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Policy Memorandum No. 4 **Page 1 of 2 pages**
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NATIONAL COMMUNITY ONCOLOGY RESEARCH PROGRAM GUIDELINES

SWOG has developed the following guidelines for National Community Oncology Research Program (NCORP) institutions that have an interest in associating with SWOG as a research base:

1. Each NCORP must submit an application to the National Cancer Institute (NCI) describing its organizational structure and governing body, and naming SWOG as its research base. NCORPs without prior experience using SWOG protocols should describe their prior experience with national or local protocols.

2. Each NCORP must submit a Statement of Assurance to ensure that every protocol to be used by any investigator affiliated with the NCORP will have prior approval by the appropriate hospital's Institutional Review Board (IRB). All participants must have given informed consent, in accordance with the National Cancer Institute and SWOG Guidelines, prior to registration and initiation of treatment. All informed consents will give permission for the participant's original medical record to be reviewed, for quality assurance, by representatives of the NCI, SWOG, and/or approved select drug monitors from the pharmaceutical industry involved in the protocol.

3. Investigators who are members of a group of practicing clinicians or a consortium must identify the location(s) in which their participants will be treated to both the NCI and SWOG.

4. Every NCORP investigator participating in SWOG protocol studies must have curriculum vitae on file in the SWOG Network Operations Center. An FDA 1572 (21 CFR 312.53(c) Statement of Investigator) and supporting documents must be submitted to the Pharmaceutical Management Branch (NCI) on an annual basis by all participating investigators. Other documentation may also be required for submission from new investigators.

5. Each NCORP will abide by rules and performance criteria governing all SWOG members in regard to participant eligibility, participant evaluability, timeliness of data submission, radiotherapy and pathology evaluability and quality control determination. SWOG will provide for participant registration, data management, statistical analysis, and training of support personnel, quality control and quality assurance in accordance with SWOG policies.

6. Each NCORP investigator will provide assurance of short and long term follow-up of all registered participants. All SWOG participants are followed long-term as specified in each individual protocol. Penalties for failure to meet this commitment may include suspension of registration, probation or termination of SWOG affiliation.

7. All NCORP members will be required to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68. and participate in Quality Assurance Audits as deemed necessary.

8. The SWOG Network Operations Center will provide assistance to proposed NCORP institutions in the preparation of their institutional applications for funding regarding the activities of the Group as the named Research Base. This assistance will include the provision of institutional performance evaluation results (as necessary), accrual data, and the development and finalization of a NCORP Affiliation Agreement with that institution. The Group Chair also provides the funding agency, the Division of Cancer Prevention (DCP), with letters of recommendation (if requested) for all proposed NCORP institutions.

9. Following approval of the institution's funding application, the Group Chair will submit a membership nomination for all new NCORP institutions to the Board of Governors. NCORPs recommended for approval by the Board of Governors will become probationary members of SWOG for a period of up to, but not exceeding, 18 months. During the period of probation, the performance of the NCORP will be monitored by the Group Chair, Network Operations Center, and Statistical and Data Management Center. The NCORP may be moved to full member status at any time during the probationary period once all criteria for full membership have been met.

10. All NCORP members (Probationary and Full Member) are eligible to attend the open scientific and administrative sessions of the SWOG semi-annual meetings. All NCORP member institutions are required to attend at least one Group Meeting every two years.

11. Each NCORP member at an institution approved for full membership is eligible, as is any SWOG member, for appointment to the Research Committees, Research Support Committees, Administrative Committees and various subcommittees. They are also entitled to participate in protocol design and coordination following the completion of the SWOG Study Chair Workshop.

CRITERIA FOR FULL MEMBERSHIP FOR NCORPs

In order to obtain full member status, the following criteria must be met:

1. Accrual of at least 20 evaluable participants to Group and Group endorsed treatment studies.

2. A successful Quality Assurance Audit.

3. Acceptable quality control standards in participant eligibility and data submission.

COMPLIANCE WITH FEDERAL REGULATIONS

Each NCORP must comply with all applicable federal regulations governing the conduct and monitoring of clinical trials, to include ensuring compliance with the Code of Federal Regulations (45 CFR 46, 21 CFR 50, 21 CFR 56, and 21 CFR 312) in the protection of human subject research and Institutional Review Board review and approval of research studies and consent forms, conducting research in compliance with the ethical principles embodied in The Belmont Report (respect for persons, beneficence and justice), and ensuring the confidentiality of participant data (e.g., the Health Insurance Portability and Accountability Act – HIPAA and reporting to the sponsor adverse experiences that occur in the course of the investigation(s)). Non-compliance with federal regulations may result in investigation censure

CRITERIA FOR CONTINUING PARTICIPATION AND SUPPORT

Each NCORP will abide by the rules and performance criteria governing all SWOG members regarding participant eligibility and evaluability, timeliness of data submission, acceptable quality assurance audits, and scientific contributions to the Group.

The NCORPs must maintain a minimal accrual contribution of 20 initial registrations to Group and Group endorsed treatment studies. The accrual will be measured as an average annual accrual of the previous three (3) years. The accrual is reviewed annually.

Failure to meet the minimum accrual standard listed above will result in the site being put into a probationary period of one year and will lose the privileges associated with being a member-in-good standing.