US Food and Drug Administration (FDA) and Related NCI and SWOG Resources Relevant to the Conduct of NCTN and NCORP Clinical Trials

FDA Regulations, Good Clinical Practice, Institutional Review Boards, NCI NCTN and NCORP Guidelines, and General Resources		
FDA Guidance Documents	**NCI**	**SWOG**
FDA Regulations: Good Clinical Practice and Clinical Trials	NCTN Guidelines Document	SWOG Trial Master File: Guidance on FDA Inspection
FDA Clinical Trials and Human Subject Protection	NCORP Guidelines (accessible via NCORP Resources, login required)	SWOG Regulatory Guidance: Expectations for a successful audit
Institutional Review Boards Frequently Asked Questions: Guidance for Institutional Review Boards and Clinical Investigators	NCI CTEP Quality Assurance, including NCI CTMB (NCTN / NCORP) Audit Guidelines	SWOG Policy 19: Quality Assurance Program
FDA Oncology Center of Excellence Guidance Documents Regarding Oncology and Hematologic Malignancies	NCI CTMB (NCTN/NCORP) Auditing Guidelines	SWOG Quality Assurance Audit Guidelines
Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs	NCI CTEP Resources for Sites, including NCI CTEP Investigators Handbook	Best Practices for SWOG Studies
Conducting Clinical Trials With Decentralized Elements (9/1/2024)	NCTN Streamlined Data Standard Practices	
	NCI CTSU Compiled DTL Site Guide (login required)	Site Authority Log (for studies that do not require a centralized DTL, maintained via CTSU)
FDA Guidance Document Search Tool	NCI CTEP Guidelines, Policies, and Memoranda	SWOG Policies
FDA Regulations & Topic-Specific Guidance Documents	**NCI Central Institutional Review Board**	**Additional Resources for Audit Preparation, Clinical Trials Records Management and FAQs**
21 CFR 56 - Institutional Review Boards	NCI Central Institutional Review Board: Creating and Updating the Annual Principal Investigator Worksheet	Internal QA Program
	NCI CIRB Establishing Your Signatory Institution and Completing the Annual Signatory Institution Worksheet	Site Preparation for an Audit (SWOG Audits)
	NCI CIRB Algorithm to Assess Potential Unanticipated Problem	SWOG Patient Chart Review Guidance
Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials	NCI CIRB Algorithm to Assess Potential Noncompliance	Record Retention Guidance
	NCI CIRB How to Open a Study	SWOG Quality Assurance Department FAQs
FDA Guidance: Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers	NCI CIRB Submit a Study Closure or Transfer of Study Review Responsibility Worksheet	SWOG Oncology Research Professional (ORP) Manual - Chapter 14: Study Protocol (login required)
21 CFR 54 - Financial Disclosure by Clinical Investigators	NCI CIRB Standard Operating Procedures (Section 8.1.2)	SWOG Policy 35: Financial Conflict of Interest Policy
21 CFR 11 - Electronic Records	NCI CIRB Standard Operating Procedures (Section 2.3.8)	Policy on Auditing Electronic Medical Records

FDA, NCI, OHRP and SWOG
Good Clinical Practice and Informed Consent Resources

General Clinical Trials and Good Clinical Practice (GCP) Training Resources		
FDA	**NIH**	**OHRP (also utilized by NCI)**
FDA Clinical Trials Training Modules | FDA	NIH Introduction to the Principles and Practice of Clinical Research (IPPCR)	OHRP Human Research Protection Foundational Training
21 CFR 50 - Protection of Human Subjects		OHRP's Human Research Protection Training
Recruitment and Informed Consent Guidance and Training Resources		
FDA	**NCI / OHRP**	**SWOG**
Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors	NCI CIRB Guidelines for Permitted Boilerplate Language Additions	SWOG Recruitment and Retention Resources (login required)
Informed Consent FAQs	What's new in Informed Consent: Revisions to the Common Rule (July 2018) (27 min video)	Informed Consent Best Practices (53 min video) (login required)
Informed Consent Tips	Simplifying Informed Consent (October 30, 2020) (1 hr 45 min video)	Plain Talk: Communicating with Participants About Clinical Trials (20 min video) (login required)
Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards	Broad Consent in the Revised Common Rule (March 2018) (18 min video)	QA Perspective on Informed Consent: A Process, Not a Document (12 min video) (login required)
		SWOG Plain Language Tools: Patient-friendly Trial Summaries (10 min video) (login required)
		Tips for the Real World (10 min video) (login required)
		So Much Consenting, So Little Time (12 min video) (login required)
		Putting it Plainly: Tips and tools for helping patients understand clinical trials (26 min video) (login required)
	NIH Office of Intramural Research Enrollment of non-English speaking participants in NIH research	Elements of Representative Enrollment: FDA Draft Guidance (16 min video) (login required)
	OHRP Guidance on Informed Consent of Subjects Who Do Not Speak English (1995)	The Art of Patient Enrollment in Genitourinary Oncology Clinical Trials (1hr 45 min video) (login required)
Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors (Section V)	NCI CIRB Short Form Q&A	El Consentimiento Informado en la Investigación Clínica (1 hr 5 min video) (login required)

FDA, NIH, NCI, OHRP and SWOG
Investigational Agent Management and Adverse Event Resources

Investigational Agent Management Regulations, Guidance, and Training Resources		
FDA	**NCI / NIH**	**SWOG**
21 CFR Part 312	NCI CTEP Agent Management Resources	SWOG Pharmaceutical Sciences Resources (login required)
21 CFR Part 812	NCT CTEP Agent Management Policies and Guidelines	Guidance for an FDA Inspection: Handling of Investigational Agents
	NCI Pharmaceutical Management Branch (PMB), CTEP Inventory Management System: AURORA Training (1 hr 53 min video in CLASS) (login required)	SWOG Biosimilars Guidelines
	NCI CTEP AURORA Document Access Training Course (11 min video in CLASS) (login required)	SWOG Oncology Research Professional (ORP) Manual - Chapter 6: Drug Ordering and Maintenance
	NCI CTEP 2016 Training Videos and Handouts	SWOG Investigational Agent Handling Workshop (~30 mins)
	NIH Principles of Clinical Pharmacology Training	
Adverse Events and Adverse Event Reporting Guidelines and Training Resources		
FDA	**NCI / OHRP**	**SWOG**
Sponsor Responsibilities - Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies	NCI Adverse Events Resources (CTCAE and Adverse Event Reporting)	SWOG Serious Adverse Events Reporting Resources
Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices	NCI Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) INDs and IDEs	SWOG Policy 23: Serious Adverse Events
	CTEP-AERS Training Guide	Expedited Reporting Submission Guide
	CTEP-AERS Training Slides	SAE Reporting Flowchart
	CTEP Guidance for Reports Accidentally Initiated Outside the Rave/CTEP-AERS integration	SAE Escape Room
	CTEP Adverse Events Start/End Date Guidance (login required)	Adverse Event Reporting (14 min video) (login required)
	NCI CTEP-AERS Help Topics	Adverse Event Assessment and Reporting (47 min video in CLASS) (login required)
	CTEP Memorandum: Global Safety Update to Expedited Reporting Requirements for Serious Adverse Events on CTEP-Supported Clinical Trials under IND and/or IDE (login required)	Navigating Adverse Events: What's New in CTCAE (47 min video in CLASS) (login required) - 1.0 CEU available until 12/7/2027
	CTEP-AERS FAQs	Serious Adverse Event Reporting (22 min video) (login required)
	OHRP Guidance: Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events	SAE Reporting - Specific Exceptions to Expedited Reporting for Lead ORPs (5 min video) (login required)
		Serious Adverse Event Reporting and Updates (57 min video) (login required) - 1.0 CEU available until 3/21/2027

SWOG-provided Quality Assurance and Regulatory Training

Additional SWOG Quality Assurance and Regulatory Training Resources		
Workshops - General Regulatory and Quality Assurance	**Short Courses - General Regulatory and Quality Assurance**	**Audits & Audit Preparation**
SWOG Oncology Research Professionals Regulatory Workshop (~2 hr 35 mins) (login required)	Regulatory Expectations from a QA Perspective - Training for Lead ORPs (14 min video) (login required)	Audits and Quality Assurance (17 min video) (login required)
SWOG Clinical Trials Training Course (~ 7hrs) (login required)	Delegation of Tasks Log for Lead ORPs (2 min video) (login required)	Audits and Quality Assurance Program - Training for Lead ORPs (21 min video) (login required)
SWOG Lead ORP Workshop (~4 hrs 35 mins) (login required)	SWOG Data Submission Guidance, Tips, and Tricks	SWOG Quality Assurance Updates - CTMB Audit Guidelines (13 min video) (login required)
	Reports and Tools to Support Quality Data (21 min video) (login required)	Lessons of an Audit (15 min video) (login required)
	Participant Follow-up: Quality Assurance Perspective (8 min video) (login required)	SWOG QA Audits - Top 10 Deficiencies (11 min video) (login required)
	How to Develop a CAPA (Corrective and Preventive Action) Plan (47 min video) (login required)	When is my Institution's next Audit Due? - Training for Lead ORPs (2 min video) (login required)
	From the ground up: Implementing QA at the site level	Quality Assurance Audits Preparing for Success (70 min video) (login required)
	SWOG SDMC Updates: Early Study Closure Requests (2 min video) (login required)	Protocol Deviations vs. Deficiencies - Training for Lead ORPs (4 min video) (login required)
	Record Retention Training for Lead ORPs (4 min video) (login required)	Research Protocol Deviations vs Deficiencies (32 min video) (login required) - 1.0 CEU available until 6/11/2026
	Upcoming Quality Assurance Webinars	Auditorías: preparación y experiencias (49 min video) (login required)

Additional FDA Informational Resources and Key SWOG Policies

FDA Presentation or Workshop Topic	Date
A Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Compliance Symposium	2/15/2024
FDA's Use of Alternative Approaches to Evaluate GCP Compliance: FDA CDER Small Business and Industry Assistance (SBIA)	12/12/2024
Investigator Responsibilities: Regulations and FDA Expectations for the Conduct of Clinical Trials: FDA CDER Small Business and Industry Assistance (SBIA)	12/12/2024
Informed Consent: More than just a document	12/12/2024
Basics of Clinical Trial Design	12/10/2024
FDA Oncology Drug Development Overview – Past to Present- FDA CDER Small Business and Industry Assistance (SBIA)	4/8/2021
FDA Oncology Center of Excellence Oncology Therapy Development Workshop	3/20/2021
FDA-AACR-ASA Workshop: Overall Survival in Oncology Clinical Trials	7/18/2023
FDA/CDER Office of Clinical Pharmacology and American Association for Cancer Research (AACR) Public Workshop: Quantitative Approaches to Select Dosages for Clinical Trials	2/16/2024
Nonclinical Safety Assessment for Small Molecules and Biologic Drug Development	5/15/2020
FDA WORKSHOP: 8th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop	6/27/2023
Introduction to Investigational New Drug (IND) Applications- FDA Regulatory Education for Industry (REdI) 2017	5/10/2017
Investigational New Drug (IND) Submission: Content/Format and First 30 Days- FDA Regulatory Education for Industry (REdI) 2018	5/16/2018
NHLBI Catalyze Annual Meeting 2024: How to Prepare for a Pre-IND and INTERACT Meeting	9/12/2024

Key SWOG Policies 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 Institutions, Investigators and Associates Maintenance Policies and Procedures
Policy 30	Responsibility for Patient Follow-Up
Policy 36	Affirmation of Integrity
Policy 39	Acquisition, Maintenance and Use in Research of Tissue and Other Biologic Patient Specimens

General Training and Information Resources

Getting Started with SWOG: Vital Information and Contacts (login at ORP Workbench | https://txwb.crab.org/TXWB/Default.aspx)

- **Key Guidance for SWOG-led study implementation:** SWOG ORP (CRA) Manual for Oncology Research Professionals (login at ORP Workbench)
- **SWOG Website and Resources Introductory Training Modules:** (Login at https://swog.expertusone.cloud/learner/swog)
  - CTSU Website Overview (9 mins)
  - SWOG Website Overview (4 mins)
  - SWOG ORP (CRA) Workbench Overview (4 mins)
  - iMedidata RAVE Access for Lead ORPs (6 mins)
  - Accessing the SWOG Specimen Tracking System (8 mins)
  - SWOG and NCI Systems Overview Training (14 mins)

Getting Started with CTSU and NCI Applications: CTSU Operations Training Modules
(Accessible after login at: login at https://ctsu.cancer.gov via Resources >> CTSU Operations Information >> General Procedures & Training)

Site Rostering: CTSU RUMS User Guide (login at https://ctsu.cancer.gov/) and SWOG FAQs: Systems Access and Rostering Maintenance

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 (11 mins) (login at https://swog.expertusone.cloud)

Data Submission and Management:

- CTSU Rave Roles, Training, and Resources (login at https://ctsu.cancer.gov/)
- CTSU Data Quality Portal (DQP) Help Topics (login at https://ctsu.cancer.gov/)
- SWOG Patient Reports and Tools for Data Quality (login at ORP Workbench)
- SWOG List of Studies with No Required Follow-up (login at ORP Workbench)
- SWOG FAQs: Data Submission and Management

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

SWOG Quality Assurance Resources: SWOG Quality Assurance & Audits, SWOG Best Practices Document and Serious Adverse Events | SWOG

Additional SWOG Training for Oncology Research Professionals:

- **SWOG Training Resources:** Announcements | List of online training courses | SWOG Quality Assurance Webinar Series
- **SWOG ORP (CRA) Workbench** (login at ORP Workbench)
- **SWOG Oncology Research Professionals** (login at SWOG.org)

Onboarding and Refresher Training: Compiled Researcher Resources List (login at: https://ctsu.cancer.gov/)

General Research Training and Informational Resources: SWOG Clinical Research Resources (A clearinghouse of resources and continuing education materials pertinent to the conduct of NCTN, including NCORP trials.)