SWOG CANCER RESEARCH NETWORK

Version Date: 04/01/2022

CONTACT REFERENCE SHEET

Contact the SWOG Data Operations Center for assistance with:

SWOG Statistics and Data Management Center:

Hours: 6:30-4:00 PST

SWOG Statistics and Data Management Center
c/o Cancer Research And Biostatistics
1505 Westlake Avenue, North, Suite 750
Seattle, Washington 98109-1024

Phone: 206/652-2267
Data submission fax line: 800/892-4007

Oncology Research Professional (ORP) Manual: The current version of the ORP Manual is accessible from the CRA Workbench under the ORP Manual navigation link, or directly from: https://txwb.crab.org/TXWB/ToolsOfTrade.aspx (Login with your CTEP IAM ID required to access this link).

CRA Clinical Trials Training Course (CTTC): The in-person CTTC course is conducted annually at the SWOG Spring Group Meeting. Registration for the in-person course opens with registration to the SWOG Spring Group Meeting. Questions pertaining to timing or registration of the in-person course should be directed to the Meetings Manager via email to: meetings@swog.org. The self-directed (online) version of the CTTC course is accessible via SWOG website under Member Resources>Training or directly at: https://www.swog.org/member-resources/training (Login with your CTEP IAM ID required to access this link). Questions pertaining to the online course should be directed to the Training Manager at: training@swog.org.

Forms Completion, Data Submission, Queries and Expectation Reports: All data are submitted electronically via either iMedidata RAVE® or the CRA Workbench at www.swog.org. All new studies require the use of Medidata Rave® as the common electronic data capture (EDC) software mandated for use by all groups within the NCTN Information regarding the proper forms to complete and when to submit them is outlined in the Data Submission section of the protocol (Section 14 of SWOG protocols). Questions about forms for SWOG-led studies, study-specific questions about iMedidata RAVE®, study-specific Expectation Reports, or outstanding queries Questions about forms, the Expectation Report or outstanding queries for SWOG-coordinated studies should be directed to the committee-specific email address below. Questions regarding multiple studies on your Expectation Report should be directed to expectationreportquestion@crab.org. Questions pertaining to iMedidata Rave® access, passwords, invitations or technical issues must be directed to the NCI Clinical Trials Support Unit (CTSU); See page 3 (below) for CTSU contact information.

BreastQuestion@crab.org	GYNquestion@crab.org	MelanomaQuestion@crab.org
CancerControlQuestion@crab.org	LeukemiaQuestion@crab.org	MyelomaQuestion@crab.org
GIquestion@crab.org	LungQuestion@crab.org	RareTumors@crab.org
GUquestion@crab.org	LymphomaQuestion@crab.org	

Pathology and Radiotherapy Material Submission: The Discipline Review section of the protocol provides details on whether pathology and/or radiotherapy review are required, and, if so, which specific materials are to be submitted, and where to send them. Questions regarding these requirements should be directed to the study Data Coordinator.

Patient Registration/Patient Eligibility: Patient registrations to all SWOG-led studies are detailed in Section 13 of each protocol. Nearly all SWOG studies now use the OPEN application accessed at https://open.ctsu.org or from the OPEN Patient Registration link on the SWOG CRA workbench. Eligibility criteria are included in Section 5 of each SWOG protocol. Questions pertaining to patient eligibility for SWOG-coordinated protocols should be directed to the study Data Coordinator.

Specimen Tracking System (SpecTrack): General questions in how to access or use the Specimen Tracking System should be directed to the study Data Coordinator. Errors or technical issues resulting in a failed submission should be emailed to us at technicalquestion@crab.org and include a screen shot or copy of the error received.

Source Documentation Portal: General information on the Source Document Portal is available on the CTSU members' website under Auditing & Monitoring > Source Document Portal in the Help Topics button or by contacting the CTSU Help Desk (1-888-823-5923 or ctsucontact@westat.com). For study specific questions on SWOG-led studies that include Central Monitoring, see the Central Monitoring appendix (Section 18.0) in the respective protocol or Email: centralmonitorquestion@crab.org.

CRA Newsletter: Would you like to write and submit an article to include in the next quarterly CRA Newsletter? Please reach out to the committee responsible for this at CRANewsletter@crab.org.

Contact the SWOG Operations Office for assistance with:

Operations Office:
Hours: 8:00-5:00 CT

SWOG Operations Office
4201 Medical Drive, Suite 250
San Antonio, Texas 78229-5631

Phone: 210/614-8808

Adverse Drug Reactions: When a patient experiences an adverse drug reaction you will file Serious Adverse Events according to protocol specifications and via CTEP-AERS. Should you need assistance with this process or are unclear if the event needs to be reported, contact the SWOG SAE Program at: adr@swog.org.

Audits: Any items related to past, present or future audits should be referred directly to the Auditor responsible for conducting the audit or (if unknown) to the Quality Assurance Department at: qamail@swog.org.

Protocol Mailings/Updates: SWOG notifications for protocol mailings and updates are sent electronically the 1st and 15th of each month and then subsequently distributed via the CTSU on the 8th and 22nd of each month. Contact protocols@swog.org or the disease-site Protocol Project Manager (https://www.swog.org/swog-network/staff) for assistance.

General Protocol Questions: Email: protocols@swog.org**.** For eligibility, data submission (and associated calendaring), forms completion, queries and expectation reports, see the data coordinator email distribution lists on Page 1. For treatment, toxicity, or other medical questions, see the study chair contact information included on the Protocol Contact Information page near the front of each SWOG protocol.

Requests for Investigator's Brochures (Investigational Drug):

- For study conducted under a **CTEP-held IND**: https://ctep.cancer.gov/branches/pmb/faq/docs/obtaining_an_investigator_brochure.pdf.
- For studies conducted under a **SWOG-held IND**: See Section 3.0 of the SWOG protocol and SWOG Policy #15: Applicability of IND Applications and Investigator Brochures/Support From Pharmaceutical Companies.

Investigational Drug Accountability, Transfer, Return, or Destruction: This information and appropriate contacts are included in Section 3 of each SWOG protocol. If not able to locate relevant drug accountability: return or destruction information in the current version of the SWOG protocol, then contact:

- For study conducted under a **CTEP-held IND**: PMBAfterHours@mail.nih.gov.
- For studies conducted under a **SWOG-held IND**: Appropriate contact information for the drug distributor will be indicated in the protocol.
  - If unable to locate distributor contract information in the protocol, contact protocols@swog.org.
  - If unable to locate information or contact for questions pertaining to drug transfers (on protocols conducted under a SWOG-held IND) direct questions to: qamail@swog.org.

Quality Assurance, Protocol Deviations, Record Retention, and other General Regulatory Questions: Email: qamail@swog.org.

Accrual Credits: Participating sites can track accrual credit through the CRA workbench > Reports link > SWOG-credited Registrations – site-specific, patient listing. If selecting "Show all registration steps", then all credit received is documented with a "Y' in the Reg Counts toward accrual column. This report can also be limited to selected registration steps by clicking on the checkbox for "Show registration steps that count for accrual". Unless otherwise stated on the funding memorandum, one (1) credit towards SWOG membership is issued upon participant registration to either an NCTN or NCORP study credited to SWOG. If the study has multiple registration steps, then the credit is issued at the first randomization step. If a participant is subsequently deemed ineligible for treatment registration/randomization after being initially registered on a study with a screening step, ¼ credit will be issued upon determination of ineligibility. Note: SWOG is only able to provide information on enrollments credited to SWOG, regardless of study sponsor Group. Other Lead Groups may have different policies. Questions should be directed to member@swog.org.

Membership/Institution Assurances: Questions about membership or updates/changes to SWOG Roster information should be directed to the Membership Department at: member@swog.org.

SWOG Group Meeting: Questions pertaining to the conduction of or attendance at the spring or fall group-wide meetings should be directed to the Meetings Manager at: meetings@swog.org.

Contact the SWOG Group Chair's Office or The Hope Foundation for assistance with:

Group Chair's Office:	SWOG Cancer Research Network Group Chair's Office
Hours: 8:00-5:00 PT	2611 SW 3rd Avenue MQ280 Portland, Oregon 97201
	Phone: 503/494-5586
The Hope Foundation:	24 Frank Lloyd Wright Drive, Suite 3600A Ann Arbor, MI 48105
Hours: 8:00-5:00 ET	Phone: 734/998-6888

SWOG study-specific funding: Payment amounts and instructions are listed on each individual study's funding memo. The funding memorandum for each study is available on the protocol abstract page of the CTSU website (www.ctsu.org) under the 'funding information' tab. For general questions about study-specific funding memorandum, please contact funding@swog.org.

Fixed-Price Agreements and Purchase Service Agreements (PSAs): SWOG uses two primary types of financial agreements for site payments: Fixed-price agreements and Purchase Service Agreements. Per NCI requirements, each site will need to establish two fixed-price agreements for federal funding: one for NCTN and one for NCORP studies. Additionally, each site will have two PSAs: one for federal funding (with the Group Chair's Office) and one for non-federal funding (with SWOG-CTP). When your site is ready to establish these required agreements, please reach out to the appropriate contact (primary contacts are listed on the funding memoranda posted on the CTSU protocol abstract page for each SWOG study); They will work with you to get all of the necessary information completed and the agreement executed. Please be sure to include a copy of your site's W-9 when reaching out to both SWOG Group Chair's Office (GCO) and SWOG Clinical Trials Program (SWOG-CTP). If questions, for federal funding agreements: contact: Kyle Theige (theige@ohsu.edu); For non-federal funding agreements, contact: Debbie Allen (debbie@thehopefoundation.org).

Payments/Reimbursement: If you have questions about specific federal or non-federal funding amounts, payments you have received, status of reimbursements or need assistance in reconciling your participating institution's records with these payments, please contact: Kyle Theige (theige@ohsu.edu) for federal funding questions and reconciliation of federal payments. Please contact Debbie Allen (debbie@thehopefoundation.org) for non-federal funding questions and reconciliation of non-federal payments.

SWOG Newsletter: Do you have an idea or suggestions for the SWOG Newsletter? Would like to provide feedback or inquiry on a current edition? Contact SWOG's Communications and Publications Manager at: communications@swog.org.

Contact the SWOG Statistical Center for assistance with:

Statistical Center:	SWOG Statistical Center Fred Hutchinson Cancer Center
Hours: 8:00-5:00 PST	1100 Fairview Ave N, MC-C102 PO Box 19024 Seattle, Washington 98109-1024
	Phone: 206/667-4623

Institutional Performance Review Reports: These reports are distributed monthly to institutions. Questions concerning the Institutional Performance Review Report are handled by Phyllis Goodman, Managing Statistician at the Statistical Center.

Meeting Report (Report of Studies): The Group *Report of Studies* is prepared by the Statistical Center. The Report of Studies and SWOG Statistics and Data Management Committee Report are posted on the SWOG website after each Group Meeting at: https://www.swog.org/member-resources/report-studies. Questions pertaining to contents of the Report of Studies should be directed to the Statistical Center.

Protocol Accrual and Statistical Analysis: Current study-specific accrual information is accessible to all NCTN and NCORP members on each individual protocol abstract of the CTSU website (www.ctsu.org). For active (or temporarily closed) studies, detailed SWOG accrual reports are accessible from the SWOG website at: https://www.swogstat.org/accrualHtml.html. Questions regarding accrual and statistical analysis of Group protocols should be directed to the disease committee Statistician at the Statistical Center.

Other Contacts:

Treatment Modification or Interpretation:

- Questions which require medical judgment should be directed to the Study Chair(s) of the respective protocol. Prior to contacting the Study Chair, the protocol should be reviewed and a physician within your institution should be consulted.
- The best contact information for the Study Chair(s) is provided on the title page of each protocol and the Protocol Contact Information page (near the front of the protocol).
- In the event that the Study Chair is not available, typically, a backup contact is also provided on both the Protocol Contact Information Page and in Sections 7.0 and 8.0 of the protocol.
- If neither is available, you can contact the disease site Committee Chair, then the Executive Officer (contact information visible by Committee Member role at: (https://www.swog.org/swog-network/committees).

Systems Access and Use Questions:

- For **iMedidata RAVE access, passwords, study invitations, or technical issues:** Contact CTSU Help Desk via Phone: 1-888-823-5923 or Email: ctsucontact@westat.com; Form or study-specific questions should always be sent by email using the committee-specific distribution lists on Page 1.
- For **issues with CTEP-IAM account credentials** (new requests, reset passwords): You can check your CTEP credentials via the IAM (Identity and Access Management Website) at: https://ctepcore.nci.nih.gov/iam/index.jsp or contact: ctepreghelp@ctep.nci.nih.gov for assistance.
- For **access to or troubleshooting of submissions in the Oncology Patient Enrollment Network (OPEN)** (https://www.ctsu.org/OPEN_SYSTEM/): Contact CTSU Help Desk at: Phone: 1-888-823-5923 or Email: ctsucontact@westat.com
- For **PMB Online Agent Ordering Processing (OAOP) application** access issues(where study drug is distributed by CTEP/PMB): http://ctep.cancer.gov/branches/pmb/agent_order_processing.htm
- For **TRIAD installation** questions: See: https://triadinstall.acr.org/triadclient/ or Email: TRIAD-Support@acr.org.

Trials Conducted by Another Group:

- Questions regarding protocols coordinated by a different Lead Group must be directed to that coordinating group or the CTSU. Contact information for the Lead Group that is coordinating the protocol (e.g., Alliance, ECOG-ACRIN, NRG, CCTG, COG) will be included on the title page of the individual protocol and/or the protocol contact information page near the beginning of the protocol, depending upon the Lead Group's template standards.
- If the study is not coordinated by SWOG, the SWOG Data Operations Center is not authorized to answer protocol related questions, including those pertaining to eligibility, treatment plan, or dosage modification.

Definition of Intergroup Studies and Determination of Lead Group:

- **Definitions:**
  - Intergroup Studies: For studies involving more than one Lead Protocol Organization (LPO) (or "Lead Group") (e.g., SWOG), it is important to note that only one LPO coordinates the study.
  - Coordinating (or Lead) Group: The LPO (or Lead Group) conducting the study writes the study, dictates eligibility, randomizes the patient to a specific treatment, collects and analyzes the data, and publishes the results of the study.
- **Purpose:** Intergroup studies (with several participating LPOs) allow for faster accrual to the study, so that the study results may be obtained in a timelier manner. Historically, many studies were limited in participation to the membership of a single Lead Group. More recently, the majority of NCTN and NCORP studies are activated as intergroup studies (wherein participating sites that are a member of any of the participating Groups can participate in the study).
- **Identifying intergroup studies:** Participating Groups are identified in the "Participants" list near the front of the protocol and on the protocol abstract page of the CTSU website (www.ctsu.org).
- **Determining the coordinating group:** The coordinating LPO of an intergroup study will be capitalized or boldfaced and is almost always at the top of the title page of the protocol.
- **Steps to follow when enrolling a patient to a non-SWOG coordinated study:** 1) Determine Eligibility. Use the eligibility criteria provided in the protocol. Some LPO's do not provide a separate checklist so it is the institution's responsibility to work through the eligibility criteria stated in the body of the protocol before completing the registration. 2) Fill out all required paperwork (e.g., eligibility checklists, randomization worksheets) and have them on hand when you initiate the enrollment in OPEN. The above steps must be completed before the registration is considered final and treatment can begin.
- **Data Flow and Expectation System for Intergroups:** SWOG Institutions are responsible for submission of all information required by the individual intergroup protocols. Required forms and follow-up information should be sent directly to the responsible LPO conducting the study. SWOG does not post expectations for studies coordinated by other LPO's. (Exceptions to this policy are for selected studies that require pathology submissions directly to SWOG. In these rare cases, expectations will continue to be posted). Institutional Performance Review (IPR) statistics only reflect data for SWOG coordinated trials.
- **Intergroup treatment start policies:** Depending on the LPO that is coordinating the study, there is a different time frame allowed between patient registration and the projected date of start of treatment. When doing a registration for a study not coordinated by SWOG, please make sure that the date on which treatment is planned to begin falls within the appropriate time frame stated in the protocol.