NRG Oncology NCORP

NRG NCORP Research Base PIs
Deborah Watkins Bruner, RN, PhD, FAAN
Joan Walker, MD

NRG NCORP Research Base Associate Chair
Lisa Kachnic, MD
National Cancer Institute Community Oncology Research Program (NCORP) Network

The NCI NCORP is a national network that brings cancer clinical trials and care delivery studies to people in their own communities. Their focus areas include:

- Cancer Control and Prevention
- Symptom Management
- Screening
- Post-Treatment Surveillance
- Quality-of-Life Studies Embedded in Treatment Trials
- Cancer Care Delivery
- Cancer Disparities
The NCORP is housed in the NCI Division of Cancer Prevention, with collaboration by the NCI Division of Cancer Control and Population Sciences, NCI Division of Cancer Treatment and Diagnosis and NCI Center to Reduce Cancer Health Disparities.

NCORP is comprised of 7 Research Bases and 46 Community Sites, 14 of which are designated as Minority/Underserved (MU) Community Sites.

- NCORP MU Community Sites have a patient population comprised of at least 30% racial/ethnic minorities or rural residents.

The NCORP Community Sites accrue participants to NCI-approved cancer clinical trials.

- The sites are consortia of researchers, public hospitals, physician practices, academic medical centers, and other groups that provide healthcare services in communities across the U.S.
The NCI Community Oncology Research Program (NCORP) brings cancer research studies and results to patients in a variety of community settings across the United States.

- 7 research bases
  - Develop and coordinate clinical trials and cancer care research

- 32 community sites
  - To bring NCI approved trials to patients

- 14 minority/underserved community sites
  - Including locations at diverse, community-based hospitals, private practices and more

February 2019
30% - 35% of patients enrolled on NCTN clinical trials, including precision medicine studies, are from NCORP sites
Benefits of Working with NRG NCORP

- Ability to run R01s through NRG and increase access to diverse populations
  - Access to over 1,800 NRG Oncology and NRG NCORP sites to conduct research

- Major Supplemental Funding

- Access to Big Data for Secondary Analyses

- Increased IMPACT of work
Member & Mentorship Opportunities

- Seed Grant Pipeline
  - Seed grant announcement yearly in late winter
- New Investigator Mentee on Protocols
  - To be mentored by senior study PI
- Travel Awards for Bi-annual Meetings
NRG Oncology NCORP Structure

NRG NCORP Exec Committee
NCORP PIs: Bruner/Walker
Associate Chair: Lisa Kachnic
NRG Oncology Group Chairs: Curran/Mannel/Wolmark;
NCORP Committee Chairs and Vice Chairs,
NRG Oncology NCORP Stats: PI Dignam and Dr. Pugh

NRG NCORP Steering Committee
NCORP PIs, Committee Chairs and Vice Chairs, Working Group Chairs and Vice Chairs,
Stats, Community Physicians, New Investigator Liaisons, Patient Advocates

Ca Prevention and Control Research (CPCR) Co-Chairs: L Kachnic, D Levine
Vice Chairs: D Barton, J Bauman
- Neurocognitive Function
- Gender-specific Symptom Mgmt
- Behavioral Interventions
- Dose Alterations
- Ca Risk Reduction

Ca Care Delivery Research (CCDR)
Chair: M Cooley
Vice Chair: M Hudson
- Ca Survivorship/
- Palliative Care
- Optimize screening in community
- Implement EBP in Symptom Mgmt

Health Disparities Research (HDR)
Chair: K Yeager
Vice Chair: C Hughes
- Racial/Ethnic Minorities
- Elderly
- Rural Populations

Patient Centered Outcomes Research (PCOR)
Chair: B. Movsas/
Vice Chairs L. Wenzel, P Ganz
- PROs tx trials
- Consult on PROs in CCC, CPC, CCD, HDC trials

NRG NCORP Operations Committee

NRG NCORP Finance Committee
NRG NCORP Core Grant Priorities

- Four symptomatic management themes:
  - neurotoxicity
  - cardiotoxicity
  - lymphedema
  - inflammation

- Cancer prevention, survivorship and palliative interventions

- Cancer care delivery

- Cancer disparity research, in collaboration with our Health Disparities Research (HDR) Program
NRG NCORP Cancer Prevention and Control Priorities

Concepts/protocols focused on:

- Improvement or delay in decline of neurocognitive function;
- Reducing of gender-specific symptoms including lymphedema and sexual function;
- Testing therapeutic delivery modifications to improve QoL and cost-effectiveness in localized cancers while maintaining efficacy;
- Reducing cancer risk through optimal screening, biomarker evaluation and risk reduction strategies; and
- Assessing behavioral interventions to decrease cancer risk and mitigate cancer treatment-related symptoms.
NRG NCORP Cancer Care Delivery Research Priorities

Concepts/protocols focused on:

- Integrating patient-reported outcomes into clinical practice (extends survival);
- Enhance access to proven survivorship and palliative care strategies optimizing survivor and family quality of life;
- Optimize screening strategies based on disease risk including patients in the post-treatment surveillance phase of care; and
- Implement evidence-based symptom management strategies addressing patients’ needs during both active adjuvant and palliative treatment.
NRG NCORP Health Disparities

WHAT are we looking for?

- Stand alone concepts/protocols focused on **interventions** to *decrease* health disparities
  - Access to care
  - Access to clinical trials

- Stand alone concepts/protocols focused on **interventions** to *improve* cancer health disparities related
  - Uptake of Screening
  - Uptake of Prevention
  - Symptom Management

- Quality of Life
- Health Literacy
- Adherence/Compliance

- Embedded health disparities related secondary endpoints on other NCORP or treatment trials

- Secondary analyses of vast NRG Oncology database posing health disparities questions that would fill gaps in the literature or guide intervention trials
  - eg. Are there differences in outcomes by travel distance? Urban vs rural?
Patient Centered Outcomes Research (PCOR)

- Work to assess and improve patient centered outcomes (PCOs) and comparative effectiveness in therapeutic and cancer control trials across NRG Oncology cancer disease site and non-disease site committees.

- Consult with disease site investigators on study design and validated metrics related to PCOs including: symptoms/toxicities, quality of life (QOL), host factors, comorbidity, survivorship, utilities, patient preferences and costs.

- Work to harmonize metrics and time points within and across disease sites when appropriate and to minimize patient burden while maximizing endpoint assessments.
NRG NCORP Changing Standard of Care

- Major changes over this past grant period:
  - R0614: Memantine during whole brain RT reduces neurocognitive deterioration
  - R0933: Hippocampal avoidance during whole brain RT leads to HVLT preservation
  - R1203: IMRT reduces bowel toxicities (over 3D RT) from the patient perspective in postop GYN cancers
<table>
<thead>
<tr>
<th>Study</th>
<th>Disease</th>
<th>Date Closed</th>
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<tbody>
<tr>
<td>G0273</td>
<td>Chemo tolerance in elderly patient</td>
<td>6/4/2014</td>
</tr>
<tr>
<td>G0244</td>
<td>Lymphedema incidence, risk factor and impact</td>
<td>11/17/2014</td>
</tr>
<tr>
<td>B-43</td>
<td>RT vs. RT+Trast</td>
<td>12/8/2014</td>
</tr>
<tr>
<td>R1203</td>
<td>3D vs. IMRT for pelvic RT</td>
<td>8/27/2015</td>
</tr>
<tr>
<td>NRG-CC002</td>
<td>Elderly post-op outcomes</td>
<td>11/2/2015</td>
</tr>
<tr>
<td>NRG-CC001</td>
<td>Memantine + WBRT w/ or w/out HA in pts w/ Brain Mets</td>
<td>3/12/2018</td>
</tr>
<tr>
<td>G225</td>
<td>Diet and Exercise to Prevent Ovarian Cancer Recurrence</td>
<td>8/24/2018</td>
</tr>
<tr>
<td>G237</td>
<td>CA-IX, p16, PHV for Dx of AGUS in Cervical Cancer</td>
<td>8/2/2019</td>
</tr>
<tr>
<td>NRG-CC004</td>
<td>Ph II Bupropion trial testing 150 vs 300 mg to improve sexual desire more than placebo</td>
<td>4/24/2020</td>
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# Ongoing NRG NCORP Trials

**Accrual as of April 30, 2020**

<table>
<thead>
<tr>
<th>Study No</th>
<th>Disease Site</th>
<th>Description</th>
<th>Date Activated</th>
<th>Target Accrual</th>
<th>Total Accrual</th>
<th>NCORP Accrual (%)</th>
<th>Expected Closure Date</th>
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<tbody>
<tr>
<td>GOG 278</td>
<td>Cervix</td>
<td>Physical fx &amp; QOL before/after non-radical surgery</td>
<td>10/1/12</td>
<td>220</td>
<td>211</td>
<td>&lt;1%</td>
<td>December 2020</td>
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<tr>
<td>NRG CC003</td>
<td>Lung</td>
<td>Seamless Ph II/III PCI vs. PCI with hippocampal sparing for cognitive fx</td>
<td>12/7/15</td>
<td>172 (II) 302 (III)</td>
<td>176 of 172 (II) 298 of 302 (III)</td>
<td>28%</td>
<td>Phase II complete: Re-opened to Phase III accrual Jan 2019</td>
</tr>
<tr>
<td>NRG CC007CD</td>
<td>Prostate</td>
<td>Survivorship care plan for prostate ca survivors on ADT to increase blood glucose and cholesterol checks in yr 2 after starting ADT &amp; lower CVD risk</td>
<td>03/27/19</td>
<td>504</td>
<td>61</td>
<td>100%</td>
<td>October 2021</td>
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## Study Champions

<table>
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<tr>
<th>Study</th>
<th>Protocol Title</th>
<th>Accrual</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>S0820</td>
<td>Double Blind Placebo-Controlled Trial to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers (PACES)</td>
<td>275/491</td>
<td>NRG is a champion for this trial and enrolled 30 participants</td>
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<tr>
<td>EA1151</td>
<td>Tomosynthesis Mammographic Imaging Screening Trial (TMIST)</td>
<td>25,216/164946</td>
<td>NRG is a champion for this trial and enrolled 1,954 participants</td>
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# Developing NRG NCORP Trials

<table>
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<tr>
<th>Study No</th>
<th>Disease</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRG-CC005</td>
<td>Forte – Five or Ten Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps</td>
<td>Protocol submitted to DCP</td>
</tr>
<tr>
<td>NRG-CC008</td>
<td>A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [SOROC]</td>
<td>Protocol pending CIRB and DCP final approval</td>
</tr>
<tr>
<td>NRG-CC1974</td>
<td>SRS vs. HA-WBRT for 10 or fewer Brain Metastases from Small Cell Lung Cancer</td>
<td>Concept submitted to DCP</td>
</tr>
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</table>
NRG NCORP Concept Development Guidelines

- All new NCORP concepts must be reviewed and vetted by the appropriate Cancer Prevention and Control, Cancer Care Delivery Research or Health Disparities committees.

- High priority concepts will then be presented by the committee co-chairs to the NCORP PIs at monthly strategy meetings.

- Those felt to be most meritorious are invited to move on to the NCORP formal concept review process.
NRG NCORP Concept Review Process

Concepts considered for NCORP formal concept review have been presented and supported by the relevant NCORP committee; **NRG disease site committee** and seen by NRG statistician to comment on potential sample size

Call for concepts will be sent to all NCORP Committees with submission deadline

Concepts meeting the requirements above are submitted to on the NCORP concept submission form

Concepts are distributed and assigned to appropriate reviewers for content, PROs, TRP, Stats, pt advocate, community feasibility and will obtain written comments

At NCORP steering committee face-to-face meeting (or conference call), PI may introduce study in a few sentences, no slides permitted. Reviewers will present comments and recommendations.

If approved, present to NRG Research Strategy Committee/CPAC, upon approval submit to NCI submission

**Approval**

Revise and Resubmit

**Disapproval**

Revise proceed through re-review as above

End
NCORP Information can be found on the NRGONCOLOGY.ORG Website
Scientific Program > NRG NCORP Resource Base

Concept development forms can be found here
CPC and CCDR Concept Development Forms

Concept Development and Evaluation Forms

- Cancer Care Delivery Research Concept (CCDR) Development Form
- Cancer Prevention and Control Concept (CPC) Development Form
- CCDR Concept Evaluation Form (Scientific)
- CCDR Concept Evaluation Form (Statistical)
- CCDR Concept Evaluation Form (Advocate)
- CPC Concept Evaluation Form

NRG Oncology Publication Policy and Guidelines

- Publications Policy & Guidelines v.03-06-2018
- NCORP Guidelines for Development of Concepts, Protocols, and Amendments
- Biomarker, Imaging, & Quality of Life Studies Funding Program (BIQSEP)
- Investigator Initiated Federally and Non-Federally Funded Studies 2017 Guidelines
INSTRUCTIONS & CONCEPT REVIEW FLOW CHART FOR COMPLETING THE CONCEPT FORM FOR REVIEW BY THE NCORP/CANCER PREVENTION & CONTROL COMMITTEE

PHASE I, III, II, I/III, or III

NRG Oncology NCORP/ CPC Committee Concept Approval Process:

- Concept approval may be a multi-step process depending on the stage of development of the concept. Study Chairs must submit to the CPC committee first to obtain feedback and guidance. Once approved by CPC and the concept is fully developed, the study chair will interact with NRG stats and NCORP Administrator prior to NCORP mock review. This process must be performed in a manner even if partially developed concepts have been previously reviewed. Note: Details that are not required for preparation of the concept for Study Chairs who want to submit a concept early, prior to full development, are denoted by an asterisk (*) in the appropriate areas below.

- At the recommendation of CPC leadership the NCORP Administrator will forward the concept to the assigned NRG Oncology NCORP Statistician and to at least five reviewers for content, Primary Reported Outcomes (PRO), Translational Research Program (TRP), community feasibility and statistics. Concepts will be reviewed at the February or July NRG Oncology meeting or via conference call in between face-to-face meetings as needed.

- Concept review will follow the NCI Symptom Management and HRQOL Steering Committee review criteria.

- The NCORP/CPC Committee Chair(s) will communicate the decisions made during the review (e.g., approval, revise and resubmit, or disapprove) to the Study Chair:
  1. Approval with or without recommendations: The Committee approves the concept and does not need to evaluate a revised concept. The concept will be presented to NRG Oncology Research Strategy for approval and if approved will be revised based on recommendations (as appropriate) before submission to the NCI Symptom Management and HRQOL Steering Committee.
  2. Revise and resubmit: The committee has determined that the concept requires additional information or has design issues that can be addressed within the next three months and asks that the investigators address that information in a revised concept.

II. Schema: This one page diagram provides an overview of the study design. A schema that includes sample size, study population, stratification factors, study design and, specific intervention.

III. Background

A. Rationale for Proposed Study:
The background is one of the most important sections of the concept and often accounts for the bulk of the concept document. It provides the reviewers with relevant information supporting the rationale for the proposed study. The scientific justification should include a focused review of relevant literature with citations covering significance of the condition to be studied, current knowledge of etiology and pathophysiology, a limited review of studies that have contributed information applicable to the proposed study, and a brief summary of pilot or preliminary data. The background should make the argument that the proposed research is a logical next step in the development of a clinical intervention. The scientific justification for an observational study should include the reason the information is required and the use of that information for developing interventions for cancer prevention and control.

B. Significance of the Study:
The background section should clearly state how the proposed research will further science in cancer prevention, symptom management, and/or quality of life. This should include a brief discussion of the potential clinical utility of the intervention. For example, the investigator should provide evidence that the measurement tool is sufficiently sensitive to detect a clinically important difference. Also, measures of the number needed to treat (NNT) to see an effect or a description of the degree of improvement that a patient would experience, may be relevant to include. Observational studies should describe the gaps in current knowledge and how increasing the knowledge base will facilitate development of interventions.

IV. Study objective(s) and hypotheses
Additional funds are often needed to facilitate the study, including:

- secondary endpoint data collection and/or analysis
- specimen banking
- drug supply and drug distribution
- correlative science
- patient-reported outcomes
- patient counseling
Any NCORP Study/PI **MUST follow Publication Guidelines**- even if YOU are the PI and the study was submitted through your institution with a sub to NRG
Why would an R01 Investigator want to run a trial through NRG NCORP?

NRG NCORP would be **MAJOR** supplemental support to R01

- Access to over 1,800 NRG Oncology Sites with no separate agreements
  - CCDR projects access to NCORP sites only
- Ability to increase access to diverse populations
- Site Research Coordinators recruit and consent patients
- Biospecimen collection by NRG sites and storage by NRG biobank
- Data entry done by NCORP
- Statistical monitoring and analysis done by NCORP
- Peer review process prior to submission
- Increased probability of publication in high impact journals
What are challenges an R01 Investigator would need to understand to run a trial through NRG NCORP?

- Must obtain NRG NCORP APPROVAL PRIOR to grant submission
  - Must undergo peer review process prior to submission
- Must work out BUDGET IN ADVANCE of what portion of R01 funding would be sub with NRG
- LEAD TIME - Takes about 6 months lead time to get through the NRG review and approval process
- NRG JOINTLY OWNS the science and data
- ACCESS TO DATA through NRG
- Must follow NRG PUBLICATION GUIDELINES
  - Cannot publish data until primary aim of study is complete
  - Access to data set may be negotiated after aims are published
- STATISTICAL AND LAB ANALYSES may be NEGOTIATED if special analysis required (e.g. genomic sequencing and statistical analysis)
Questions an R01 investigator new to NRG NCORP may ask…

- Q: As PI of an NRG NCORP R01 funded trial, do I get funding for me or my research staff from BOTH the R01 and NRG?
  - A: NO, NRG Oncology does not pay study chairs or research staff, but your R01 may

- Q: Can I name all of the study co-chairs or add co-chairs (co-investigators) as I see fit?
  - A: NO, NRG would co-own the study and the study co-chairs would have to be a mix of collaborators needed to conduct the study and some who are members of specific disciplines or committees in NRG NCORP. It would be an a priori negotiation BEFORE the grant is submitted

- Q: Once the R01 is funded can I open the study at my site before NRG opens it?
  - A: NO, the grant will still need to go through the NCI for protocol development and approval and opened to all sites through NRG at the same time
Bringing Grant Funded Opportunities to NRG NCORP

- Prior to seeking any type of funding, the concept chair must seek official approval for the concept by the following: CPC, CCDR or other NCORP committee, committee co-chairs and NCORP Review Committee

- Within the grant application budget, there must be an appropriate amount of funding for NRG personnel for any extra work required to meet the aims of the R01. To ascertain the amount needed for the budget, the concept chair should contact NRG Oncology HQ (Erica Field) who will work with the appropriate personnel to determine NRG needs.
  - Note: NRG holds the data for the trial and a contract can be established (re: data sharing) with the investigator to provide the dataset after publication

- The complete application must be approved by the NRG NCORP chair leadership prior to grant submission and submitted to NCI 4 weeks prior to grant submission
Data Sharing of My R01 Data

- NRG JOINTLY OWNS the data
- ACCESS TO DATA is through NRG
- Must follow NRG PUBLICATION GUIDELINES
  - Cannot publish ANY data until primary aim of study is complete (full accrual and published)
  - Access to data set may be negotiated after all aims are published
- Can I add my postdoc or students or other mentees to NRG publications?
  - Not without NRG approval and STRONG rationale of unique contribution!

READ NRG PUBLICATION GUIDELINES IN ADVANCE
Examples of R01s Conducted Through the National Clinical Trials Networks

Financial support was from the National Institute of Nursing Research R01 NR07971-01, the National Cancer Institute through the Community Clinical Oncology Program (CCOP), the Radiation Therapy Oncology Group Grants CA21661, CA32115, and CA37422.
Welcome to the WRITE Symptoms (GOG-259) Research Study Homepage

WRITE Symptoms (Written Representational Intervention To Ease Symptoms) is a web-based symptom management program for women with recurrent ovarian cancer. The program is designed to help women find new ways to get better control over their symptoms. WRITE Symptoms is offered in two different formats: (1) nurse-delivered (through interactions with a study nurse) and (2) self-directed (through an interactive computer module).

The goal of the WRITE Symptoms Study is to find out whether these educational programs can improve symptoms and quality of life for women with recurrent ovarian cancer.

This study is an approved Gynecologic Oncology Group trial and is supported by the National Cancer Institute and the National Institute of Nursing Research (RO1NR010735).

GOG -259

Nurse-delivered WRITE Symptoms vs. Self-directed WRITE Symptoms vs. Care as Usual for optimal symptom management for women with recurrent ovarian, fallopian tube, or primary peritoneal cancer

To learn more about the Gynecologic Oncology Group visit www.gog.org

Study Chair: Heidi S. Donovan, PhD, RN
University of Pittsburgh School of Nursing
Examples of R01s Conducted Through the National Clinical Trials Networks

Quality of Life of African American Cancer Survivors

Ferrans, C. (PI), Kornblith, A., Bonner, G., Freels, S., Lake, D., Warnecke, R.

Funded through a National Cancer Institute (NIH R01 CA89418) and the Cancer and Leukemia Group B (CALGB) [now Alliance].
<table>
<thead>
<tr>
<th>Category</th>
<th>Chair Name</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Control and Symptom Management</td>
<td>Lisa Kachnic, MD;</td>
<td><a href="mailto:lak2187@cumc.columbia.edu">lak2187@cumc.columbia.edu</a></td>
</tr>
<tr>
<td></td>
<td>Debra Barton, PhD;</td>
<td><a href="mailto:debbartn@med.umich.edu">debbartn@med.umich.edu</a></td>
</tr>
<tr>
<td>Health Disparities</td>
<td>Kate Yeager, RN;</td>
<td><a href="mailto:kyeager@emory.edu">kyeager@emory.edu</a></td>
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<td></td>
<td>Chanita Hughes-Halbert, PhD;</td>
<td><a href="mailto:hughesha@musc.edu">hughesha@musc.edu</a></td>
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<tr>
<td>Cancer Prevention</td>
<td>Douglas Levine, MD;</td>
<td><a href="mailto:Douglas.Levine@nyulangone.org">Douglas.Levine@nyulangone.org</a></td>
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<td></td>
<td>Julie Bauman, MD;</td>
<td><a href="mailto:jebauman@email.arizona.edu">jebauman@email.arizona.edu</a></td>
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<tr>
<td>Patient Centered Outcomes Research</td>
<td>Ben Movsas, MD; Movsas,</td>
<td><a href="mailto:BMOVSA1@hfhs.org">BMOVSA1@hfhs.org</a></td>
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<td></td>
<td>Patricia Ganz, MD;</td>
<td><a href="mailto:pganz@mednet.ucla.edu">pganz@mednet.ucla.edu</a></td>
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<td></td>
<td>Lari Wenzel, PhD;</td>
<td><a href="mailto:lwenzel@uci.edu">lwenzel@uci.edu</a></td>
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<td>Cancer Care Delivery Research</td>
<td>Mary Cooley, PhD, RN, FAAN;</td>
<td><a href="mailto:Mary_Cooley@dci.harvard.edu">Mary_Cooley@dci.harvard.edu</a></td>
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<td></td>
<td>Matthew Hudson, PhD, MPH;</td>
<td><a href="mailto:Matt.Hudson@prismahealth.org">Matt.Hudson@prismahealth.org</a></td>
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<tr>
<td>Budgets/Other NCORP Questions</td>
<td>Erica Field, NCORP Administrator;</td>
<td><a href="mailto:fielde@nrgoncology.org">fielde@nrgoncology.org</a></td>
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