The following letter of agreement is written to confirm and facilitate the cooperation of the SCCC institutions* in the conduct of the NCI Community Clinical Oncology Program (CCOP) via a consortium agreement with the Southeast Cancer Control Consortium, Inc. (SCCC), of Winston-Salem, North Carolina. The agreement is intended to assure compliance with all requirements of the National Institute of Health (NIH), the National Cancer Institute (NCI), Office for Human Research Protection (OHRP), the Food and Drug Administration (FDA), and the CCOP Research Bases to promote efficient and effective collaboration in the conduct of cancer clinical trials and cancer control programs.

**Research Base Resource Affiliations**

The Southeast Cancer Control Consortium (SCCC) will utilize NCI-approved clinical trials and cancer control studies from the following research bases in the conduct of projects sponsored for the CCOP program:

1. Cancer and Leukemia Group B (CALGB), a national multispecialty, multidisciplinary cooperative group.
2. Comprehensive Cancer Center of Wake Forest University (CCCWFU), a comprehensive cancer center for treatment and cancer control studies.
3. Cancer Trials Support Unit (CTSU), a national cooperative group sponsored by the NCI for "intergroup studies".
4. The National Surgical Adjuvant Breast and Bowel Project (NSABP), a national cooperative group for treatment of breast and bowel cancers, breast cancer prevention studies, and cancer control studies.
5. Radiation Therapy Oncology Group (RTOG), a national multidisciplinary, multispecialty cooperative group for clinical trials and chemoprevention studies.
6. Southwest Oncology Group (SWOG), a national multispecialty, multidisciplinary cooperative group.
7. University of Rochester Cancer Center (URCC), a comprehensive cancer center for cancer control studies.

**SCCC Community Representatives to the Board of Directors**

James N. Atkins, MD will be the SCCC Principal Investigator. Each community will be represented in the SCCC organization by a board member, a physician designated in consultation with the community members and the SCCC Operations Office. This board will meet at required intervals, but at least bi-annually, to review the program, to agree upon priorities in studies, to promote the most effective utilization of resources, and to avoid competitive bias among programs sponsored via the SCCC.

**Quality Control Assurances/Audits**

Assurances from each community component (hospital, clinic, or private office) are required by the NIH, NCI, and OHRP. Failure to maintain assurance can result in termination of the total program by the NCI. Each community component/affiliate must comply with the assurances provided to and approved by the OHRP (45 CFR 46). No protocol should be applied to patient treatment without completion of full board review by the local institutional review board (IRB), and an RSS 2.0 form completed and submitted to the SCCC Operations Office prior to patient registration.

On-site access to all procedures, medical records, and other data must be available to quality assurance auditors who may visit the community representing the NCI, the FDA, Research Bases (CALGB, CCCWFU, CTSU, NSABP, RTOG, SWOG, and URCC), the SCCC, OHRP, and/or pharmaceutical companies supplying drugs via the NCI.

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**SCCC Office Use Only:**  
*Individual agreements are on file in the SCCC Operations Office. Signature pages for each community are appended at the end of this agreement.*
The institution will submit to the SCCC, assurances required by the NIH as follows:

1. Appropriate review of each protocol and updates requiring IRB approval or project to assure local approval as required by the OHRP.

2. To make available all records required for quality assurance review of clinical activities related to the program, and qualifications of physicians as required by the NIH, NCI, FDA, and other regulatory agencies.

3. All subjects for cancer clinical trials and participants in cancer control protocols must review and sign an informed consent before participating in a protocol. A copy of the informed consent will be given to the patient, a copy forwarded to the respective research base operations office (if required) and the original will be maintained in the patient's local protocol file.

4. Control inventory and dispensing of investigational drugs.

5. Continuous update on the incidence of cancer in the community participating in the program.

6. The development and maintenance of American College of Surgeons Cancer Program in the individual member hospitals.

7. Inclusion of women and minorities; no discrimination based on age.

**Funding**

I. NCI/SCCC

The SCCC, which is funded by the NCI for the conduct of CCOP activities, will maintain a headquarters office for coordination and supervision of the program. Personnel from the Operations Office will be available for support/education for physicians and non-physician participants to assure enthusiastic and competent conduct of the program. Registrations to both cancer clinical trials and cancer control activities will be conducted via the registrar at the appropriate research base office.

Community components/affiliates will be supported by quarterly reimbursement by check from the SCCC for each eligible/evaluable registration to treatment and cancer control protocols. The amount of reimbursement depends on funding from the NCI. The SCCC/CCCWFU database (ORIS) will be used to determine the number of qualified patients/participants for which the community is due reimbursement. (The SCCC database is Year 2000 compliant).

Should registrations exceed the funding allowed for community reimbursement, a request to NCI for additional funding will be made; however, there is no assurance that additional funding will be available.

Reimbursement for registrations should be used as a charge-back against individual community expenses incurred for participating in the CCOP program. Expenditure of grant funds at the community level are subject to review and approval by the SCCC Operations Office auditor.

II. Community

Each new community/institution must invest $2,000.00 in order to become a member of the CCOP. This investment is used by the SCCC Operations Office to defray the expenses incurred in implementing a new site and training new community personnel. Annual membership fee is $50/each physician, due upon application for membership and on June 1st annually thereafter.
Community Personnel

Each SCCC community institution will require a physician "Community Leader" as the sponsoring coordinator of the program in the community, as well as physicians who participate. There will also be a nurse or clinical research professional to assume the role of "Study Coordinator." These designated local CCOP leaders will be responsible for communications related to protocols, registration of patients, collection of data in proper format, and local educational activities to support the full development of a program of clinical trials and cancer control projects. Each community may require additional staff for data management and clerical support of the program, depending upon the activity in the community. Payments and benefits for these core personnel will be assumed by the local institution, in compliance with their institutional policies.

Inasmuch as communication between the community members and SCCC is essential to the conduct of this program, all community and Operations Office personnel will seek to maintain an alert, timely communication and data processing program.

Activity Credits

The program requires specific credits for clinical trials and cancer control registrations as established by the NCI-CTEP and DCPC Cancer Therapy Evaluation Program (CTEP) and Division of Cancer Prevention and Control (DCPC). The SCCC is obligated to attain its assigned quota. Future funding depends upon meeting the registration requirements mandated by the NCI.

Failure to provide eligible/evaluable registrations may result in suspension of registration privileges until a plan is submitted for correcting the registration deficit.

Duration of Agreement

This agreement is goes into effect on the date of approval of membership application, and continues through 5/31/2005. The agreement may be extended thereafter by mutual agreement of the participants.

Withdrawal from SCCC Program

The NCI requires written notice of withdrawal from the program. This must be provided to the SCCC Operations Office by any physician or institution wishing to withdraw from participation in the program.

Inventions/Patents-N/A

Ownership and Disposition of Data

All data generated via participation in the CCOP research base protocols is the property of the research bases. Confidentiality of data is assured. Data will be submitted to the research base statistical headquarters for analysis and publication. SCCC physicians, nurses, and CRPs will not publish data independently of the research bases.

Acceptance

The undersigned, assuring that they are informed of the nature of this program and the benefits the community gains through improved cancer treatment and the prevention of cancer through education, and early detection programs, enter into this program confirming their enthusiastic support and cooperation.

7/03

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Compliance with NIH Consortium Agreements

The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the NIH consortium agreement policy (Attachment II) and are prepared to establish the necessary inter-institutional agreement(s) consistent with that policy.

______________________________________   ____________________________
Community Physician Leader                            Date

______________________________________   ____________________________
Hospital Administrator                                Date

Community

_______________________________________
Hospital

_______________________________________            ____________________________
James N. Atkins, MD                                   Date
Principal Investigator