S1400 Guidance on an FDA Inspection

S1400 has the potential for FDA registration for each sub-study and as such, has the potential to be inspected by the FDA . While it is anticipated that the highest accruing sites are the most likely to be targeted for an inspection, all sites participating in **S1400** should be prepared for an FDA inspection. This is the first of a three part series designed to help sites prepare for a possible FDA inspection. Part Two will address instructions for handling and accountability of investigational agents. Part Three will address what to expect during an inspection and how to interact with the FDA.

A **Trial Master File** contains **essential documents** for a clinical trial that may be subject to FDA oversight. These documents show whether the investigator has complied with the principles and guidelines of good clinical practice and with the applicable regulatory requirements. In preparation for a potential FDA inspection, a **Trial Master File** must be created by assembling the following documents in a central location and must be maintained by routinely updating these documents with the most current version on an as needed basis.

Regulatory documents

- IRB approval documents of initial review, annual continuing review, revisions/amendments, safety reports and memos
- Correspondence between the IRB and the investigator/institution
- Reports of protocol deviations
- All approved informed consent versions
- Policy on alternate procedures for submission of external safety reports and internal SAEs, if applicable
- IRB composition (list of board members)

- Copy of the most current protocol which includes the Monitoring Plan and Investigator Brochures
- CLIA Certificates and list of normal lab values/ranges for any clinical lab which performs laboratory testing for protocol assessments
- List of local SOPs related to the research process
- Site training documents (GCP, **S1400** specific, etc.)
- Site Authority Log (delegation of authority)
- Communications with sponsor (Study Chair, Data Coordinators, QA, etc.)
- Monitoring reports

The following documents are maintained centrally by the NCI or SWOG:

- Current 1572s and CVs
- Current Financial disclosures
- Affirmation of Integrity – per SWOG Policy #36
- Certification of Education in the Protection of Human Subjects – per SWOG Policy #37
- Data and Safety Monitoring Committee correspondence – per SWOG Policy #21

These documents will be subject to audit and must be available for inspection by regulatory agencies. For questions, please contact Elaine Armstrong at the SWOG Operations Office at (210) 614-8808 or qa@swog.org.