Trial Activation and Facilitation Resources

Online resources are accessible via hyperlinks below (login required, where indicated).

Identifying Upcoming Studies:

SWOG Protocol Development Tracking Reports and Dashboards (login required)

- These webpages provide real-time status updates on SWOG-led studies in the development pipeline, including targeted activation dates.

Feasibility Assessment Tool: Clinical Trial Review Guide

Getting Started with CTSU and NCI Applications:

CTSU Operations Training Modules, accessible via CTSU.org >> Resources >> CTSU Operations Information >> General Procedures & Training (login required)

Site Rostering:

- CTSU RUMS User Guide (login required) and
- SWOG FAQs: Systems Access and Rostering Maintenance

Site Initiation: Refer to Section 13 of the SWOG-led protocol.

- SWOG FAQs: Funding, Financials, and Study Payments
- The CTSU Site Registration Help Topics (login required)
- NCI CIRB Standard Operating Procedures and Start Guide (login required)
- NCI CIRB How to Open a Study Guide (login required)
- The CTSU Regulatory Submission Portal User Guide (login required)

Participant Enrollment: Refer to Section 13 of the SWOG-led protocol.

- Oncology Patient Enrollment System (OPEN) user guide (login required)
- Open Funding (login required)

Data Submission and Management:

- CTSU Rave Roles, Training, and Resources (login required)
- CTSU Data Quality Portal (DQP) Help Topics (login required)
- SWOG Patient Reports and Tools for Data Quality (login required)
- SWOG List of Studies with No Required Follow-up (login required)
- SWOG FAQs: Data Submission and Management (login required)

Key Guidance for SWOG-led Study Implementation:

- SWOG CRA Manual for Oncology Research Professionals (login required)
- SWOG Best Practices Document
- SWOG Quality Assurance & Audits, includes essential guidelines.

Key SWOG Policies and Procedures for Study Management:

Policy 12	SWOG Registration and Treatment Policies
Policy 15	Applicability of IND Applications and Investigator Brochures/Support From Pharmaceutical Companies
Policy 18	Data Evaluation Policy and Procedure
Policy 19	Quality Assurance Program
Policy 20	New Agent Studies and Safety Monitoring
Policy 21	Data and Safety Monitoring
Policy 22	Ethical and Regulatory Considerations
Policy 23	Serious Adverse Events
Policy 25	Drug Ordering
Policy 29	Roster of Investigators Maintenance Policies and Procedures
Policy 30	Responsibility for Patient Follow-Up
Policy 33	Institutional Performance Review
Policy 36	Affirmation of Integrity
Policy 38	Research Calculations for Clinical Trials
Policy 39	Acquisition, Maintenance and Use in Research of Tissue and Other Biologic Patient Specimens

General Training and Informational Resources

Getting Started with SWOG:

- Vital Information and Contacts
- SWOG CRA Manual for Oncology Research Professionals (login required)
- CTSU Website Overview (9 mins) (login required)
- SWOG Website Overview (4 mins) (login required)
- SWOG CRA Workbench Overview (4 mins) (login required)
- iMedidata RAVE Access for Lead ORPs (6 mins) (login required)
- SWOG Specimen Tracking System for Lead ORPs (8 mins) (login required)

NCORP-provided materials (accessible via the NCORP-Portal):

- NCORP Resources, includes NCORP Guidelines walkthrough, Site Orientation, and funding overview information. (login required)
- NCORP Meeting/WebEx Materials, includes helpful resource materials from monthly administrator meetings, study-specific webinars, and prior NCORP annual meeting materials. (login required)

SWOG-led Study Accrual Tracking: Reports & Dashboards (login required)

Tools for Clinical Trial Conduct: SWOG CRA Workbench Tools (login required)

Tools for a Successful Audit: SWOG Quality Assurance & Audits

SWOG Training for Oncology Research Professionals:

Clinical Trials Training Course (login required)

Specimen Submission Training:

- Improving Submissions to the SWOG Biospecimen Bank (login required)
- Biospecimen Quality, Compliance, Tips and Tricks (login required)
- Complete Guidelines for Specimen Submission

SWOG Regulatory Workshop

SWOG Quality Assurance Webinar Series, including:

- Serious Adverse Event Reporting & Updates (login required)
- Disease Assessment in Solid Tumors (1 CEU contact hour) (login required)
- Workload Prioritization in Clinical Trials (1.5 CEU contact hours) (login required)
- Best Practices for Informed Consent (1 CEU contact hour) (login required)
- Research Protocol Deviations vs Deficiencies (1 CEU contact hr) (login required)
- Adverse Event Reporting (login required)
- SWOG Audits: Preparing for Success and Audit Process (login required)
- How to Develop a CAPA Plan (login required)

Additional SWOG-provided Training:

- For more training resources refer to:
  - SWOG Training Resources
  - SWOG CRA Workbench (login required)
  - SWOG Oncology Research Professionals (login required)

Onboarding and Refresher Training:

Compiled Researcher Resources List, now accessible via CTSU.org >> Resources >> Researcher Resources. This is a downloadable / sortable (by Topic area and Source) / editable list that sites can use as a basis for local staff onboarding or continuing education. (login required)

General Research Training and Informational Resources:

SWOG Clinical Research Resources, a clearinghouse of resources and continuing education materials pertinent