sheet and Forms, are available from the RSS tab on the CTSU website (www.ctsu.org).

Once your institution's IRB has reviewed and approved a study, please complete these forms and mail or fax to both addresses below.

Coalition for National Cancer Cooperative Groups
1818 Market Street
Suite 1100
Philadelphia, PA 19103
FAX: (215) 569-0206

Southwest Oncology Group Operations Office
14980 Omicron Drive
San Antonio, TX 78245-3217
FAX: (210) 677-0006

If your institution is participating in SELECT or PCPT, please mail or fax these specific IRB approvals to the Southwest Oncology Group Operations Office only. You may continue using the SWOG IRB Certification form if you choose.