Introductory Information for New SWOG Investigators

SWOG – Who We Are:

- The SWOG Cancer Research Network is a publicly-funded global cancer research network that designs and conducts oncology research trials. SWOG is:
  - 1 of 4 adult US cooperative oncology research groups in the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), along with the Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, and NRG Oncology.
  - 1 of 7 research bases in the NCI Community Oncology Research Program (NCORP).
- SWOG is comprised of roughly 20,000 volunteer members – physician researchers, nurses, clinical research associates, pharmacists, patient advocates, lab scientists, and more – at more than 1,300 member institutions, all dedicated to fulfilling our mission to significantly improve lives through cancer clinical trials and translational research.
- At SWOG, we primarily design and conduct Phase II and Phase III multi-institution cancer trials for adult and young adult patient populations, but we also conduct data studies, secondary analyses, and translational medicine studies.
- Patient-centric integrity, accountability, and ethics, as well as scientific innovation and accuracy, are values expressed throughout SWOG's work, including our clinical trials and other committee activities.

SWOG – Impact (1956-2023):

- From its inception in 1956 through 2023, SWOG has enrolled more than 230,000 participants, to over 1,400 clinical trials.
- Based primarily on evidence from these trials, at least 14 drugs have been approved by the US Food and Drug Administration for cancer indications, 2 drugs have been taken off the market because of safety or efficacy concerns, and well over 100 changes have been made to standard of care practices.
- According to an analysis by SWOG statisticians published in 2022, NCI-funded treatment trials in adults conducted within the NCTN from 1980 to 2020 have extended the lives of patients with cancer in the U.S. by at least 14.2 million life-years, at an estimated federal investment per life-year saved of only $326 – a clear testament to the impact of the NCTN, its participating sites, and the patient volunteers who enroll to our trials.

SWOG – Member Benefits:

As an investigator at a SWOG Cancer Research Network Member Institution, you have the following membership benefits:

- Ability to enroll participants to active SWOG and NCTN (including NCORP) trials.
- Access to a network of scientific expertise via our Research, Research Support and Administrative Committees.
  - We encourage you to take advantage of this network and actively participate in SWOG committees relevant to your area of expertise and interests.
- Ability to contribute to SWOG research trial design and publication.
  - All SWOG's trials are developed and promoted via its Research and Research Support Committees.
- Access to SWOG Group Meetings (hosted in the Spring and Fall) and interim virtual events such as semiannual "Best of SWOG" webinars.
- Ability to participate in SWOG educational activities, such as the Early-Stage Investigator Training Course.
- Ability to apply for funding opportunities through The Hope Foundation.

Vital Information for New SWOG Investigators

Establishing and Maintaining your NCI Investigator Credentials:

- You must establish your NCI investigator credentials and maintain them annually to access NCI systems and enroll participants to NCTN and NCORP trials. To complete credentialing, you *must* contact your site's designated SWOG Lead Oncology Research Professional (Lead ORP), or designee at: *<Insert Institution's Lead ORP (or designee) Name, Email and Phone>.*
  - The SWOG and NCI Systems Overview briefly introduces the systems used for NCTN and NCORP trial rostering, participant enrollment, data submission and communications.

Accessing NCTN and NCORP Clinical Trial Information:

- Current trial information (protocols, supporting documents, trial status, and accrual information) is on the NCI Cancer Trials Support Unit (CTSU) website at www.CTSU.org (login required). We encourage you to familiarize yourself with the CTSU website content areas. Additional information is at:
  - CTSU website features, Where to find protocols and related documents on CTSU.org and CTSU.org protocol document types
  - SWOG has also provided a brief CTSU website overview.

SWOG Clinical Trial Conduct and Compliance:

- For institutional requirements and compliance information, contact *<Insert Institution's Regulatory Contact (or designee) Name, Email and Phone>.*
- SWOG-led clinical trials are compliant with US Food and Drug Administration (FDA), US Department of Health and Human Services (DHHS) Office of Human Research Protections, and US DHHS Office of Civil Rights regulations.
- SWOG also adheres to NCI policies and procedures for all NCTN and NCORP research trials. For information on these, we encourage you to review the following:
  - NCI Cancer Therapy Evaluation Program (CTEP) Investigator's Handbook,
  - NCTN Program Guidelines,
  - NCORP Program Guidelines (if applicable to your institution), and
  - NIH Standards of Conduct
- You should also review the information on SWOG clinical trial conduct and auditing that's available in the SWOG Policies and Procedures and SWOG Quality Assurance and Audits webpages.
  - In particular, please review the following for important information about SWOG trial conduct that may not otherwise be specified in the protocol, such as: allowable treatment or procedure windows, dose modification (or rounding) allowances, investigator's brochures, and serious adverse event reporting.
    - SWOG Best Practices Guidance Document (allowable treatment/procedure windows, specimen collection and submission, consent scenarios)
    - SWOG Policies
      - Policy 12: Registration and Treatment Policies
      - Policy 15: Applicability of IND Applications and Investigator Brochures/Support from Pharmaceutical Companies
      - Policy 19: Quality Assurance Program
      - Policy 22: Ethical and Regulatory Considerations
      - Policy 23: Serious Adverse Events
      - Policy 24: Guidelines for Publications
      - Policy 25: Drug Ordering
      - Policy 30: Responsibility for Patient Follow-up
      - Policy 33: Institutional Performance Review
      - Policy 38: Research Calculations for Clinical Trials
      - Policy 42: Policy on Advertising for Subject Recruitment and Trial Promotion
    - Patient Chart Review Guidance Document
    - SWOG Frequently Asked Questions

Questions? For protocol-specific questions, contact information is near the front of the protocol. For general compliance, quality assurance or audit-related questions, email: qamail@swog.org. For questions on NCI systems access, email: ctsucontact@westat.com.

Important Considerations for Trial Participation and Management

Accrual:

- Not only is your institution's performance monitored for SWOG-credited accruals, SWOG's overall funding is also dependent on the number of accruals credited to SWOG.
  - It is important that your institutional site staff who manage participant registrations in the NCI OPEN system also understand the importance of – and the performance requirements associated with – determining which Group is credited with a participant enrollment.

Confidentiality:

- Information in NCTN protocols is considered confidential and should not be used or shared beyond the purposes of the protocol requirements or unless additional permission is obtained from the Lead Group. Confidentiality of study results until after publication is a principal of good research, and confidentiality must be strictly maintained until results are published or formally presented.
  - At times, results information may be shared with sites for delivery to study participants prior to publication. Sharing of this information should be limited to participant notifications, until the results are published.

Funding: Research Participant Costs and Site Payments:

- **Costs to Research Participants:** Prior to activation, the NCI CTSU conducts a review of all research-directed components, interventions and procedures associated with all NCTN and NCORP clinical trials to determine which are expected to be covered under standard of care billing procedures (as compared to U.S. national guidelines and coverage rules). This review is referred to as the National Coverage Analysis (NCA). Since coverage may still vary at the local or institutional level, the CTSU-provided NCAs are intended to be a guide for participating sites to conduct their own local coverage analysis.
  - In the CTSU-provided Coverage Analysis Worksheet, generally, all research components are categorized as either "Routine Cost that is billable to Medicare/government payer/commercial payers", "Sponsor paid (or provided) Cost", "Non-billable item" (e.g., patient-reported outcome questionnaires), or "Billable as conventional care in a clinical trial that does need to qualify for coverage".
- **Institutional (Site) Funding:** Your institution will receive funding for NCTN and NCORP studies via accrual-based site payments. All funding available for the study will be outlined in a study-specific Funding sheet, which shows the breakdown of funds (e.g., screening, base intervention/accrual, biospecimen collection, patient-reported outcomes, or reimbursed procedures), the sources that pay those funds (federal or non-federal), the components that trigger the funds (or how to claim them), and contact information.
- For more a more detailed overview, see: NCTN and NCORP Participating Site Funding Mechanisms Training, OPEN Funding, SWOG Membership Site Payment Distribution Infographic and National Coverage Analysis.

New Trial Announcements, Study Feasibility, and Implementation Considerations:

- New trials are regularly activated (by all Network Groups) for NCTN-wide participation, with activation notices disseminated via CTSU.org. Investigators are encouraged to work with their site staff in order to be made aware of available trials shortly after activation. Prior to activation, participating sites can track SWOG trials in the development pipeline and anticipated activation dates via: 1) Updates provided at time of SWOG Group Meeting, 2) Regular participation in SWOG Committee Meetings (many Committees meet monthly), 3) Monitoring the SWOG Protocol Tracking Reports dashboard under Member Resources on SWOG.org.
- SWOG strongly encourages sites to maximize the benefits of the NCTN network and open available trials, with consideration for the long-term responsibilities of trial participation and the requirement to maintain active regulatory approvals from the time of activation until query resolution for all NCTN sites and publication.
  - Note: For all NCTN and NCORP trials activated after March 1, 2019, institutions must utilize the NCI Central Institutional Review Board (IRB) as the IRB of record.
- Patient population and accrual planning feasibility assessment is of critical importance to successful trial implementation. Prior to locally activating a protocol, sites should carefully consider: The competitive landscape of the trial locally, in terms of patient populations, disease type and stage, eligibility criteria, and population subgroups in light of local (institution) clinical workflows and referral pathways to ensure that the study is ultimately a good fit for the institution.
  - Investigators should identify potential challenges at the site level (staffing, site burden, approvals), patient/participant level (eligibility criteria, visit timing, or scheduling of procedures), or research team level (expertise or training) that may inhibit successful trial implementation locally, and either plan mitigation strategies prior to local protocol activation or defer local participation in the trial.

Timely and Accurate Data and Specimen Submission:

- Timely and accurate data and specimen submission are essential to the success of SWOG trials. Requirements (and allowable timeframes) for submission are identified in the respective protocol (Protocol Section 14 in SWOG-led studies).
    - If there are questions about the accuracy of the data or additional information required, site staff will receive queries.
    - We encourage SWOG Investigators to work closely with site staff who are responsible for data and specimen submission and to regularly monitor performance pertaining to the submissions for participants that you have enrolled to SWOG trials. In addition, investigators should monitor that subsequent queries are answered and resolved in a timely manner.
- Note: The requirements for data and specimen submission, documentation, and monitoring may vary between (or across) NCTN Lead Groups. Site staff must refer to the respective protocol for data and specimen submission requirements and direct related questions to the NCTN Group leading the protocol.

Importance of and Requirements for Study Participant Follow-up:

- Missing data due to participants who are lost to follow-up or withdraw consent can have a tremendous effect on the outcomes of a clinical trial. Participant follow-up directly impacts clinical data science and the statistical aspects of clinical trials. Specifically, statistical designs assume no (or minimal) missing data other than specified in the design; Unequal consent withdrawal or missing data can lead to unintentional and uncorrectable bias, and ultimately this missing data can have a direct effect on the assessment of differences between study arms and trial outcome determinations. For this reason, your institution's work as it pertains to participant follow-up is fundamental to the goal of a well-conducted clinical trial.
- Participating sites that enroll study participants to a SWOG trial are responsible for participant follow-up in accordance with SWOG Policy 30: Responsibility for Patient Follow-up. In short, participants registered by the institution or investigator at the institution must be followed (with participant consent) for the duration of time specified in the protocol (or for as long as the participant is alive), whichever is shorter. The commitment to participant follow-up is required regardless of the funding status or membership status within SWOG.
    - Participant retention to SWOG trials is critical and lost to follow-up or consent withdrawals should be considered as rare events. In order to be considered lost to follow-up, participants must meet the criteria outlined and be documented as indicated in Policy 30. If a participant withdraws consent after registration, then the investigator (or designee) must determine with the participant whether the participant 1) no longer wishes to be treated per protocol, 2) no longer wishes to be followed per protocol, or 3) both no longer wishes to be treated nor followed per protocol, and the site must clearly document the participant wishes as indicated in Policy 30. For more information, refer to: Patient Follow-up and Unusual Situations.

Publication:

- At time of results publication, high-accruing site(s) may be granted an authorship slot on the publication of the trial. SWOG will contact the Site Principal Investigator at your institution in regard to authorship and defers to your local institution to determine which investigator will be included as an author.

SWOG Communications and E-mail Distribution lists:

- SWOG bi-monthly Trial and Business Updates are distributed by email on the 1st and 15th of the month and are subsequently posted to www.CTSU.org on the 8th and 22nd of each month.
    - To receive these updates, contact member@swog.org.
- To receive SWOG's weekly "The Front Line" and related News and Events updates, complete the form at: Sign Up For E-mail Updates. Or,
    - Follow SWOG on Twitter
- To receive updates from The Hope Foundation for Cancer Research, complete the form at: Join Our Email List.
    - View News on the Hope website, or follow The Hope Foundation on Twitter and friend them on Facebook
- To help participating sites and investigators monitor data quality for their institution, on a monthly basis SWOG provides an Expectation Report, Institutional Performance Review (IPR) Report and Query Report via email distribution to your institution's designated Site Principal Investigator and Lead ORP.
    - For more information on what is included in these reports, see: Institution Performance Reports and Tools to Support Data Quality.

SWOG Committee Involvement, Group Meetings, and Resources

Joining a SWOG Committee:

- Investigator requests for SWOG Committee Membership must be submitted to SWOG by the Site Principal Investigator for your institution. To express your interest, please contact: *<Insert Institution's Site PI (or designee) Name, Email and Phone>*.
  - Committee membership is open to SWOG members who treat cancer or perform cancer related research and are interested in providing intellectual input to the SWOG disease-specific cancer study portfolio, research support and administrative committees. Note: Applicants should meet at least 2 of the following criteria:
    - Involved in care of patients with cancer related to their committee interest at an institution that participates in SWOG and/or other NCTN/NCORP studies.
    - Sustained and documented study participant accrual to SWOG or other NCTN/NCORP cancer trials related to their committee interest.
    - Evidence of engagement in clinical and/or translational cancer related research or patient advocacy and outreach related to their committee interest.
    - Sustained commitment to SWOG through regular attendance of and active participation in SWOG Group Meetings and, once approved, Committee specific meetings.

SWOG Group Meetings:

- SWOG meetings occur twice yearly (in the Spring and Fall). These events: highlight the work of SWOG members, foster dialogue within the Group, provide an opportunity to address upcoming NCI systems or policy changes, serve as a forum in which sites can voice administrative concerns and provide ongoing educational opportunities for SWOG members. Meeting dates are published well in advance under the "Upcoming Group Meetings" section of the SWOG Meetings webpage.
- Group Meetings are broadly attended and in-person attendance may afford invaluable opportunities for networking. However, in the event that you are not able to attend a Group Meeting in-person, SWOG also now offers virtual attendance options for most portions of each Meeting.
  - Each Meeting will include sessions that are open to all SWOG members and sessions that are limited (by invitation only) to respective Committee (or Working Group) members.
  - Members are encouraged to register in advance of the meeting.
    - A detailed schedule of meeting events and hotel information is posted to the Group's website when meeting registration opens, approximately nine weeks prior to each meeting.
    - Most session agendas – including information and links for virtual "open" sessions – are also subsequently published in a dedicated meeting section on SWOG.org.
    - For SWOG members, there is no registration fee to attend SWOG Group Meetings.
    - SWOG members may qualify for Travel Support, provided by The Hope Foundation.
  - After each meeting, materials that were shared at open sessions are also posted on SWOG.org.
  - For questions about SWOG group meetings, email meetings@swog.org.

Report of Studies:

- The SWOG Report of studies is a comprehensive summary of SWOG active or recently closed to accrual trials, which is published to the member-only section of SWOG.org twice a year, prior to the SWOG Spring and Fall Group Meetings. Refer to the report of studies for current accrual, toxicity, participant characteristics, and other pertinent trial information or updates.

Funding Opportunities via The Hope Foundation:

- The Hope Foundation for Cancer Research is a public charity which supports the SWOG Cancer Research Network members and research initiatives. SWOG members have access to a variety of Research Support, Career Development, and Community Support Awards provided via The Hope Foundation. These awards include programs such as the:
  - **SWOG/Hope Impact Award Program** to encourage novel and innovative SWOG research by funding the early and conceptual stages of trial-related projects.
  - **Dr. Charles A. Coltman, Jr. Fellowship** to engage outstanding early career investigators, protecting time as they learn clinical trial methodology within an academic and network group environment, and leading to independent clinical research.
  - **Trial-Specific Education Fund** to support education and training for sites participating in complex SWOG trials. Studies that are deemed to have non-standard endpoints, complicated design, and/or registration potential are eligible for funding.
- A complete list of announcements and application deadlines are accessible from the Funding Opportunities link above or refer to the current program overview.

Additional Education and Information Resources are accessible via the SWOG website. In particular, note the links to Clinical Investigator Resources and Continuing Education and Training Programs. As new online training materials and educational opportunities become available, announcements are also posted on the website.