NCI COMMUNITY CANCER CENTERS PROGRAM

NCI Community Cancer Centers Program
Pilot Work Plan and Deliverables Summary

Biospecimens

INTRODUCTION: The NCI Community Cancer Centers Program (NCCCP) pilot research initiative will explore the development of a national network of community-based cancer centers. The focus of the pilot will be to research how best to accomplish the following:

- increase accruals to NCI-sponsored clinical trials, especially for underrepresented and disadvantaged populations;

- develop new or expanded programs to increase outreach to the uninsured, underrepresented, and disadvantaged populations for prevention, screening, treatment, follow-up care, palliative care, survivorship plans, and end-of-life care;

- increase knowledge of infrastructure requirements, necessary interfaces, and applicability of specific components of caBIG™ for community hospital settings, and increase implementation of electronic medical records and exploration of the application of electronic medical records in the provision of cancer care;

- increase knowledge of infrastructure requirements, policies and procedures, costs, and other issues (e.g. collaborations or contracts necessary for biospecimen collection, annotation and storage) required for implementation of NCI Best Practices for Biospecimen Resources, thus enabling community hospitals to participate in biospecimen initiatives that will advance the NCI's research agenda.

The NCCCP pilot will incorporate key NCI initiatives into the examination of a model for hospital-based community cancer care to include the four focus areas listed above. In addition, there is interest in exploring the following special areas of interest that could serve to enhance the model:

- Models for effective linkages with NCI-designated cancer centers or academic medical research institutions that would support the program goals;
- Effective linkages with state-sponsored cancer initiatives;
- The potential benefit of participation in healthcare information technology initiatives such as a RHIO (Regional Health Information Organization) or similar initiative;
- Working with providers to examine the potential for the development of new reimbursement models for cancer prevention, screening and treatment;
- Models for survivorship plans that would support the overall goals of the program;
- Exploration of the benefit of linkages with the NCI-sponsored Cancer Expert Corps, a program under development, to bring cancer expertise to locations where there is a gap in a needed service;
- The value of a knowledge exchange network for community hospital-based cancer providers;
- Models for co-investment with the NCI to broaden the effective reach of the NCI research programs;
- Models of multidisciplinary cancer care that incorporate the continuum of services including early detection, prevention, therapy, survivorship follow-up and end-of-life support programs;
- Working with providers that have developed successful approaches for accrual of patients into NCI-sponsored clinical trials. NCCCP pilot sites are not expected to encompass all areas of special interest;
- Programs in locations where the population has significant hardships affecting access to healthcare; and
- Whether selecting a site that is part of a national health system might speed the replication of a successful model.

WORKSCOPE: Although the pilot will not focus specifically on collecting biospecimens, the pilot sites will commit to describe their current efforts around biospecimens and will assess the implementation requirements for the NCI Best Practices for Biospecimen Resources for a hospital-based community cancer program. The pilot sites will devote time and expertise throughout the pilot to assess the implications, barriers, costs, necessary processes, procedures, personnel, and relevant infrastructure for implementation in a hospital-based community setting. The organization will participate in routine conference calls with the NCI and SAIC-Frederick staff, to include representatives from the entire pilot group.

The pilot sites represent institutions with varying experiences, accomplishments, and dedicated staff devoted to biospecimens. Pilot sites also operate under different administration, pathology, and nursing structures and interactions. The pilot will be especially successful if the following is accomplished:

- CEO and other leadership must be fully committed and be willing to remove individual-specific obstacles.
- Annotation, collection, processing, and storage of specimens will use NCI Best Practices, and SOPs will be standardized as per National Biospecimen Network concept.
- caBIG™ will be implemented including necessary clinical specimen annotation (e.g., anesthesia and nursing).
- Lead and development sites will be connected if feasible and appropriate.
- Pathologists' staffing and schedules will be evaluated to support the coverage needed to follow the requirements for the NCI Best Practices.
- Collected data will follow the Commission on Cancer-approved CAP Cancer Protocols using SNOMED-CT.
- All cancer-related diagnosis and treatment providers will utilize shared information and best practices for improved patient care/safety overriding specific individual, departmental and organizational concerns.

The following caBIG™ applications will be applicable to the biospecimens workscope:

APPLICATION	FUNCTIONALITY	PILOT FOCUS AREA
C3PR	Subject/participant registry	Clinical Trials, Biospecimens
caTissue	Biospecimen repository	Biospecimens
caXchange	Automated transfer of clinical data	Clinical Trials, Biospecimens

During the pilot period, specific research questions will include the following:

- Can community cancer centers participate in the NCI Best Practices for Biospecimen Resources?

- Can the pilot organizations complete the baseline assessment, identify gaps in the biospecimen-related processes, and identify the required resources to address those gaps?

DELIVERABLES: Throughout the pilot, the pilot sites will work with NCI and SAIC-Frederick staff for the review of the NCI Best Practices for Biospecimen Resources to complete a detailed report with recommendations on the necessary infrastructure requirements, policies and procedures, cost and other implementations issues, such as collaborations necessary for biospecimen collection and storage, required for implementation enabling community hospitals to participate in biospecimen initiatives that will advance the NCI's research agenda. The pilot sites will provide quarterly reports and a final report to include the work completed to address the focus area of biospecimens.

Performance will be measured by assessing the level of activity. Quarterly reports should monitor progress towards achieving year 1-3 activities and should discuss plans for improving performance when achievement of activities is delayed – problems and potential solutions should be highlighted.

TIMELINE – MAJOR ACTIVITIES AND SAMPLE METRICS:

YEAR 1 – PLAN
Assess biospecimen capabilities/challenges of each site, stratify sites into tiers, determine strategy **Baseline:** • Stand-Alone Pathology Laboratory Work Process • Site-specific Operating Procedures • No/Minimal Biospecimen Annotation **Tier 1… Baseline plus:** Identify collaboratively and deploy *Best Practices for Biospecimen Resources* (BPs) that would add value to the site, either • using NCICB as an application service provider, or • installing infrastructure locally, or • adapting local systems to share data in a caBIG™ compliant manner **Tier 2… Tier 1 plus:** Use local electronic medical record infrastructure, either pre-existing or open source, to prototype an end-to-end clinical research data pipeline for biospecimen annotation, collection, processing, reporting, and storing **Tier 3… Tier 2 plus:** Primary pilot site sharing data bidirectionally with secondary site(s) or: Two or more pilot sites sharing data bidirectionally with common clinical data warehouse
Complete baseline and gap analyses and prioritize detailed Gap Matrix for each site – stratify sites to Tiers
Identify resources necessary for filling each Gap and identify barriers
Implement key infrastructural elements
Educate and orient stakeholders at each site
Participate in the formal program evaluation
YEAR 2 – DO
Develop and apply quantifiable site-specific monitors for filling each gap and begin filling gaps using priority list
Harmonize monitors for inter-site comparisons if possible
Participate in the formal program evaluation
YEAR 3 – ASSESS and EXTEND
Develop and implement intra-pilot IT connectivity between primary and developmental sites if possible
Test inter-primary site IT connectivity if at least two primary sites have reached requisite level of IT infrastructure using caBIG™ (virtual clinical data base)

Prepare a detailed report (site specific and pilot group report) with recommendations on the necessary infrastructure requirements, policies and procedures, cost and other implementations issues such as collaborations necessary for biospecimen collection and storage, required for implementation enabling community hospitals to participate in biospecimen initiatives that will advance the research agenda of NCI
Prepare a matrix of “Lessons Learned” for the various administration, pathology/laboratory, medical staff, nursing, etc., to include structures and interactions that have been encountered, what worked and what didn’t
Participate in the formal program evaluation