# SWOG CANCER RESEARCH NETWORK 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 | | |
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| **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 |
| FDA: 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 |
| FDA: Conducting Clinical Trials With Decentralized Elements (9/1/2024) Guidance Document | NCTN Streamlined Data Standard Practices | |
| FDA Bioresearch Monitoring (BIMO) Information | | FDA BIMO Inspections (66 mins) (login required) |
| | 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 |

# Good Clinical Practice & Investigational Agent Management Resources and Key SWOG Policies

| General Clinical Trials and Good Clinical Practice (GCP) Training Resources | | |
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| **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 |

| Investigational Agent Management Regulations, Guidance, and Training Resources | | |
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| **FDA** | **NCI / NIH** | **SWOG** |
| 21 CFR Part 312 | NCI CTEP Agent Management Resources | Pharmaceutical Sciences Resources (login to https://www.swog.org prior to following the link) |
| 21 CFR Part 812 | NCT CTEP Agent Management Policies and Guidelines | FDA Inspection: Investigational Agent Handling Guidance |
| | NCI Pharmaceutical Management Branch (PMB), CTEP Inventory Management System: AURORA Training (1 hr 53 mins in CLASS) (login required) | Safeguarding the Science: Best Practices for Investigational Drug Documentation and Management (1 hr) - 1.0 CEU available until 6/17/2028 |
| | NCI CTEP AURORA Document Access Training Course (11 mins in CLASS) (login required) | SWOG Oncology Research Professional (ORP) Manual - Chapter 6: Drug Ordering and Maintenance |
| | NCI CTEP 2016 Training Videos and Handouts | Pharmaceutical Science Committee Biosimilars Guidelines |
| | NIH Principles of Clinical Pharmacology Training | SWOG Investigational Agent Handling Workshop (~30 mins) (login required) |

## Key SWOG Policies for Study Management:

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| 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 |

# FDA, NCI, OHRP and SWOG Recruitment, Informed Consent, Plain Language and Patient-Reported Outcomes Resources

| FDA | NCI / OHRP | SWOG |
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| Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors | NCI CIRB Guidelines for Permitted Boilerplate Language Additions | SWOG Recruitment and Retention Resources (login to https://www.swog.org prior to following above link) |
| Informed Consent FAQs | What's new in Informed Consent: Revisions to the Common Rule (July 2018) (26 mins) | SWOG Patient-Friendly Plain Language Clinical Trial Summaries |
| Informed Consent Tips | Simplifying Informed Consent (October 30, 2020) (1 hr 45 mins) | **SWOG Training Courses** (in ExpertusOne or CLASS; 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 mins) | • Informed Consent Best Practices (53 mins)<br>• Plain Talk: Communicating with Participants About Clinical Trials (20 mins) (20 mins)<br>• QA Perspective on Informed Consent: A Process, Not a Document (12 mins)<br>• SWOG Plain Language Tools: Patient-friendly Trial Summaries (10 mins)<br>• Tips for the Real World (10 mins)<br>• So Much Consenting, So Little Time (12 mins)<br>• Putting it Plainly: Tips and tools for helping patients understand clinical trials (26 mins)<br>• Elements of Representative Enrollment: FDA Draft Guidance (16 mins)<br>• Patient Enrollment to Industry-Sponsored versus Federally Sponsored Cancer Clinical Trials (9 mins)<br>• Building Patient Partnerships-A Roadmap for Meaningful Collaboration (25 mins)<br>• Outreach to Native Hawaiian/Pacific Islander (NHPI) Communities: A Pilot Project (13 mins)<br>• The Art of Patient Enrollment in Genitourinary Oncology Clinical Trials (1 hr 45 mins)<br>• Adolescent and Young Adult (AYA) Patient Experience (24 mins)<br>• In Spanish: El Consentimiento Informado en la Investigación Clínica (1 hr 5 mins) |
| Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors (Section V) | NIH Office of Intramural Research Enrollment of non-English speaking participants in NIH research | |
| | OHRP Guidance on Informed Consent of Subjects Who Do Not Speak English (1995) | |
| | NCI CIRB Short Form Q&A | |
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| SWOG Patient-Reported Outcomes Resources | |
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| SWOG Quality Assurance Webinar Series Presentation on Patient-Reported Outcomes (1 hr) - 1.0 CEU available until 9/1/2028 | Patient Reported Outcomes - Part of the SWOG Clinical Trials Training Course (CTTC) |
| | Comprehensive Overview of Patient Reported Outcomes |
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# SWOG-provided Quality Assurance and Regulatory Training

(in ExpertusOne or CLASS; login required)

| Workshops - General Regulatory and Quality Assurance | Short Courses - General Regulatory and Quality Assurance | Audits & Audit Preparation |
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| SWOG Oncology Research Professionals Regulatory Workshop (~2 hrs 35 mins) | From the ground up: Implementing QA at the site level (1 hr) - 1.0 CEU available until 3/5/2028 | Audits and Quality Assurance (17 mins) |
| SWOG Oncology Research Professionals Spring 2026 Jeri & Noburu Oishi Symposium (~2 hrs 44 mins) | How to Develop a CAPA (Corrective and Preventive Action) Plan (47 mins) | SWOG Quality Assurance Updates - CTMB Audit Guidelines (13 mins) |
| SWOG Clinical Trials Training Course (~ 7hrs) | Quality Assurance in FDA Registration Trials (9 mins) | Lessons of an Audit (15 mins) |
| SWOG Lead ORP Workshop (~4 hrs 35 mins) | Participant Follow-up: QA Perspective (8 mins) | SWOG QA Audits - Top 10 Deficiencies (11 mins) |
| **Data Submission/Data Quality** | Early Study Closure Requests (2 mins) | Quality Assurance Audits Preparing for Success (70 mins) |
| • Data Submission (24 mins)<br>• Reports & Tools to Support Quality Data (21 mins) | Protocol Deviations vs Deficiencies (28 mins) | SWOG Quality Assurance Preparing for an Audit - A Focus on myeloMATCH (23 mins) |
| For Lead ORPs:<br>• Central Monitoring (5 mins)<br>• Data Entry in Difficult Situations (2 mins)<br>• Expectations and Expectation Reports (10 mins)<br>• Vital Status Expectations Training (5 mins)<br>• Institution Performance Review (IPR) (10 mins)<br>• Query Reports Training (4 mins)<br>• CTSU reports - Data Quality Portal (DQP) (7 mins) | For Lead ORPs:<br>• Delegation of Tasks Log (2 mins)<br>• Regulatory Expectations from a QA Perspective - (14 mins)<br>• Record Retention Training (4 mins) | For Lead ORPs:<br>• Audits and Quality Assurance Program (21 mins)<br>• Protocol Deviations vs. Deficiencies (4 mins)<br>• When is my Institution's next Audit Due? (2 mins) |
| | See also:<br>• Upcoming Quality Assurance Webinars<br>• SWOG Data Submission Guidance, Tips, and Tricks | In Spanish:<br>Auditorías: preparación y experiencias (49 mins) |
| **Biospecimen Collection, Labelling, Tracking and Submission :** | | |
| Collection, Labelling and Submission:<br>• SWOG Specimen Labeling Guide (8 mins)<br>• Biospecimen Tracking and Submission (30 mins)<br>• Biospecimen Collection and Submission (1 hr) - 1.0 CEU available until 10/12/2027 | For Lead ORPs:<br>• SWOG Specimen Tracking System (8 mins)<br>• Specimen Expectations (8 mins) | Quality:<br>• Improving Specimen Submissions to the SWOG Biospecimen Bank (11 mins)<br>• Biospecimen Quality, Compliance, Tips & Tricks (25 mins) |
| **Adverse Event (AE) and Serious Adverse Event (SAE) Resources:** | | |
| SWOG Serious Adverse Events Reporting Resources, including Expedited Reporting Submission Guide, SAE Reporting Flowchart, SAE Escape Room, & SWOG Policy 23: SAEs | | |
| SWOG-provided AE and SAE Training in CLASS (login required):<br>• Adverse Event Assessment and Reporting (47 mins)<br>• Navigating AEs: What's New in CTCAE (47mins) - 1.0 CEU available until 12/7/2027<br>• SAE Reporting and Updates (57 mins) - 1.0 CEU available until 3/21/2027 | SWOG-provided AE and SAE Training in ExpertusOne (login required):<br>• Adverse Event Reporting (14 mins)<br>• SAE Reporting - Specific Exceptions to Expedited Reporting for Lead ORPs (5 mins)<br>• Serious Adverse Event Reporting (22 mins) | |

# SWOG, NIH & NCI Clinical Trial Funding - Informational Resources

**SWOG Lead Oncology Research Professional Training: SWOG Lead ORP Workshop** (login at https://swog.expertusone.cloud/learner/swog), including:

- NCTN and NCORP Study Funding and Payment Distribution (20 mins)
- Open Funding (10 mins)
- National Coverage Analysis Overview (4 mins)
- SWOG and NCI Systems Overview Training (14 mins)

**NCI Oncology Patient Enrollment Network (OPEN) System - Funding Considerations and Data Entry During Participant Enrollment:**

- **Refer to Section 13 of the SWOG-led protocol and:**
  - NCI CTSU Oncology Patient Enrollment System (OPEN) user guide (login at https://ctsu.cancer.gov/)
  - NCI CTUS Oncology Patient Enrollment Network Funding Screen User Guide (login at https://ctsu.cancer.gov/)
  - NCI CTUS OPEN: Patient Enrollment and Entering Funding Information (login at https://ctsu.cancer.gov/)
  - SWOG Open Funding Overview Presentation (11 mins) (login at https://swog.expertusone.cloud)

**Additional SWOG Resources:**

- The Role of Federal Sponsorship in Cancer Clinical Research (15 minutes)
- SWOG FAQs: Funding, Financial Agreements and Study Payments
- SWOG Financial Agreements webpage (login at https://www.swog.org prior to following link)
- SWOG Spring 2026 Administration & Funding Updates-Part of the SWOG Oncology Research Professionals Spring 2026 Site Operations Committee Meeting (login at https://swog.expertusone.cloud/learner/swog)
- SWOG: Overview of National Coverage Analysis in NCTN Trials - Considerations for Participating VA Sites (25 mins) (login at https://classlms.org/)

**NIH / NCI Informational Resources:**

- NIH Grants and Funding: Human Subjects Research webpage
- NCI Division of Cancer Treatment and Diagnosis (DCTD) Grant Funding Portfolio webpage
- Types of NIH funding opportunities
- NIH - Get Ready for Grants Management
- NIH - Grants Process Overview (How to Get Started, Apply, Tutorials, and More)
- NCI - The Grants Process Book
- NCI Biomarker, Imaging and Quality of Life Studies Funding Program (BIQSFP) Information

**Where to Find Funding Opportunities:**

- The Hope Foundation Funding Opportunities for SWOG members webpage (login at https://www.swog.org prior to following link)
- NCI Research Funding Opportunities
- NCI Division of Cancer Control & Population Sciences Funding Opportunities
- NCI Division of Cancer Prevention Funding Opportunities
- NIH Grants and Funding Opportunities Search
- U.S. Department of Defense Electronic Biomedical Research Application Portal

# 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

**Data Submission and Management:**

- SWOG ORP Manual, incl.: Chapter 4: Data Submission, 8: Expectation & IPR Reports, 10: LTFU, 13: SAE, 15: AE & 16: Forms (login at ORP Workbench)
- 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

**NCORP-provided materials** (login to the NCORP-Portal prior to following the link below):

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

**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