Request for Application (RFA) – Reissuance

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In collaboration with the Divisions of Cancer Treatment & Diagnosis & the Center to Reduce Cancer Health Disparities
NCI Community Oncology Research Program (NCORP) is an Academic/Community Partnership

**Clinical Trials** for cancer control and prevention, comparative effectiveness, and screening

**Accrual** to National Clinical Trials Network (NCTN) treatment and advanced imaging trials

**Cancer Care Delivery Research** to develop clinical practices that achieve optimal clinical outcomes

**Incorporation of Cancer Disparities Research** into clinical trials and cancer care delivery research
NCI Community Oncology Research Program: Research Bases & Community Sites

National Clinical Trials Network (NCTN) Group & NCORP Research Base

NCORP Community Sites

NCORP Minority/Underserved Community Sites
NCORP Community Site, M/U Community Site and Research Bases Geographic and Organizational Diversity

- Investigators (4,025)
- Components/Subcomponents (938)

Community Sites (34)
- Distributed network (25)
- Integrated System (7)
- Small Network (2)

MU Community Sites (12)
- Academic (8)
- Non-Academic (4)

Research Bases (7)
- Research Bases

Updated: May 2017
NCORP Accrual*  
2014 - 2016

- CP/C & Treatment  
  2014: 5982  
  2015: 5855  
  2016: 6004

* Does not include accrual to CCDR studies
NCORP Minority Enrollment by Community Type

NCORP Community Sites - 2016

- Minority: 15.2%
- Non-Minority: 81.7%
- Not Reported: 0.3%
- Unknown: 2.8%

NCORP Minority/Underserved Sites - 2016

- Minority: 52.7%
- Non-Minority: 42.5%
- Not Reported: 0.4%
- Unknown: 4.4%
Cancer Control & Prevention Trials

- Currently: 52 Active Trials available from NCORP Research Bases
- Trials activated & completed during NCORP thru 8/1/17

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Title</th>
<th>Activation date</th>
<th>Accrual Cut Off Date</th>
<th>Planned Accrual</th>
<th>Actual Accrual</th>
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<tbody>
<tr>
<td>A221303</td>
<td>Randomized Study of Early Palliative Care Integrated with Standard Oncology Care Versus Standard Oncology Care Alone in Patients with Incurable Lung or Non-Colorectal Gastrointestinal Malignancies</td>
<td>5/15/2015</td>
<td>4/10/2017</td>
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<td>E4112</td>
<td>Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma In Situ (DCIS)</td>
<td>2/17/2015</td>
<td>4/28/2016</td>
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<td>368</td>
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<td>NRG-CC002</td>
<td>Pre-Operative Assessment and Post-Operative Outcomes of Elderly Women with Gynecologic Cancers</td>
<td>2/10/2015</td>
<td>11/2/2015</td>
<td>228</td>
<td>190</td>
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<tr>
<td>URCC-13070</td>
<td>Improving Communication for Cancer Treatment: Addressing Concerns of Older Cancer Patients and Caregivers</td>
<td>10/29/2014</td>
<td>4/30/2017</td>
<td>1056</td>
<td>973</td>
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<td>URCC-13091</td>
<td>Feasibility of Omega-3 Supplementation for Cancer-Related Fatigue</td>
<td>2/26/2015</td>
<td>3/31/2016</td>
<td>75</td>
<td>108</td>
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<tr>
<td>URCC-14079</td>
<td>Effectiveness of Prophylactic Topical Agents for Radiation Dermatitis</td>
<td>10/13/2015</td>
<td>6/30/2016</td>
<td>180</td>
<td>192</td>
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# NCORP Quality of Life Accrual

<table>
<thead>
<tr>
<th>Enrollment Accrual</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollments to QOL sub-studies to treatment trials</td>
<td>2485</td>
<td>1897</td>
<td>2391</td>
</tr>
<tr>
<td>NCORP Community Sites</td>
<td>957</td>
<td>821</td>
<td>1333</td>
</tr>
<tr>
<td>Non-NCORP Sites, i.e., LAPS, Main members, affiliates</td>
<td>1528</td>
<td>1076</td>
<td>1058</td>
</tr>
</tbody>
</table>
Symptom Science: Symptom Management & QOL Steering Committee Priorities

- **Cardiovascular Toxicity:** 7 Trials – e.g., ALTE11C2-Health Effects after Anthracycline and Radiation Therapy (HEART): Dexrazoxane and Prevention of Anthracycline–related Cardiomyopathy

- **Cognitive Impairment:** 5 Trials – e.g., NRG C003 Randomized Phase II/III of Prophylactic Cranial Irradiation with/without Hippocampal Avoidance for Small Cell Lung Cancer.

- **Fatigue:** 1 trial -A221101 – A Phase III Randomized, Double Blind Placebo Controlled of Armodafinil to Reduce Cancer-Related Fatigue in Patient in High Grade Glioma

- **Cancer Specific Pain:** 2 trials , e.g., E1Z11 A Cohort Study to Evaluate Genetic Predictors of Aromatase inhibitor Musculoskeletal Symptoms
Accomplishments of Cancer Care Delivery Research

- 2 Capacity Assessments covering 225 practice units
- 5 open studies have accrued over 1,300 patients and clinicians
- 7 protocols in development

**Study features**
- Topics include use of guidelines, financial toxicity, smoking cessation, and geriatric assessment
- 6 with additional funding (3 NIH, 1 AHRQ, 1 PCORI, 1 Leukemia & Lymphoma Society)
- 5 cluster-randomized controlled trials
NCORP’s Contributions in NCI’s Precision Medicine Initiatives
Molecular Analysis for Therapy Choice (MATCH)

“A trial of therapy based on genetic characteristics of the tumor is feasible in the institutions of the NCTN and NCORP”

Collectively, 342 NCORP sites contributed 44 percent (2788/6408) of patients registered for screening in MATCH
New-Onset Diabetes (NOD) Cohort Study
NIDDK, Pancreatic Cancer Consortium & Early Detection Research Network

• Background: 25-40% of pancreatic ductal adenocarcinoma cancer patients (PDAC) develop diabetes between 6-24 months prior to diagnosis

• Goals:
  o Identify and follow a large cohort
  o Develop a biorepository
  o Clinically validate promising biomarkers of PDAC
  o Develop an early detection protocol for sporadic PDAC

• Planned enrollment from NCORP: 6,000/10,000
  o Estimated number of PDAC cases: 85 (over 3 year follow up)
Early Onset Malignancy Initiative (EOMI):
Cancer Disparities: Priority Opportunity Area

- Discover mechanisms for early onset cancer
- Determine if there is genetic variation between/among groups
- Identify rare genetic variants that drive differences
- Identify risk factors that impact outcome
- Use information to better treatment options and prognosis

### Cancer Sites | Age Cut Offs
---|---
Breast | ≤45
Colorectal | ≤55
Liver | ≤55
Multiple Myeloma | ≤50
Prostate | ≤55
Renal* | ≤50

*Renal in Native Americans Only

Populations: African American, Caucasian, Hispanic, Native American
External Evaluation
Working Group
Report
1. Overall Scientific & Clinical Value and Impact

Response(s) to Recommendations/Plans for Reissuance

• To Focus on Symptom Science Steering Committee priorities:
  o Cardiovascular Toxicity; Cognitive Impairment; Fatigue; and Cancer Specific Pain
  o Steering Committee Planning Meeting for peripheral neuropathy

• To evaluate the mechanistic basis of symptoms:
  o Program will request funding for correlative sciences and biobanks to support symptom science
2. Infrastructure Support of Research Portfolio

Response(s) to Recommendations/Plans for Reissuance

• Expand cancer care delivery research infrastructure at the Sites:
  ➢ Program will request increased funding for implementation & site infrastructure

• Increase minority/underrepresentation from Community Sites:
  ➢ Trans-Group concept development for trials to address research questions for underrepresented populations

• Provide support in the transition from large adjuvant trials to new molecularly targeted and precision trials
  ➢ Program is reviewing information about best practices and strategies to sustain them
3. Efficiency of Study Development and Accrual

Response(s) to Recommendations/Plans for Reissuance

- Research Bases and NCI should identify ways to expedite the timeline for trial and study development
  - NCI has formed a Working Group to assess the variations in timelines and review processes, and to establish guidelines & stopping rules for the heterogeneous research portfolio
  - NCI has a Screening Log to capture number of individuals screened per trial
  - Program proposes increased funding for screening and enrollment activities
4. Collaboration

Response to Recommendations (s)/Plans for Reissuance

- NCORP plans to continue to promote trans-Research Base research, e.g., AYA, elderly, including advocates
- NCORP Working Groups are designed to work together with experts to serve as champions for NCORP research, address barriers to enrollment
- Several ongoing collaborations exist, e.g., PCORI, ASCO, AACR, International Research Groups, and other NIH Institutes
5. Cancer Care Delivery Research

Response to Recommendations (s)/Plans for Reissuance

- NCORP should expand participation of community oncologists, primary care physicians and chief operating officers in Study design:
  - CCDR Landscape Assessments have provided opportunity to engage these stakeholders

- NCORP should explore opportunities for studies involving payers, big data, and policy change:
  - Investigators are welcome to explore these possibilities, bearing in mind that the capacity for conducting trials distinguishes NCORP from other components of the NCI portfolio
NCORP: Future Directions

- Ongoing: **TMIST** and its associated biorepository

- **Surveillance:** colon cancer screening surveillance, pancreatic cyst progression

- **Cancer Prevention:** topical applications, e.g., breast, HPV dose scheduling, and utilization in pediatric cancer survivors

- **PreCancer Atlas:** molecular characterization of preneoplastic lesions

- **Symptom Science:** assessing immunotherapy related toxicities

- **NCORP Expansion:** capture underrepresented geographical areas
Potential Topics for Cancer Care Delivery
Randomized Clinical Trials

• **Implementation**
  - Any type of tumor DNA sequencing (< 1/4 of CCDR practices report routine use)
  - Early palliative care (15% survival improvement at one year)
  - Telehealth (< 1/3 of CCDR practices report using for care)

• **De-implementation**
  - Contralateral prophylactic mastectomy (no survival benefit yet use > 10%)
  - Use of serum tumor markers for breast cancer surveillance (no survival benefit yet use > 20%)

• Intervene on **financial toxicity** (bankruptcy associated with 50% decreased survival)

## 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>CCDR Funding $ Millions</th>
<th>Total Annual Funding</th>
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<tbody>
<tr>
<td><strong>NCORP Community Sites</strong></td>
<td>40</td>
<td>$47</td>
<td>$9.5</td>
<td>$56.5</td>
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<tr>
<td><strong>NCORP-M/U Sites</strong></td>
<td>14</td>
<td>$10</td>
<td>$4.0</td>
<td>$14.0</td>
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<tr>
<td><strong>NCORP Research Bases</strong></td>
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<td>$43</td>
<td>$6.5</td>
<td>$49.5</td>
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<tr>
<td><strong>SUBTOTAL</strong></td>
<td>61</td>
<td>$100</td>
<td>$20</td>
<td>$120</td>
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<tr>
<td><strong>Large Scale Screening/Prevention Trials+</strong></td>
<td></td>
<td>$25</td>
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<td>$25</td>
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<tr>
<td><strong>Total RFA Request</strong></td>
<td>61</td>
<td>$125</td>
<td>$20</td>
<td>$145*</td>
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|                        |              |                            |                         |                      |
| **Biobanking Support**  |              | $2.5                       | …                       | $2.5                |
| **Imaging and Radiation Oncology Core Support** | | $1.5                       | …                       | $1.5                |
| **NCI DCTD Contract ++** |              | $8.5                       | $2                      | $10.5               |
| **SUBTOTAL**            |              | $12.5                      | $2                      | $14.5               |

| **Total NCORP Initiative Funding**  |              | $137.5                     | $22                     | $159.5              |

* The 6-Year Total RFA Funding Request for NCORP for FY 2019 to FY 2024 is $870 Million.

+ Includes Year 3 TMIST (FY2019)
++ DCTD Contract Support: NCI Core Systems, CIRB, CTSU, CT Log
# Funding Request with Proposed Increases
## NCI Community Oncology Research Program (NCORP)

<table>
<thead>
<tr>
<th>NCORP Component</th>
<th>No. of Sites 2017 / Increase</th>
<th>Clinical Trials 2017 Base / Increase $ Millions</th>
<th>CCDR Funding 2017 Base / Increase $ Millions</th>
<th>Total 2017 Base / Increase $ Millions</th>
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<td><strong>NCORP Community Sites</strong></td>
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<td>$35.4 / $11.6</td>
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<td><strong>NCORP-M/U Sites</strong></td>
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<td>$7.3 / $2.7</td>
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<td>$9.3 / $4.7</td>
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<td>$38.3 / $4.7</td>
<td>$5 / $1.5</td>
<td>$43.3 / $6.2</td>
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<td><strong>SUBTOTAL</strong></td>
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<td><strong>$81 / $19</strong></td>
<td><strong>$12 / $8</strong></td>
<td><strong>$93 / $27</strong></td>
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<tr>
<td><strong>Large Scale Screening/Prevention Trials+</strong></td>
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<td>$5 / $20</td>
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<td><strong>RFA Base/Increase Total</strong></td>
<td>53 / 8</td>
<td><strong>$86 / $39</strong></td>
<td><strong>$12 / $8</strong></td>
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<tr>
<td><strong>Biobanking Support</strong></td>
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<td>.....</td>
<td><strong>$2.5</strong></td>
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<td><strong>Imaging and Radiation Oncology Core Support</strong></td>
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<tr>
<td><strong>NCI DCTD Contract ++</strong></td>
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<td>$5 / $3.5</td>
<td>$1.2 / $0.8</td>
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<td><strong>Subtotal</strong></td>
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<td><strong>$5 / $7.5</strong></td>
<td><strong>$1.2 / $0.8</strong></td>
<td><strong>$6.2 / $8.3</strong></td>
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<tr>
<td><strong>Total NCORP Initiative Funding (Base/Increases)</strong></td>
<td></td>
<td><strong>$91 / $46.5</strong></td>
<td><strong>$13.2 / $8.8</strong></td>
<td><strong>$104.2 / $55.3</strong></td>
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</tbody>
</table>

+ Includes Year 3 TMIST (FY2019)
++ DCTD Contract Support: NCI Core Systems, CIRB, CTSU, CT Log
Questions?