U-10 Cooperative Agreement for NCI Community Oncology Research Program (NCORP)

Request for Application

Board of Scientific Advisors
June 24, 2013

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Division of Cancer Prevention

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Chief, Outcomes Research Branch
Division of Cancer Control & Population Sciences

In Collaboration with the Division of Cancer Treatment and Diagnosis and the NCI Center to Reduce Cancer Health Disparities
NCORP Vision: Preserve & Enhance Cancer Research in the Community

• Build upon clinical trial success of the Community Clinical Oncology Program (CCOP) and Minority-Based CCOP (MB-CCOP) network
  – Development and conduct of cancer prevention and control trials
  – Accrual to National Clinical Trials Network (NCTN) treatment and imaging trials
  – Enrollment of minorities into clinical trials
• Expand to include cancer care delivery research (CCDR)
• Enhance focus on disparities questions in clinical trials and CCDR studies

OVERARCHING GOAL

*Bring state-of-the art cancer prevention, control, treatment, and imaging trials, as well as CCDR and disparities studies, to individuals in their own communities*
Why Support Cancer Research in the Community Setting?

• Majority of cancer care is provided in the community
• Access to larger, more diverse patient populations
• Access to “real world” healthcare delivery settings
• Tests feasibility of implementing new interventions and processes
• Accelerates the uptake of new interventions and processes into routine practice
• Enhances potential that outcomes will be broadly applicable in practice
CCOP, MB-CCOP and Research Bases
Geographic and Organizational Diversity

- 3400 Physicians
- 780 Performance sites

CCOPs (49)
- Distributed networks (30)
- Integrated Systems (11)
- Small Networks (8)

MB-CCOPs (17)
- Academic (11)
- Non-Academic (6)

Research Bases (13)
- (13)
NCI Community Clinical Oncology Program Network
Accrual 2000 – 2012

Minority accrual:
MB-CCOPs: 63%
CCOPs: 10%

Total accrual 161,000 -
(40% to NCTN treatment)

Participants (in thousands)

2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012*

Treatment  Prevention & Control

*9 month annualized data
Selected Major Accomplishments from Cancer Prevention and Control Trials

• **Chemoprevention**
  - **BCPT, STAR:** Breast Cancer Prevention Trials
  - **PCPT, SELECT:** Prostate Prevention Trials
  - Large, clinically annotated biorepositories for use in research

• **Symptom Management**
  - **CALGB 170601:** Pain reduction in chemotherapy induced peripheral neuropathy
  - **NCCTG:** Non-hormonal reduction of vasomotor symptoms (gabapentin & venlafaxine)

• **Health Related Quality of Life**
  - **RTOG 0214:** Prophylactic cranial irradiation results in memory decline; reduced brain metastasis; no survival benefit
Future Research Agenda for Cancer Prevention and Control Trials

• Molecularly targeted agents
• Post-treatment surveillance
• Over-diagnosis and under-diagnosis
• Management of precancerous lesions
• Mechanisms of cancer-related symptoms
• Biomarkers of risk for treatment-related toxicities
• Enhance accrual of racial/ethnic and other under-represented populations
Expansion to Cancer Care Delivery Research

- Cancer Care Delivery Research
- Minority Accrual
- Treatment Clinical Trials
- Cancer Prevention and Control Clinical Trials
Why Support Cancer Care Delivery Research in the Community Setting?

• Precision medicine increasingly complicates care
• Rapidly changing health care system
  • Affordable Care Act
  • Accountable care organizations
  • Merging of practices
  • Diverse, often fragmented provision of care
• Urgent need for evidence about how these changes influence:
  – Patient outcomes
  – Disparities in care

*Dynamic healthcare environment demands a better understanding of routine oncology care delivery*
Cancer Care Delivery Research Portfolio

CCDR grants in the oncology specialty setting (N=197) (FY2007-2012)

<table>
<thead>
<tr>
<th>NCI</th>
<th>NIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>161 grants</td>
<td>36 grants</td>
</tr>
<tr>
<td>$175.6 million</td>
<td>$52.4 million</td>
</tr>
</tbody>
</table>

Key Findings: Care Delivery (N=157)
- 72% Academic
- 21% Community
  - Most within a single geographic area

Key Findings: Population-Based Datasets (N=40)
- 71% use national data sources
- 3 grants use hospital-based registry data

*NCORP addresses a key gap by providing a diverse, geographically distributed, multi-site platform for CCDR*
NCORP Cancer Care Delivery
Potential Research Agenda

• Observational studies
  - Patterns of care or service utilization data
  - Alternate organizational structures (e.g., integrated healthcare systems versus free-standing hospitals)
  - Alternate models for implementing multidisciplinary care planning (e.g. tumor boards versus multi-disciplinary clinics)

• Interventional studies
  - Implementation of new technologies (e.g., decision-making tools)
  - Incorporation of patient reported information into clinical decision-making
  - Implementation of new supportive/palliative care models
  - Introduction of patient navigators targeted at an underserved population
Why Focus on Cancer Disparities Research in NCORP?

• Persistent disparities
  – Cancer incidence, mortality, and quality of life
  – Access to and quality of care

• Increase in the number of underserved/underrepresented populations

• Determinants of disparities (social factors, health care systems, co-morbidities) disproportionately affect outcomes for underserved populations

• Challenging to fully and equitably implement new technologies and targeted therapies for the underserved

Need for further research to reduce disparities and improve outcomes for underserved populations across the continuum of care
Synergy of Clinical Trials, Care Delivery, and Disparities Research - Cardiotoxicity

- Acute and long-term cardiovascular adverse effects from therapy
- CCOP/MB-CCOP prospective studies
  - Cardiac biomarker study to predict anthracycline cardiac toxicities (BNP, troponin, ECHO, exam) - MD Anderson Research Base
  - ACE versus blocker/placebo study to prevent trastuzumab LV dysfunction/CHF – Sun Coast Research Base
- DCCPS epidemiological studies
  - Population-based, retrospective cohort study of risk of CHF from anthracycline and trastuzumab
NCORP Cardiotoxicity Research
Future Directions

• Clinical trials investigating mechanisms, pathways, genomic and other biomarkers, imaging/diagnostic tools

• Longitudinal cohort studies of patients in routine care

• Cancer disparities studies to assess differential adverse effects in populations with a higher inherent risk of cardiovascular disease
NCORP Component Characteristics

• Research Bases
  - Scientifically strong and feasible research agenda
  - Scientific and statistical leadership
  - Operational processes and personnel
  - Collaboration across Research Bases including for CCDR research priorities and data standards

• Community Sites
  - Minimum of 80 accruals annually
  - Recruitment and retention plan
  - Clinical research leadership and operations team
  - Capacity to support CCDR studies

• Minority/Underserved Sites
  - 30% of cancer patients and accrual from racial/ethnic minority or other underserved population
  - Potential to contribute data on disparities in outcomes and care
NCORP Evaluation Criteria

- Incorporation of emerging science, novel ideas and trial/study designs
- The degree to which NCORP prevention, treatment, and control trials lead to practice change
- Meeting or exceeding accrual requirements
- Increased accrual of populations underrepresented in clinical trials
- Development of a coordinated portfolio of CCDR studies
- Participation of young investigators in community oncology research
## FOAs and Estimated # Grants

<table>
<thead>
<tr>
<th>Network Component</th>
<th>Mechanism (Duration)</th>
<th>Est. Max. # Grants</th>
<th>Frequency New Application Accepted?</th>
<th>Multiple PI Option?</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCORP Research Base</td>
<td>U10 (5 Yrs)</td>
<td>Up to 7</td>
<td>Every 5 Years</td>
<td>Yes</td>
</tr>
<tr>
<td>NCORP Community Site</td>
<td>U10 (5 Yrs)</td>
<td>Up to 40</td>
<td>Every 5 Years</td>
<td>Yes</td>
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<tr>
<td>NCORP Minority/Underserved</td>
<td>U10 (5 Yrs)</td>
<td>Up to 14</td>
<td>Every 5 Years</td>
<td>Yes</td>
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</table>
Clinical Trial Funding Principles for NCORP Research Bases

- Annual infrastructure funding
- Study specific support
  - Protocol development
  - Statistics and data management
  - Trial monitoring and auditing
  - Specimen collection and banking
- Per case payments to non-NCORP sites for cancer prevention and control accrual
- Source of funds
  - DCP CCOP/MB-CCOP Research Base operating budget
CCDR Funding Principles for NCORP Research Bases

• Annual infrastructure funding

• Single pool of funds for competitively awarded study specific support

• Staged funding model for first award cycle
  – Year 1: 100% infrastructure and training
  – Year 2: 75% infrastructure, 25% study specific
  – Year 3: 50% infrastructure, 50% study specific
  – Year 4/5: 25% infrastructure, 75% study specific

• Source of funds
  – NCCCP operating budget
  – DCCPS
Clinical Trial Funding Principles for NCORP Community Sites

- Fixed baseline funding per award
  - Establish and maintain a clinical trials infrastructure

- Standardized per case funding based on the trailing three-year average annual accrual

- High accruing sites (≥200 accruals/year) receive increased per case funding

- Source of funds
  - DCP CCOP/MB-CCOP community site operating budget
CCDR Funding Principles for NCORP Sites

• Fixed baseline funding per award
  – Support Lead Investigator, study coordinator, and data system staff
  – Estimate $100K per award

• Increased funding for awardees with substantial CCDR experience and capacity
  – Estimate average of $300K per award

• Source of funds
  – NCCCP operating budget
# CCOP/NCCCP and NCORP Funding (dollars in thousands)

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>CCOP/MBCCOP Total Program Grant Funds</th>
<th>NCCCP Total Contract Funds</th>
<th>Total Combined Funding</th>
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<tbody>
<tr>
<td>2011</td>
<td>89,000</td>
<td>34,413</td>
<td>123,413</td>
</tr>
<tr>
<td>2012</td>
<td>87,400</td>
<td>38,575</td>
<td>125,975</td>
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<tr>
<td>2013 Estimate</td>
<td>81,370</td>
<td>11,783</td>
<td>93,153</td>
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<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>NCORP Clinical Trial Funding</th>
<th>NCORP Cancer Care Delivery Funding</th>
<th>Total Combined Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>81,000</td>
<td>12,000</td>
<td>93,000</td>
</tr>
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# Annual Funding Request

**NCI Community Oncology Research Program (NCORP)**

<table>
<thead>
<tr>
<th>NCORP Component</th>
<th>No. of Sites</th>
<th>Clinical Trials $ Millions</th>
<th>No. of Sites</th>
<th>CCDR Funding $ Millions</th>
<th>Total Annual Funding</th>
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<tbody>
<tr>
<td><strong>NCORP Sites</strong></td>
<td>40</td>
<td>$35.4</td>
<td>40</td>
<td>$5.4</td>
<td>$40.8</td>
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<tr>
<td><strong>NCORP-M/U Sites:</strong> Subtotal</td>
<td>14</td>
<td>$7.3</td>
<td>14</td>
<td>$2.0</td>
<td>$9.3</td>
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<tr>
<td><strong>SUBTOTAL:</strong></td>
<td>54</td>
<td>$42.7</td>
<td>54</td>
<td>$7.4</td>
<td>$50.1</td>
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<tr>
<td><strong>NCORP Research Bases</strong></td>
<td>7</td>
<td>$38.3</td>
<td>7</td>
<td>$4.6</td>
<td>$42.9</td>
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<tr>
<td><strong>Total RFA Funding</strong></td>
<td></td>
<td>$81.0</td>
<td></td>
<td>$12.0</td>
<td>$93.0*</td>
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* The 5-Year Total Grant Funding Request for NCORP for FY 2014 to FY 2018 is $465 Million.

Clinical Trial Funding: NCORP and NCORP-M/U Sites - $280,000 Infrastructure funding + $2,500/accrual for sites with < 200 accruals annually or + $4,000/accrual for sites with >200 accruals annually.

CCDR Funding for NCORP & NCORP M/U Sites: Standard funding at $100K per award and enhanced funding at $300K per award on average.
Tentative Timeline for Potential Implementation

- Board of Scientific Advisors: June 2013
- NCI DEA & NIH Review Funding Opportunity Announcement and Guidelines
  - Fall of 2013 with a goal of making awards in 2014
NCORP Vision for Cancer Research in the Community

• **Build upon clinical trial success** of the Community Clinical Oncology Program (CCOP) and Minority-Based CCOP (MB-CCOP) network

• **Expand to include cancer care delivery research**

• **Enhance focus on disparities research** (both stand-alone and integrated studies) with clinical trials and CCDR

• **Capitalize on synergies** between clinical trials, CCDR, and disparities research questions