SWOG

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Policy Memorandum No. 50
Subject: Description and Responsibilities of a SWOG Lead Oncology Research Professional
Departments Affected: All

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DESCRIPTION AND RESPONSIBILITIES OF A

SWOG LEAD ONCOLOGY RESEARCH PROFESSIONAL

The SWOG Lead Oncology Research Professional has been historically referred to as the SWOG Institution's "Head CRA." This position is being renamed to better reflect the leadership responsibility associated with the role. Both the SWOG Cancer Research Network and the National Cancer Institute Offices will consider the person designated as the SWOG Lead Oncology Research Professional as a Principal Point of Contact (POC) that coordinates all levels of communications between the member institution and the SWOG and NCI Offices (respectively). Herein, the designated POC will also have inherent responsibility for internal institutional coordination with and/or dissemination of communications to the appropriate identified institutional personnel with decision and/or signatory authority for each (respective) type of communication identified below.

All institutions actively participating in clinical trials as a member of SWOG, including institutions in a follow-up only status, must assign a Lead Oncology Research Professional.

Variance in Structure Across SWOG Member Institutions

The SWOG Lead Oncology Research Professional (Lead ORP) position description will vary amongst the respective SWOG member institution(s).

The following description details responsibilities that may be appropriate for inclusion in the identified SWOG CRP's position description. This description is intended as a guideline for institutional reference and to provide examples of the types of communications that institutions may expect to be directed to the SWOG Lead ORP for appropriate institutional dissemination, review, action, follow-up, and/or resolution.

It is the responsibility of the participating SWOG member institution(s) to structure the position description of the person identified to SWOG as the SWOG Lead ORP in a way that efficiently supports institutional participation in SWOG and NCTN (including NCORP) clinical trials.

Recommendations

All identified SWOG Lead ORPs should be a member of the SWOG Oncology Research Professionals Committee, should be able to attend at least one SWOG Group Meeting annually (virtual meeting attendance is allowable, if available), and should have attended the Clinical Trials Training Course (CTTC) (in-person-preferred, or online if not able to attend in-person) and the online SWOG Lead Oncology Research Professional Training Course.

- SWOG hosts a Spring and Fall meeting: typically, in April and October.
  - Future meeting dates are published in advance: SWOG Cancer Research Network Meetings.
    - Meeting details are posted on the website about 9 weeks prior to each Group Meeting.
  - After each Group Meeting, all "open" (or member-wide) meeting materials are also posted.
  - For additional information, contact meetings@swog.org.

SWOG Lead Oncology Research Professional (formerly "SWOG Head CRA") Responsibilities

The SWOG Lead ORP serves as a leader (in some institutions may be a Program Leader) and SWOG liaison for the institutional SWOG membership program, communicating with the NCI, SWOG and other NCTN affiliates on behalf of the institution and the Subrecipient Principal Investigator.

1. It is anticipated that the identified Lead ORP will have a direct working relationship with the SWOG institutional Site Principal Investigator (Site PI), leadership responsibility within the respective SWOG institution(s) as pertains to the conduct of SWOG clinical trials and will serve as the primary POC for coordination of all logistical aspects of NCI and SWOG clinical trial conduct within the respective institution(s).
2. The SWOG Lead ORP may be directly involved with and responsible for some or all of the following (dependent upon the local institutional infrastructure). In the event that the following responsibilities are supported via another institutional department or position, the Lead ORP will be responsible for coordinating any communications pertaining to below responsibilities with the NCI, SWOG, and other NCTN affiliates (including NCORP) that are directed to the Lead ORP.
    a. In coordination with the Site PI, institutional investigators, and identified study staff, the Lead ORP will ensure institutional conduct of feasibility reviews of protocol requirements and ensure all study team members are notified of study status and approval.
    b. The Lead ORP will coordinate (and/or ensure institutional processes are in place) to monitor financial aspects of SWOG trial activity, manage study coverage and coordinator assignment, and facilitate partnerships with departments and collaborators.
    c. The Lead ORP will coordinate and/or disseminate NCI, SWOG, and other Lead Network Group communications pertaining to institutional status reports (e.g., regarding: NCTN (including NCORP) clinical trial start-up procedures and timelines, study prioritization, IRB and/or CIRB submissions and approval, institutional accrual, data submission, clinical trial participant status and follow-up inquiries, study closure, and record retention) with and to appropriate institutional staff (e.g., institutional investigators, pharmacists, laboratory, pathology, or radiology personnel, study coordinators, data managers, regulatory associates, administrative offices, and budget/contracts personnel).
    d. Examples of communications and study-related queries that may be directed to the SWOG Lead ORP as the primary POC for appropriate, dissemination, consideration, action, and/or resolution, include the following.
        1) Direct communications from NCI and NCI Offices such as the: NCI Clinical Trials Support Unit (CTSU) or NCI Cancer Therapy Evaluation Program (CTEP).
        2) Direct communications from the SWOG Contracts and Budgets offices as pertain to required purchase service agreements, subcontracts, or payments.
        3) Reconciliation of data submission queries and receipt of SWOG Query Reports, SWOG Expectation Reports, and SWOG Institutional Performance Reports.
        4) Reconciliation of Institutional Investigator (or support staff) membership status or access to NCI / SWOG systems.
        5) General study broadcast communications from SWOG or NCI CTSU as pertain to study status, updates, amendments or related information.
        6) General Lead Group or NCI broadcast communications as pertain to new or updated policies, procedures, or systems for management and conduct of NCI or Lead Group clinical trials.

For Lead ORPs at international member site(s): Communications pertaining to identification and resolution of potential barriers to international site participation in NCTN (including NCORP) studies.

e. Coordination (and, in some institutions, oversight) of the activities of other research staff working on SWOG trials to ensure that research is done in accordance with NCI and SWOG policies and all applicable regulations. This includes coordination of data and quality management review (and/or review meetings), implementation of tracking systems to ensure compliance, and coordination of Quality Assurance audits for NCTN (and NCTN affiliates, including NCORP) clinical trials.

Direct responsibilities will vary per the structure and type of institution. In larger institutions, this coordination may (will often) be fulfilled via dissemination and collation of communications with the respective departments/staff supervisory personnel. Whereas in other smaller institutions the Lead ORP may assume direct responsibilities for oversight. In many institutions, the Lead ORP also has a supervisory role to help ensure that day-to-day operations are compliant with NCI and Lead Group requirements for conduct of clinical research trials.

3. It is anticipated that the SWOG Lead ORP will be aware of the requirements of their respective position description in any relevant NCI, SWOG and/or NCTN affiliate grant(s) (or subawards) and ensure that those requirements are met.

4. The SWOG Lead ORP should be familiar with the Site PI's position description and NCTN Program Responsibilities, as identified in SWOG Policy 46, the NCTN Program Guidelines (Part 1, Section 4), and (for NCORP institutions) the NCORP guidelines in order to help support the Site PI in administration of SWOG clinical trials at the Member Institution(s).

5. Refer to the Glossary on SWOG.org for definition of terms.

6. Refer to the SWOG Oncology Research Professionals, SWOG ORP (CRA) Workbench (including the SWOG CRA Manual for Oncology Research Professionals (ORP)) and Clinical Research Resources webpages for a list of ORP contacts, information pertaining to conduct of SWOG research trials and general resources.