

SWOG
<http://swog.org>

Policy Memorandum No. 46

Subject: Job Description of Principal Investigator

Departments Affected: All

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JOB DESCRIPTION OF A PRINCIPAL INVESTIGATOR

All institutions actively participating in clinical trials as a member of SWOG, including institutions in a follow-up only status, must assign a Principal Investigator who directs and oversees all research activities within the institution.

General Responsibilities

The Principal Investigator (PI) assumes responsibility for the overall scope of their institutional program, including, but not limited to, ensuring that the institution meets the procedures and standards set forth by SWOG, notifying SWOG of important changes in member relationships, agreeing to quality assurance audits, and communicating all policies (and any changes in policy) on the conduct of clinical research to clinical researchers and staff members. The PI is further charged with promoting SWOG activities within the institution, ensuring investigators and trainees are provided the opportunity to learn about SWOG and participate in SWOG activities, as well as identifying institutional research that could be translated to cooperative group science and assisting in bringing those ideas forth within SWOG.

Qualifications

The institution's Principal Investigator must be a licensed physician and be qualified to personally supervise all aspects of clinical trial conduct at the site. Principal Investigators must have a minimum of three years clinical faculty experience in conducting clinical trials. The Principal Investigator should possess effective communication skills and the ability to work as part of a multidisciplinary team to provide leadership in the development of the institution's program both scientifically (protocol development and coordination, publications, committee leadership and participation) and by accrual contributions.

If a Principal Investigator that does not meet the above minimum requirements is designated, it is recommended that a senior Co-Principal Investigator (at least at an Associate Professor or equivalent level) be identified to provide additional support and mentorship.

Effective April 6, 2024, all newly designated Principal Investigators must complete the SWOG Site Principal Investigator Workshop within 90 days of designation. In addition, PIs at Accruing Member Institutions that are Not in Good Standing (on probation or suspended) may be required to complete assigned modules of the Site PI training Workshop as part of a corrective action plan to return the institution to Good Standing.

Specific Responsibilities

1. Understands and upholds the policies and procedures of the Group and assist with, and participates in communications as necessary with all clinical researchers and staff members in ensuring the same.
2. Ensures that specialists from relevant oncology disciplines, as well as appropriate data management and ancillary clinical resources, are available within the institution to support the activities of SWOG.
3. Regularly monitors institutional accrual and ensures the institution meets minimum accrual goals set forth by SWOG to maintain membership.
4. Monitors performance of affiliate sites and provides support to those sites as needed.

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5. Directs the use of funds received by SWOG to support SWOG activities.
6. Assumes participant follow-up responsibility from investigators at their institution or affiliates in accordance with Group Policy No. 30.
7. Participates in the SWOG audit exit interview for a recap of the audit findings and to provide clarification of issues raised by the auditors.
8. Ensures that deficiencies in institutional performance reviews and quality assurance audits are addressed and corrected.
9. Ensures that procedures are in place to approve all new investigator membership nominations at his/her institution and affiliates.
10. Appoints individuals from their institution as authors on Group publications in accordance with Group Policy No. 24, as requested.
11. Attends at least one semi-annual Group meeting every two years.
12. Principal Investigators from Accruing Member Institutions in Good Standing that have met accrual and scientific standards for Governing Membership (see Policy 03), have been nominated by the Professional Review Committee, and have been approved by a majority of the standing Board of Governors, will serve on the Board of Governors. Once elected, Governing Membership is maintained by the institution for two years at which point the institution must be re-reviewed and re-elected.
13. When resigning as the Principal Investigator, the Principal Investigator is responsible for ensuring that the Group Chair is informed of this decision and that a new Principal Investigator is named.