NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG Oncology NCORP

NRG NCORP Research Base PIs

Deborah Bruner, RN, FAAN, NCORP Contact PI
Lisa Kachnic, MD, NCORP Co-PI

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

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
- Health Care Access

NCI NCORP Network Structure

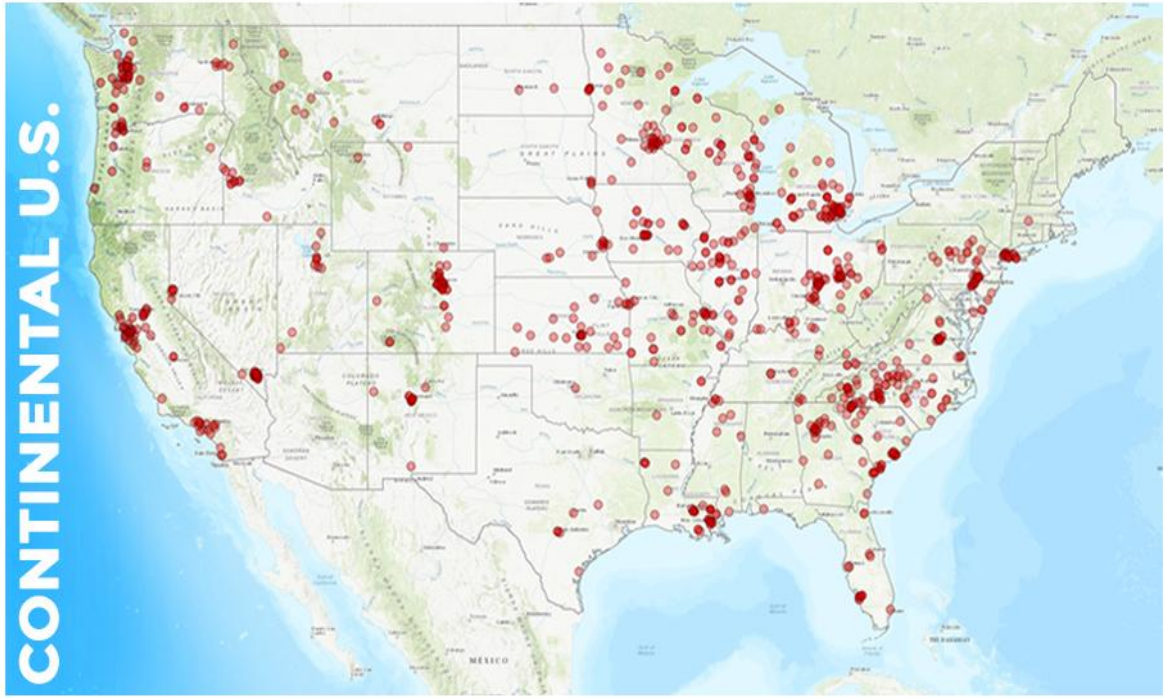
- The NCORP is housed in the NCI Division of Cancer Prevention, with collaboration by the NCI Division of Cancer Control and Population Sciences, NCI Division of Cancer Treatment and Diagnosis

- NCORP is comprised of 7 Research Bases and 46 Community Sites

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

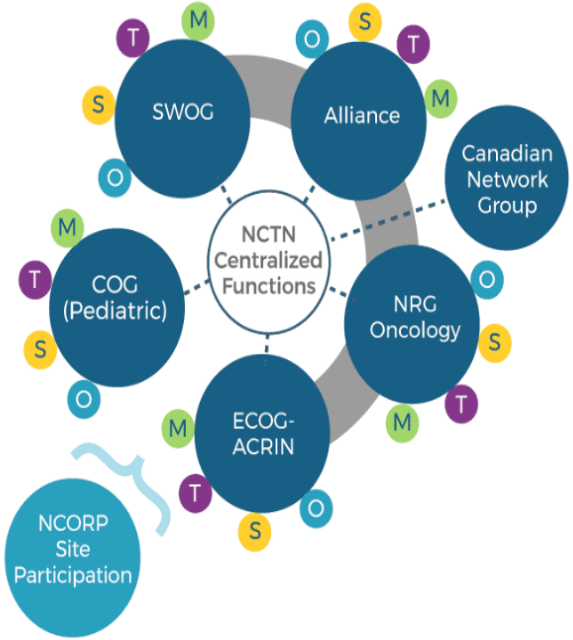
  The sites are consortia of researchers, public hospitals, physician practices, academic medical centers, and other groups that provide healthcare services in communities across the U.S

NCI Community Oncology Research Program (NCORP) Sites



February 2019

NCTN: National Clinical Trials Network



LEGEND

- Centralized Functions:
  - Centralized Institutional Review Board
  - Cancer Trials Support Unit
  - Imaging and Radiation Oncology Core (IROC) Group
  - Common Data Management System Central Hosting
- 32 Lead Academic Participating Sites (LAPS)
- O Operations
- S Statistics & Data Management
- T Tissue Banks
- M Member Sites

7 RESEARCH BASES — Develop and coordinate clinical trials and cancer care research

for

32 COMMUNITY SITES + **14** MINORITY/UNDERSERVED COMMUNITY SITES — to bring NCI approved trials to patients

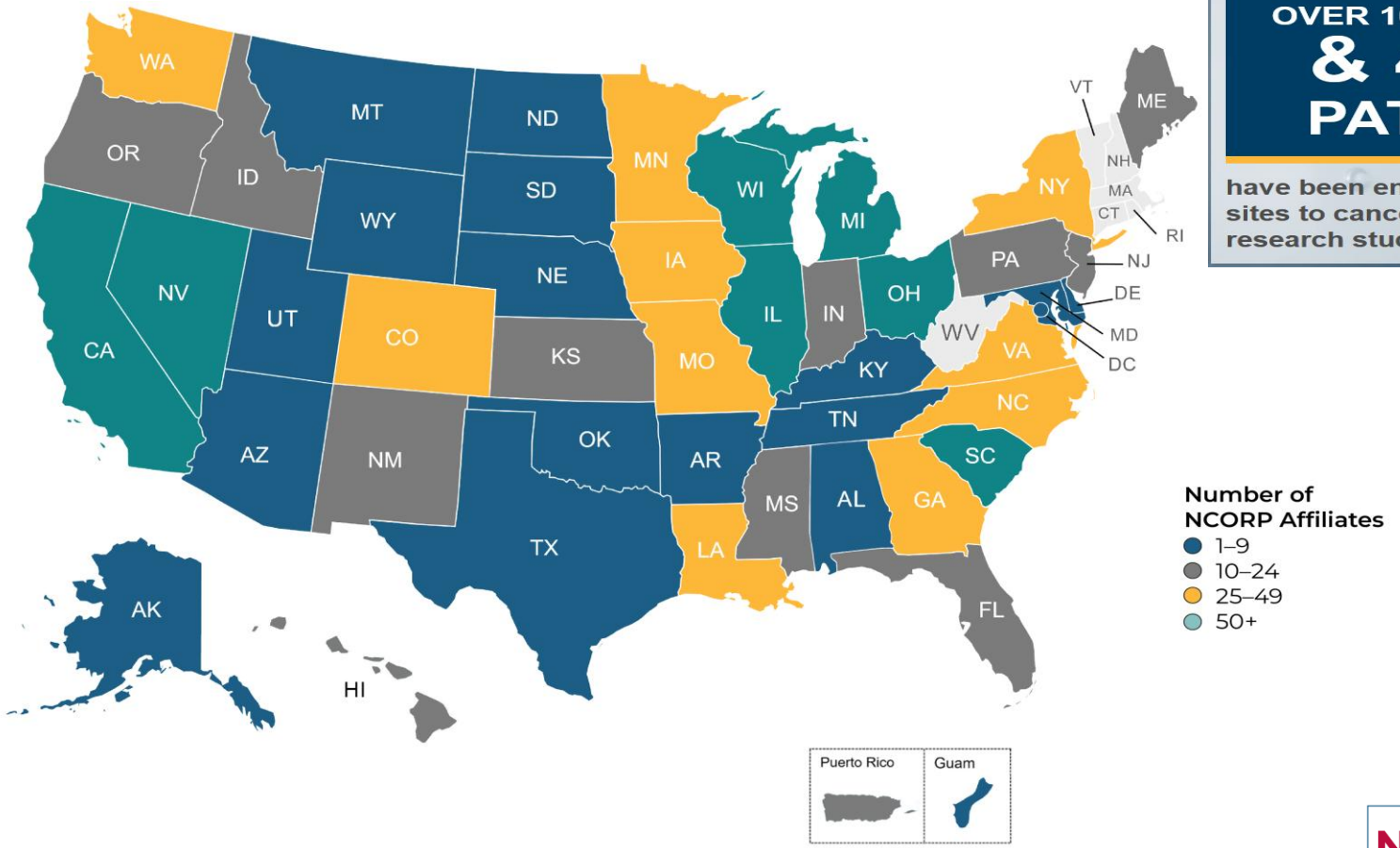
including

1,000+ PRACTICES — at diverse, community-based hospitals, private practices and more

From 2014-2018

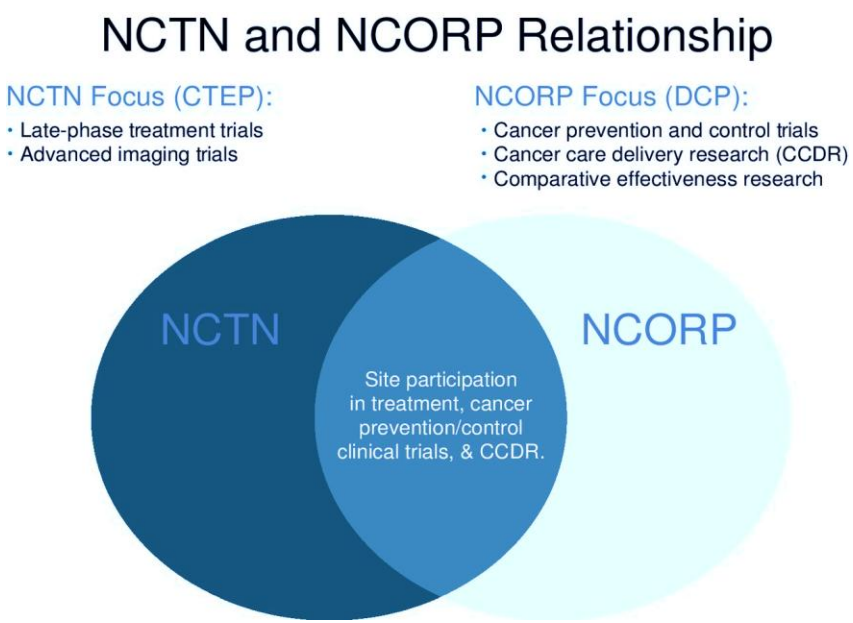
OVER 100 CLINICIANS & 4,500 PATIENTS

have been enrolled by NCORP sites to cancer care delivery research studies



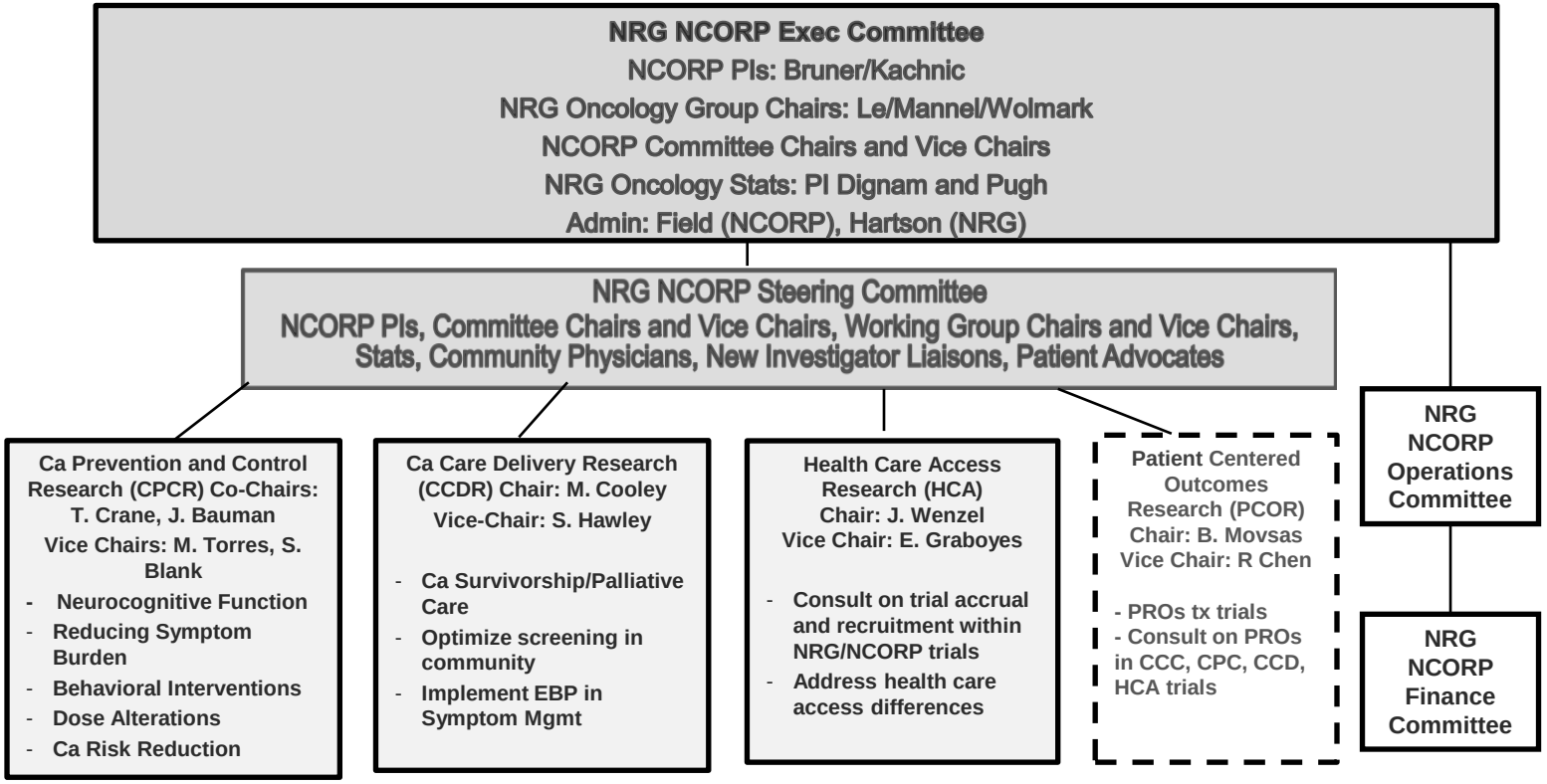
NCI Community Oncology Research Program

NCTN and NCORP



NCTN (CTEP) Trials	NCORP (DCP) Trials
Endpoints include: • PFS • OS • Compare cancer treatments (ph 1, 2, 3) Goals: • New treatment • Biomarker driven treatment • Targeted therapy • Radiation • Chemotherapy • Immunotherapy	• Cancer Prevention • Patient Reported Outcomes • Cancer Care Delivery Research • Health Care Access • Control/Symptom Management

NRG Oncology NCORP Structure



NRG NCORP Committees/Core Grant Aims

Aim 1: Cancer Control Research (CCR)

- Interventions designed to reduce cancer morbidity, improve quality of life, enhance cost effectiveness, such as
  - neurocognitive function
  - reducing the symptom burden of cancer treatment
  - radiation technology innovation
  - behavioral interventions

Aim 2: Cancer Prevention Research (CPR)

- improving effectiveness of cancer prevention interventions
- evaluating biomarkers of risk of malignancies; cancer risk reduction

Aim 3: Cancer Care Delivery Research (CCDR)

- improving cancer care delivery through multidisciplinary interventions from diagnosis, treatment and survivorship to palliative and hospice care
- optimize screening in community and rural settings

Aim 4: Health Care Access (HCA)

- integrating health care access questions into cancer prevention, control and therapeutic clinical trials as well as cancer care delivery research
- consulting on each NCORP and CTEP developing new trial to construct a recruitment strategy

Aim 5: Patient-Centered Outcomes Research (PCOR)

- developing important hypothesis-driven patient-reported secondary endpoints on disease-site CTEP trials

Aim 6: Provide Mentorship and Training to the Next Generation of Clinical Cancer Investigators

NRG NCORP Impact: Changing the Standard of Care

- Major national guideline changes over this past grant period:
  - **R0614**: Memantine during whole brain RT reduces neurocognitive deterioration (*Neuro Oncol 2013*)
  - **R0933**: Hippocampal avoidance during whole brain RT leads to HVLT preservation (*JCO 2014*)
  - **R1203**: IMRT reduces bowel toxicities (over 3D RT) from the patient perspective in postop GYN cancers (*JCO 2020*)
  - **CC001**: Further preservation of neurocognitive function using hippocampus avoidance with memantine during whole-brain RT (*JCO 2020*)
- **Accrual:** NRG NCORPs contribute ~33% to NRG treatment trials

Working with NRG NCORP

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

Submit an NRG NCORP Concept Idea

- We welcome all concept ideas
- All new NCORP concepts must be reviewed and vetted by the appropriate 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 and if met favorably move onto an NCI review and hopefully a trial

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

Concept development forms can be found here

NCORP Concept Development Forms

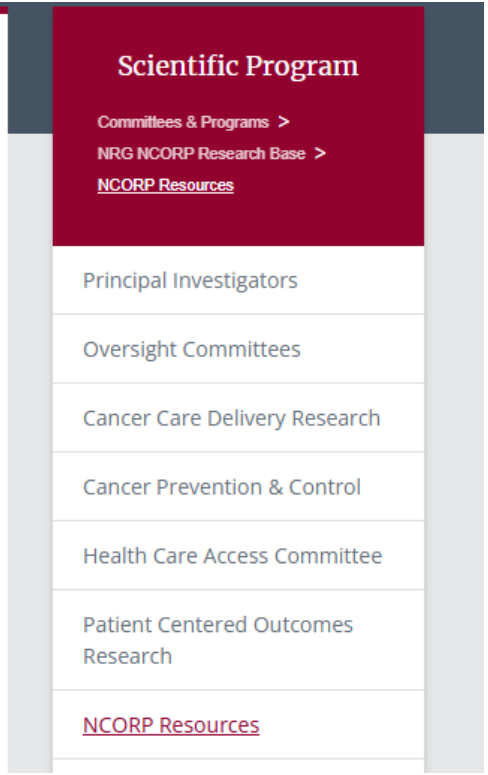
Concept Development and Evaluation Forms

Overview of NRG Oncology NCORP Concept Development: Navigating NCI and R01 Submissions

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 NCI Guidelines

Publications Policy & Guidelines
NCORP Guidelines for Development of Concepts, Protocols, and Amendments
Biomarker, Imaging, & Quality of Life Studies Funding Program (BIQSFP)
Investigator Initiated Federally and Non-Federally Funded Studies - NCORP Guidelines



Become an NRG NCORP Committee Member

- Committees solicit new members in the early Fall:
  - liaisons to the disease site committees
  - study champions of Alliance, SWOG, ECOG trials
  - co-investigators with a senior mentor on developing protocols

- And consider applying for a travel grant to attend semi-annual meetings
  - call for applications is 8-10 weeks prior to each semiannual meeting

Additional NRG NCORP Opportunities

- **Apply for a Pilot Grant – ***NEW PROCESS**
- Health Care Access Fellowship
- Apply for a Secondary Analysis
- Apply to Use Biospecimens
- Use NRG NCORP to Run your R-01 Trial

New Process for NCORP Pilot Project Applications

Goal: to prepare investigators to develop NCORP pilot concepts that are aligned with the aims of NCORP committees including CPC, CCDR and HCA. Pilot projects are funded specifically to lead to full NCORP concepts.

- Application requires investigators to submit a two-page LOI form.
- NCORP committee chairs will review LOIs and select those best aligned with the committee goals, NCORP priorities, and deemed most feasible for future Phase II – III NCORP concepts.
- Selected investigators will be invited to attend a 1-hour workshop during an NRG meeting and paired with a mentor.

The LOI process is a prerequisite for pilot grant application submission in 2025.

- The request for funding application (RFA) for NCORP pilot projects will be released in Spring 2025.
- This year we selected 11 LOI applications for the workshop
- While workshop selection and enrollment does not guarantee pilot funding, the activities are designed to facilitate successful submissions.

The next LOI announcement will be coming summer 2025!

NRG Health Care Access Fellowship

- *This program matches early-stage researchers who wish to develop a successful research career with more experienced NRG Oncology investigators*

Strategic, high-level goals:

- Improving health care access
- Selected early-stage NRG Oncology investigators will be mentored in clinical trials education, resources, and training
- Building trust between communities and developing successful clinical trials scientists

Eligibility criteria:

1) Medical, surgical, gyn, or radiation oncologists or PhD researchers who have completed fellowship/postdoc. **NRG is partnering with various organizations and foundations to offer the fellowships**
2) Anyone who has not been a PI or co-PI on a clinical trial/NIH R level grant within the past 10 years
3) Experience within NRG Oncology
4) Strong desire to develop a research career, with special priority given to those addressing health care access
5) Support from their institution/employer (protected time, access to research resources, etc.)

NRG Secondary Analysis

https://www.nrgoncology.org/Resources/Ancillary-Projects-Data-Sharing-Application

NRG NCORP Inventory of Data and Specimens for Future Research

Trial	Ascites	Buffy Coat	CSF	FFPE	Isocode Card	OCT	Plasma	Peritoneal Fluid	RBCs	Serum	Snap Frozen	Stool	ThinPrep	Urine	Whole Blood
NRG-CC001										3870 (S) 317 (P)					1184 (S) 288 (P)
NRG-CC003										3423 (S) 219 (P)					652 (S) 186 (P)
NRG-CC005		271 (S) 135 (P)					500 (S) 134 (P)					935 (S) 468 (P)			
NRG-CC008				39 (S) 4 (P)			1,666 (S) 270 (P)			1,629 (S) 269 (P)					366 (S) 270 (P)
NRG-CC009										136 (S) 16 (P)					
NSABP-B-43				3,089 (S) 1,850 (P)											

https://www.nrgoncology.org/Scientific-Program/Biospecimen-Access

Running an R01 via NRG NCORP

Benefits of Working with NRG NCORP

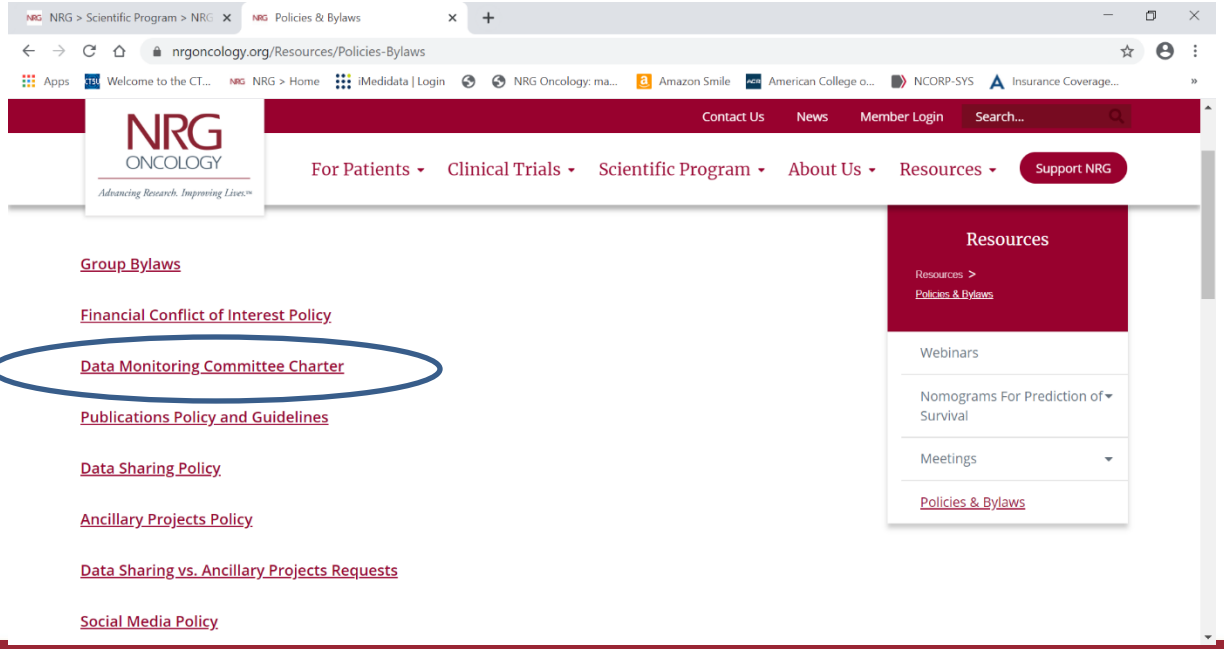
- Access to over 1,800 NRG Oncology and NRG NCORP sites to conduct research
- Major Supplemental Funding
- Access to Big Data for Secondary Analyses
- Increased IMPACT of work

NRG NCORP Study Objectives Requiring Additional Funding

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-award 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 committees, 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!

REMEMBER TO READ THE NRG PUBLICATION GUIDELINES IN ADVANCE

Examples of R01s Conducted through the National Clinical Trials Networks

Activated February 2, 2024

- **NRG-CC011:** ***Cognitive Training For Cancer Related Cognitive Impairment In Breast Cancer Survivors: A Multi-Center Randomized Double-Blinded Controlled Trial.*** (*NIH R01 #1R01CA276222-01, MPIs D. Von Ah, P. Ganz, B. McDonald*)

Activated May 20, 2024

- **NRG-CC012CD:** ***Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment.*** (*NIH R01 #1R01CA279472-01, MPIs A. Sikorskii, T. Badger, T. Crane*)

Completed

NRG/GOG 0259: ***Effects of the WRITE Symptoms Interventions on Symptoms and Quality of Life Among Patients With Recurrent Ovarian Cancers: An NRG Oncology/GOG Study*** (*NIH R01 #R01NR010735, MPI H. Donovan*)

NCORP Contact Information

NCORP PIs

Deborah Bruner, PhD, RN, FAAN
deborah.w.bruner@emory.edu
Lisa Kachnic, MD
lak2187@cumc.columbia.edu

Cancer Control/Symptom Management

Chair: Tracy Crane, PhD;
tecrane@med.miami.edu
Vice-Chair: Mylin Torres, MD;
matorre@emory.edu

Cancer Prevention

Chair: Julie Bauman, MD;
jebauman@gwu.edu
Vice-Chair: Stephanie Blank, MD;
Stephanie.Blank@mountsinai.org

Health Care Access

Chair: Jennifer Wenzel, PhD; jwenzel@jhu.edu
Vice-Chair: Evan Graboyes, MD; graboyes@musc.edu

Cancer Care Delivery Research

Chair: Mary Cooley, PhD, RN, FAAN;
Mary_Cooley@dfci.harvard.edu
Vice-Chair: Sarah Hawley, PhD, MPH
sarahaw1@umich.edu

Patient Centered Outcomes Research

Chair: Ben Movsas, MD; BMOVSAS1@hfhs.org
Vice-Chairs: Ronald Chen, MD; rchen2@kumc.edu

Budgets/Other NCORP Questions

Erica Field, MPH, MPH, NCORP Administrator;
fielde@nrgoncology.org

NRG ONCOLOGY™