SWOG-VA CONSORTIUMS

The mission of a VA Consortium is to facilitate access to NCI-funded clinical trials through participation in SWOG and other NCTN network groups, allowing Veterans a broader and more accessible avenue to innovative cancer clinical trials by including more treatment resources for them. The overall goal of a VA Consortium is to provide support in creating infrastructure and operational processes to perform clinical investigations that will contribute toward traditional research objectives, advance clinical care, and provide measurement of healthcare system equality.

A VA Consortium would incorporate multiple VA centers under the direction of a Storefront/Main Member parent site (herein referred to as the Storefront), with a Principal Investigator identified who will assume responsibility for the overall scope of the VA Consortium. The Principal Investigator will ensure that each site meets the policies, procedures and standards set forth by SWOG, notifying SWOG of important changes in member relationships, agreeing to quality assurance audits, and communicating all policies (and any changes in policy) on the conduct of clinical research to staff members. SWOG Policy No. 46 will describe the Principal Investigator responsibilities in more detail.

Additionally, a Head Clinical Research Associate (HCRA) must be identified as a primary contact for the VA Consortium. The HCRA will act as the liaison between SWOG and the Principal Investigators, sub-investigators and staff. The HCRA will work with investigators and staff to ensure that research is done in accordance to SWOG policies and regulations. The HCRA may also be responsible for handling financial aspects; overseeing staff; maintaining investigator and staff rosters and roles for access to CTSU applications (e.g., RUMS, OPEN, RAVE, TRIAD); Institutional Review Board (IRB) submissions to the local IRB, CIRB and CTSU; and, other general administrative tasks.

The Storefront should have the capability of entering a minimal annual average accrual of 10 initial SWOG-credited registrations based over a three-year period with acceptable quality control, record-keeping, and excellent protocol compliance. SWOG Policies No. 3 and No. 33 will describe the criteria for membership status and performance expectations in more detail.

The Storefront will assume the responsibility of assuring that research is being properly conducted, recruitment goals are being met, reporting of adverse events and filing of regulatory documentation is timely, research is conducted safely, and study close-out procedures are executed properly. The Storefront will also ensure the appropriate hiring and training of staff and provide the tools necessary for successfully conducting research.

Elements of responsibility and rights include, but are not limited to:

- Provide guidance for operational and logistical aspects of participating in SWOG/NCTN trials.

- Provide instruction to site physicians and research staff in SWOG procedures, assuring data are submitted at appropriate intervals, and monitoring each site's overall participation.

- Oversee the data management, registrations, regulatory data, and financial aspects (i.e., execution of SWOG and SWOG-CTI Purchase Service Agreements /Amendments / Subawards) for each site, in conjunction with the associated VA site nonprofit corporation (NPC) where appropriate.

- Assure that quality control and quality assurance guidelines are met.

- Provide education to sites in the collection and shipment of specimen samples.

- Review and assess NCTN protocols for potential barriers to participation at VA sites.

- Provide support for site audits, including preparation and pre-review of audit documents to ensure compliance with SWOG policies during the formal audit, as well as follow-up to address any non-compliance or areas for improvement.

- Manage site rosters and roles through CTSU-RUMS; although, it is acceptable to designate Co-Lead CRAs to manage site rosters at the local level.

- Convene regular teleconferences to review new trials for feasibility and expansion and discuss emerging issues in oncology.

- The Storefront has the right to add sites to their consortium at any time to foster the development of research programs within the site.

- The Storefront has the right to withdraw individual sites for any reason and at any time. These reasons may be due to continued lack of participation/accrual to clinical trials or not following/meeting the requirements set forth (as outlined below) for site participation.

The VA Storefront also has the right to create certain requirements for the sites to participate within the Consortium. Examples of these requirements may include:

- Adherence to all SWOG policies, including trial participant follow-up requirements.

- At least one site staff member must attend at least one SWOG Group Meeting per year.

- At least one site staff member must attend at least 10 SWOG-VA Consortium calls per year.

- Agreement to attend (by phone) one internal review conducted by Storefront team per year, to review metrics, progress, and any issues at the site.