Trial Activation and Facilitation Resources

Online resources are accessible via hyperlinks below.
(Where indicated, login is required; Recommend login prior to clicking on the link.)

Identifying Upcoming Studies:

SWOG Protocol Development Tracking Reports and Dashboards (login at SWOG.org)

- 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 (login at SWOG.org)

Getting Started with CTSU and NCI Applications:

- CTSU Operations Training Modules, accessible via CTSU.org >> Resources >> CTSU Operations Information >> General Procedures & Training (login at https://ctsu.cancer.gov/)
- SWOG and NCI Systems Overview Training (login at https://swog.exphosted.com/)

Site Rostering:

- CTSU RUMS User Guide (login at https://ctsu.cancer.gov/) 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 at https://ctsu.cancer.gov/)
- NCI CIRB Standard Operating Procedures and Start Guide (login at https://ctsu.cancer.gov/)
- NCI CIRB How to Open a Study Guide (login at https://ctsu.cancer.gov/)
- The CTSU Regulatory Submission Portal User Guide (login at https://ctsu.cancer.gov/)

Informed Consent Process: (For all of the following login at https://swog.exphosted.com/)

- Plain Talk: Communicating with Participants About Clinical Trials
- QA Perspective on Informed Consent: A Process, Not a Document
- SWOG Plain Language Tools: Patient-friendly Trial Summaries
- Tips for the Real World
- So Much Consenting, So Little Time

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

- Oncology Patient Enrollment System (OPEN) user guide (login at https://ctsu.cancer.gov/)
- Open Funding (login at https://swog.exphosted.com/)

Data Submission and Management:

- CTSU Rave Roles, Training, and Resources (login at https://ctsu.cancer.gov/)

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

(Where indicated, login is required; Recommend login prior to clicking on the link.)

Getting Started with SWOG:

- Vital Information and Contacts
- SWOG CRA Manual for Oncology Research Professionals (login at https://swog.exphosted.com/)
- CTSU Website Overview (9 mins) (login at https://swog.exphosted.com/)
- SWOG Website Overview (4 mins) (login at https://swog.exphosted.com/)
- SWOG ORP (CRA) Workbench Overview (4 mins) (login at https://swog.exphosted.com/)
- iMedidata RAVE Access for Lead ORPs (6 mins) (login at https://swog.exphosted.com/)
- SWOG Specimen Tracking System for Lead ORPs (8 mins) (login at https://swog.exphosted.com/)

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 ORP Workbench & SWOG.org)

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

Tools for a Successful Audit: SWOG Quality Assurance & Audits

SWOG Training for Oncology Research Professionals:

Clinical Trials Training Course (login required)

Specimen Submission Training:

- SWOG: Biospecimen Tracking and Submission Training (login at https://classlms.org/)
- Improving SWOG Biospecimen Bank Submissions (login at https://swog.exphosted.com/)
- Biospecimen Quality, Compliance, Tips and Tricks (login at https://swog.exphosted.com/)
- Complete Guidelines for Specimen Submission

SWOG Regulatory Workshop

SWOG Quality Assurance Webinar Series, including:
(Login at https://classlms.org/ required to access the following QA Webinar Series enduring courses)

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

Additional SWOG-provided Training:

- For more training resources refer to:
  - SWOG Training Resources
    - Announcements
    - List of online training courses
  - SWOG ORP (CRA) Workbench (login at ORP Workbench)
  - SWOG Oncology Research Professionals (login at SWOG.org)

Onboarding and Refresher Training:

Compiled Researcher Resources List, now accessible via CTSU.org >> Resources >> Researcher Resources.