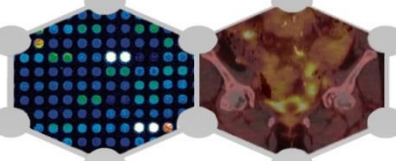

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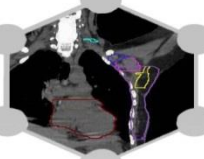

# NRG NCORP Town Hall

PIs
Deborah Watkins Bruner, RN, PhD, FAAN
Joan Walker, MD


# to our

# DISTINGUISHED SPEAKERS and NRG NCORP MEMBERS

# AGENDA
# NCORP TOWN HALL

| | | |
|---|---|---|
| **11:15 – 11:30am** | **Welcome**<br>**NRG NCORP Updates** | **Deborah Watkins Bruner, PhD, RN**<br>**NRG NCORP contact PI** |
| 11:30 – 11:40am | NRG-CC005/FORTE<br>Poll 1 | Robert Schoen, MD<br>FORTE Study Chair |
| 11:40 – 11:50am | NRG-CC008/SOROCk<br>Poll 2<br>Poll 3 | Douglas Levine, MD<br>SOROCk Study Chair |
| 11:50am – 12:00pm | Q&A – Open Discussion – moderators, Dr. Lisa Kachnic and Kati Stoermer | |
| 12:00 – 12:03pm | Introduction of NCI speakers | Deborah Watkins Bruner, PhD, RN |
| 12:03 – 12:15pm | NCI NCORP Report | Worta McCaskill-Stevens, MD, Chief, Community Oncology and Prevention Trials Research Group |
| 12:15 – 12:25pm | Measuring Organizational Context in NCORP CCDR | Ann Geiger, PhD, Scientific Director, Cancer Care Delivery Research in the NCI Community Oncology Research Program |
| 12:25 – 12:40pm | Q&A – Open Discussion –moderators, Dr. Lisa Kachnic and Dr. Douglas Levine | |
| 12:40 – 12:45pm | Closing Remarks | Deborah W. Bruner, PhD and Joan Walker, MD |

# NRG Oncology NCORP Org Chart

# NRG NCORP Core Grant Aims and Priorities

- Four symptom management themes:
  - ***neurotoxicity***
  - cardiotoxicity
  - lymphedema
  - sexual function
- Cancer prevention, survivorship and palliative interventions
- Cancer care delivery
- Cancer disparities research

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# NRG NCORP IMPACT - Changing Standard of Care

- R0614: Memantine during whole brain RT reduces neurocognitive deterioration
- R0933: Hippocampal avoidance during whole brain RT leads to memory (HVLT) preservation
- R1203: IMRT reduces bowel toxicities (over 3D RT) from the patient perspective in postop GYN cancers

On average NRG NCORPs contribute 33% of accrual to NRG treatment trials

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# 36 NRG NCORP Member Sites

Aurora NCORP

Bay Area Tumor Institute NCORP

Cancer Research Consortium of West Michigan NCORP

Cancer Research for the Ozarks

Cancer Research of Wisconsin and Northern Mich. Consortium

Carle Cancer Center NCORP

Catholic Health Initiatives NCORP

Columbia University M/U NCORP

Columbus NCORP

Dayton NCORP

Delaware/Christiana Care Essentia Health NCORP

Geisinger Cancer Institute

Georgia Cares M/U NCORP

Georgia NCORP

Gulf South M/U NCORP

Hawaii M/U NCORP

Heartland Cancer Research NCORP

Iowa-Wide Oncology Research Coalition NCORP

Kaiser Permanente NCORP

Maine-Health Cancer Care Network

Medical University of South Carolina M/U NCORP

Metro Minnesota Community Oncology Research Consortium

Montana Cancer Consortium NCORP

Montefiore M/U NCORP

NCORP of the Carolinas

Nevada Cancer Research Foundation

New Mexico M/U NCORP

Northwell Health NCORP

Pacific Cancer Research Consortium

Puerto Rico M/U NCORP

Sanford NCORP of the North Central Plains

Southeast Clinical Research Consortium NCORP

Stroger Hospital of Cook County M/U NCORP

Upstate Carolina Consortium Comm. Oncology Research Program

VCU Massey Cancer Center M/U NCORP

Western States Cancer Research NCORP

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# Top NCORP Accruing Sites 2017 - 2020

## Top Accruing NCORP Sites - CTEP Trials

Helen F Graham Cancer Center*
Carle Cancer Center
Maine Medical Center- Scarborough
Beebe Health Campus
University of New Mexico Cancer Center*
CaroMont Regional Medical Center
Northwell Health/Center for Advanced Medicine
Decatur Memorial Hospital
University of Kansas Cancer Center*
NYP/Columbia University Medical Center

## Top Accruing NCORP Sites - DCP Trials

University of New Mexico Cancer Center*
Helen F. Graham Cancer Center*
Augusta University Medical Center
John H. Stroger Jr. Hospital of Cook County
University of Kansas Cancer Center*
Medical University of South Carolina
Lewis Cancer & Research Pavilion-Saint Joseph's
Oschner Medical Center Jefferson
Sparrow Hospital
Saint Joseph Mercy Hospital

# Open NRG NCORP Trials

****accrual as of June 30, 2020**

| Study No | Disease Site | Description | Date Activated | Target Accrual | Total Accrual | NCORP Accrual (%) | Expected Closure Date |
|---|---|---|---|---|---|---|---|
| **GOG 0278** | Cervix | Physical fx & QOL before/after non-radical surgery | 10/1/12 | 220 | 212 | <1% | December 2020 |
| **NRG CC003** | Lung | Seamless Ph II/III PCI vs. PCI with hippocampal sparing for cognitive fx | 12/7/15 | 172 (II)<br>302 (III) | 176 of 172 (II)<br>204 of 302 (III) | 28% | Temp. closure 5/28/20; amendment to increase accrual |
| **NRG CC007CD** | Prostate | Survivorship care planning for prostate ca survivors who receive ADT | 03/27/19 | 504 | 75 | 100% | December 2023 |
| **NRG CC008** | Ovarian | Non-randomized prospective trial comparing non-inferiority of **S**alpingectomy to salpingo-**O**ophorectomy to **R**educe risk of **O**varian **C**a among *BRCA1* carriers (SOROCk) | 6/23/2020 | 2262 | | | |

# Developing NRG NCORP Trials

| Study No | Disease | Comments |
|---|---|---|
| **NRG-CC005** | Forte – Five or Ten Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps | Pre-activation revision submitted to DCP |
| **NRG-CC009** | SRS vs. HA-WBRT for 10 or fewer Brain Metastases from Small Cell Lung Cancer | Protocol – 1st circulation |

| NCORP Concept review – July 2020 | |
|---|---|
| Gynecologic cancer therapy, the Vaginal Microbiome and Patient Symptom Experience | D. Bruner, PhD |
| Impact of Sentinel Lymph Node Mapping on Patient Reported Lower Extremity Limb Dysfunction in Endometrial Cancer | E. Tanner, MD |

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# NCORP CCDR Fellow

## A Unique Partnership with U Michigan

## PI T32, Dr. Chris Friese, Professor of Nursing and Public Health

**Megan Mullins, PhD, MPH**

**Post-Doctoral Fellow, 2020-2022**
**University of Michigan**

Dr. Mullins' work focuses on :

- Identification of gaps in the quality of cancer care among cognitively impaired older adults
- Increase understanding of functional aging trajectories among cancer patients
- Focus on gynecologic cancers and disparities among racial and sexual/gender minorities

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# NRG NCORP Pilot Project Awardees

**CPC Award**

***Buprenorphine a less toxic opioid substitute for treatment of radiation induced mucositis pain in head and neck cancer patients***

Aditya Varnam Shreenivas MD, MS

Medical College of Wisconsin

**CCD Award**

***Assessing the impact of financial toxicity in head and neck cancer patients and their caregivers***

Krupal B. Patel, MD, M.Sc, FRCS(C) & Maija Reblin, PhD

H. Lee Moffitt Cancer Center

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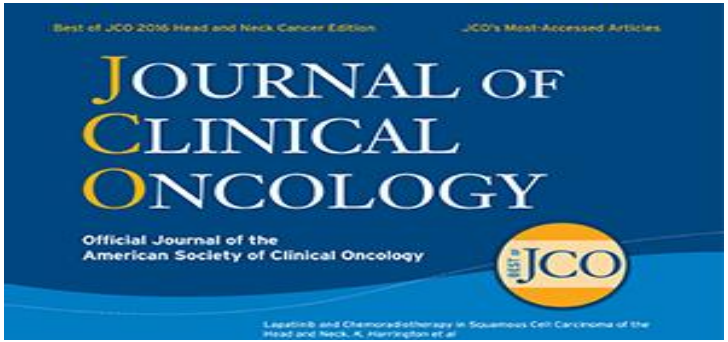
# NCORP Recent Publications

- NRG CC001
  - Brown, PB, Gondi V, et al. **Hippocampal Avoidance** During Whole-Brain Radiotherapy **Plus Memantine** for Patients with Brain Metastases: Phase III Trial NRG Oncology CC001. J Clin Oncol. 2020 38:10, 1019-1029




- RTOG 1203
  - Yeung AR, Pugh SL, Klopp AH, et al. **Improvement in Patient-Reported Outcomes With Intensity-Modulated Radiotherapy** (RT) Compared With Standard RT: A Report From the NRG Oncology RTOG 1203 Study. J Clin Oncol. 2020;38(15):1685-1692. doi:10.1200/JCO.19.02381

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# BCPT and STAR Biospecimens AVAILABLE

**Biospecimens + metadata are available for research from the two historic prevention trials that accrued 13,000 and 19,000 participants**

| | NSABP P1 (BCPT) | NSABP P2 (STAR) |
|---|---|---|
| **Buffy coat and Plasma** | 73,218 specimens | 286,159 specimens |
| **Fasting lips** | 500 specimens | N/A |
| **Tissue blocks (FFPE)** | 11,432 specimens | 16,197 specimen |

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# Questions

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# NRG-CC005: Five or Ten Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps (FORTE)


**Robert Schoen, MD**

**Professor of Medicine and Epidemiology**

**University Pittsburgh**


**NRG-CC005/FORTE Study Chair**

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# Study Team

| | |
|---|---|
| **Robert Schoen, MD, University of Pittsburgh Medical Center** | Study Chair |
| **Jeffrey Dueker, MD, University of Pittsburgh Medical Center** | Study Co-Chair |
| **Hanna Bandos, PhD, NRG Oncology SDMC** | Statistician |
| **Douglas Corley, MD, Kaiser Permanente** | Chief Scientific Officer, Community Co-Chair |
| **Christine Lorson, NRG Oncology** | FORTE Education and Communications Specialist |

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# FORTE – 5,10 vs 10 Year Colonoscopy for Non-Advanced Adenomas

Robert E. Schoen, MD, MPH
Professor of Medicine & Epidemiology
PI, FORTE Trial
University of Pittsburgh | UPMC
Pittsburgh, PA

FORTE five ten
A COLORECTAL CANCER PREVENTION TRIAL

NIH NATIONAL CANCER INSTITUTE Community Oncology Research Program (NCORP)

NCI National Clinical Trials Network
a National Cancer Institute program

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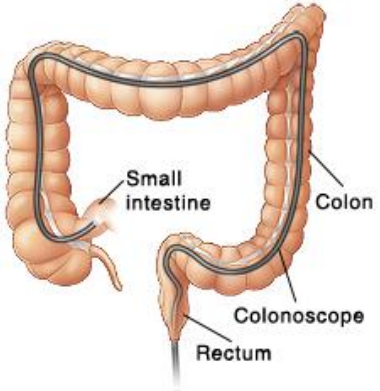
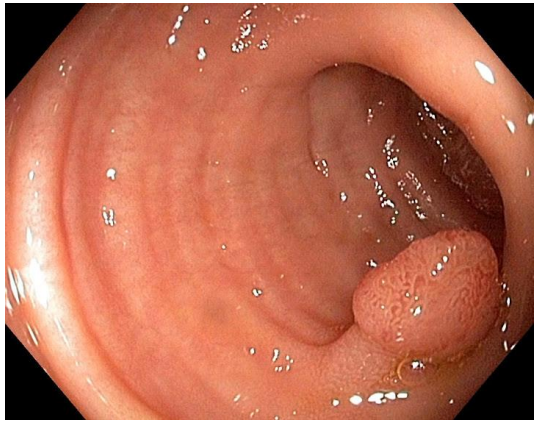
# Surveillance Colonoscopy



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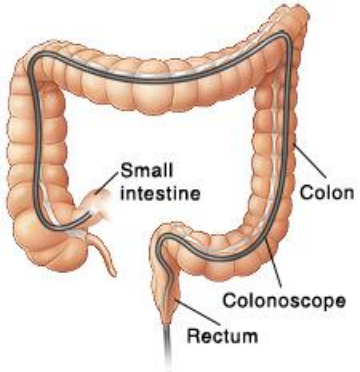


25% of Colonoscopy is for Surveillance

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# “Recent” Multi-Society Task Force Surveillance Recommendations

FiveFORTenE
A COLORECTAL CANCER PREVENTION TRIAL




**No polyps, or hyperplastic polyps in rectum/sigmoid**

Repeat in 10 years

**Neoplasia found**

| Serrated polyps/lesions | High risk adenomas | Low risk adenomas |
|---|---|---|
| **Serrated polyposis** Repeat in 1 year | **> 10 Adenomas** Repeat in less than 3 years | **1–2 Tubular adenomas < 10 mm** Repeat in 5–10 years |
| **≥ 10 mm or With dysplasia or traditional serrated adenoma** Repeat in 3 years | **3–10 Adenomas** Repeat in 3 years | |
| | **Villous adenoma(s) or tubular adenoma(s) ≥ 10 mm** Repeat in 3 years | |
| **< 10 mm in Proximal colon and without dysplasia** Repeat in 5 years | **Adenoma(s) with high grade dysplasia** Repeat in 3 years | |

**These recommended intervals assume a complete exam to cecum, adequate bowel prep, and complete removal of polyps at the baseline exam.**

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# MSTF New Recommendations: March 2020

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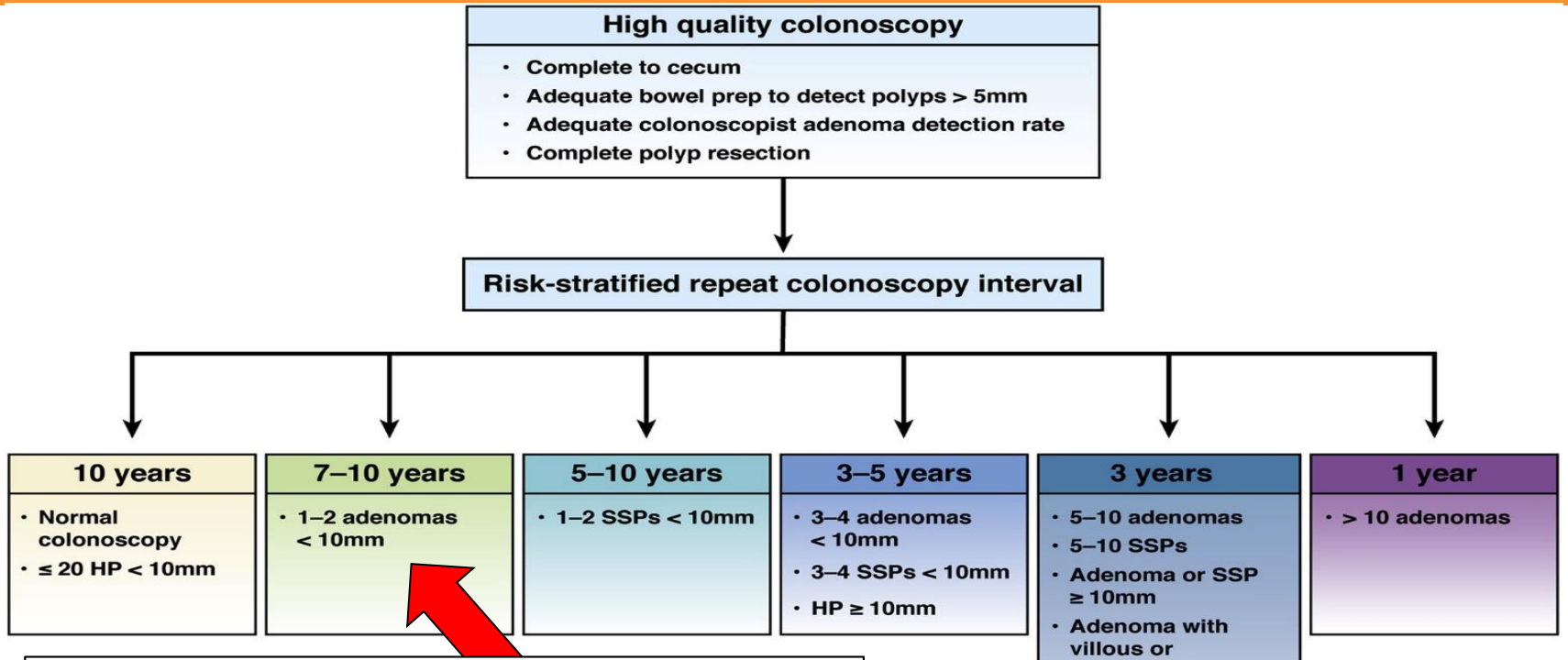


Patients with previous recommendations for shorter interval can reasonably follow original recommendation

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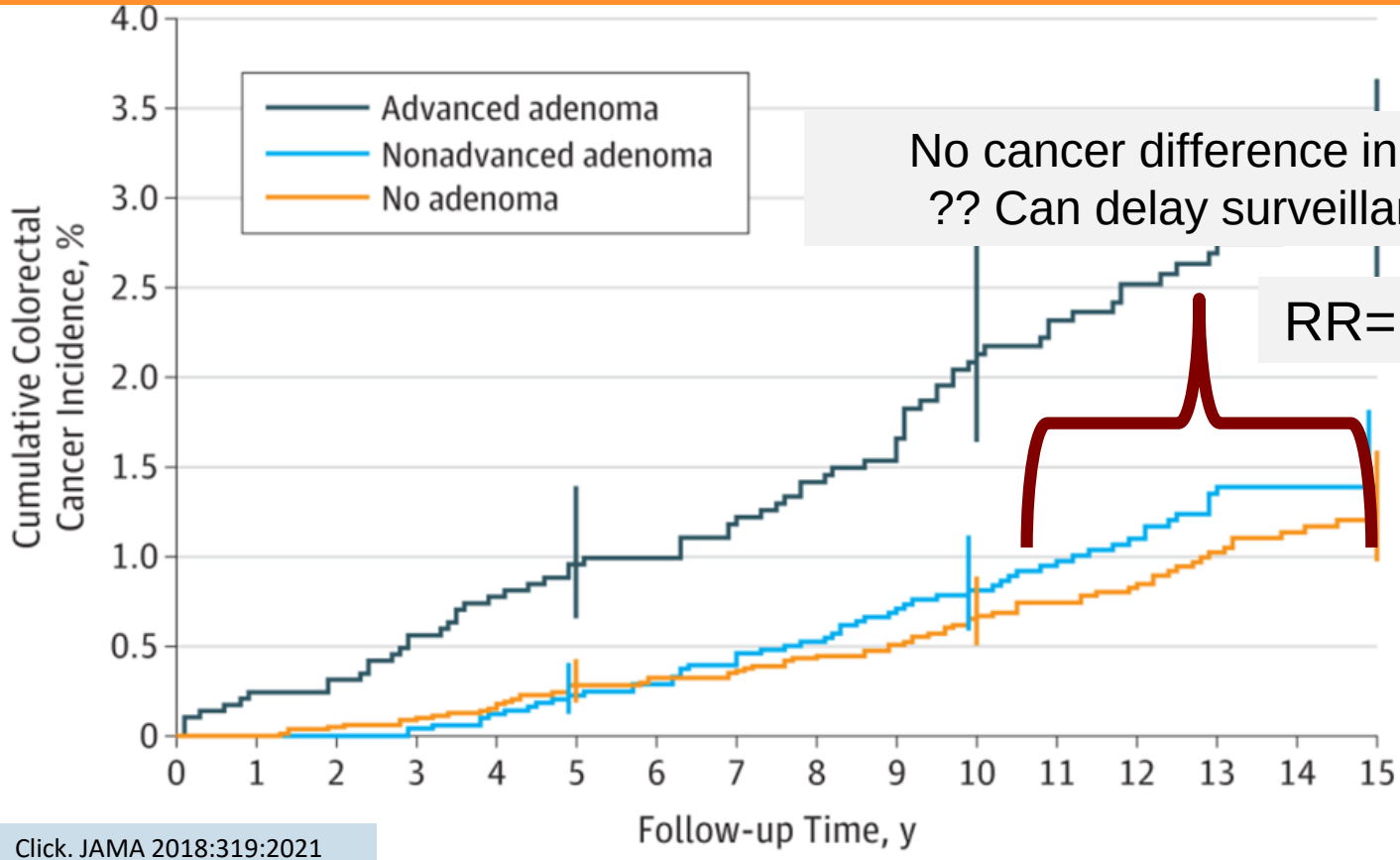
# PLCO Trial: Long-term CRC Incidence

FiveFORTenE
A COLORECTAL CANCER PREVENTION TRIAL




No cancer difference in NAA vs NA:
?? Can delay surveillance for 10 y

RR=1.2 (0.8-1.7)

Click. JAMA 2018:319:2021

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# Ignoring the Effect of the Surveillance That Already Occurred

Higher rate of surveillance/adenoma removal in subjects with Non-Advanced Adenoma may have reduced CRC incidence in NAA group

# PLCO Trial: NAA Group had More Adenomas Removed

| | | % of Pts at Risk | | |
|---|---|---|---|---|
| | No. | 5 Yr | 7 Yr | 9 Yr |
| **NAA** | | | | |
| **1-2** | 857 | 16.4 | 24.3 | 31.1 |
| | | | | |
| **NA** | 1208 | 8.8 | 15.7 | 20.3 |

11% Increase: Is that enough to influence cancer incidence?

Yes, there is impact

Pinsky. CGH 2020

**Table 4.** Original and Adjusted CRC Incidence Rate Ratios and 95% Confidence Intervals for Colonoscopy Cohort (Within 10 Years)

| | AA | $NAA_{1-2}$ + $NAA_{3+}$ | $NAA_{1-2}$ | NA |
|---|---|---|---|---|
| Original[a] | 3.3 (2.2–4.8) | 1.2 (0.8–1.9) | 1.2 (0.8–1.9) | Reference |
| Adjusted[b] | 3.2 (2.3–4.5) | 1.5 (0.99–2.1) | 1.4 (0.93–2.0) | Reference |

AA, advanced adenoma; CRC, colorectal cancer; NA, no adenoma; NAA, nonadvanced adenoma.

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We need to evaluate the benefit of surveillance to decide how best to employ it – retrospective studies are limited by past practice - we can ONLY clarify benefit with a randomized trial

That's Why, FORTE

# Schema

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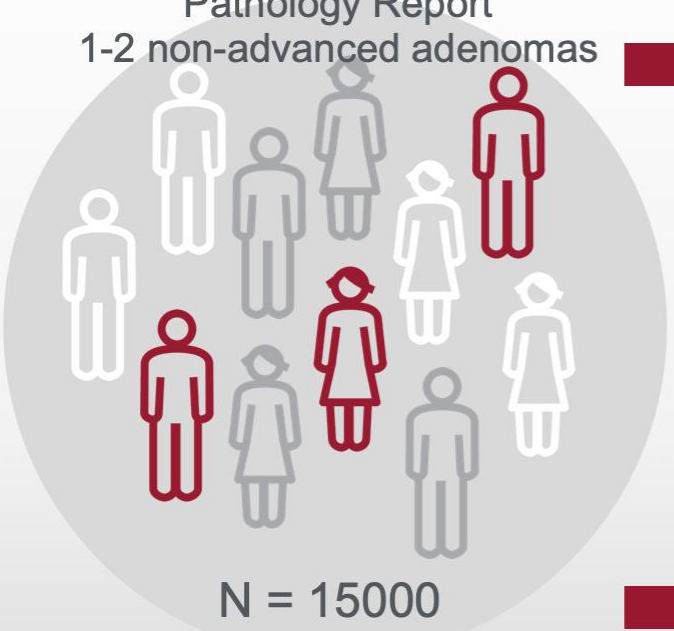
Pathology Report
1-2 non-advanced adenomas

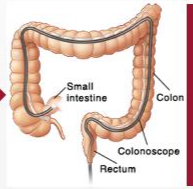


N = 15000

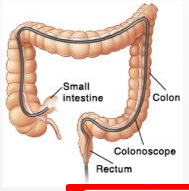
Colonoscopies up to 4 years ago

RANDOMIZED

5 Yr.



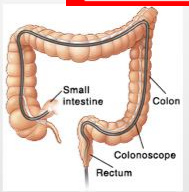

10 Yr.




Surveillance Colonoscopy

**End Point: CRC Incidence**

10 Yr.




Secondary endpoint:
Advanced Adenoma

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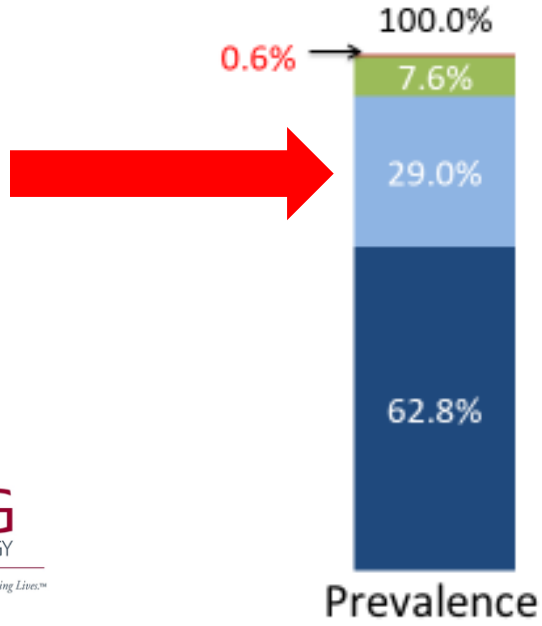
# Will I Find Eligible Participants?

FORTE
A COLORECTAL CANCER PREVENTION TRIAL

## Distribution of Colonoscopy Findings (N=9,989)




| Finding | Valid Cases |
|---|---|
| CRC | 65 |
| Advanced Adenoma | 757 |
| Non-advanced adenoma | 2,893 |
| Negative | 6,274 |

Likely underestimate – emphasis on ADR

Imperiale TF. N Engl J Med 2014;370(14):1287

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# Two Groups

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A COLORECTAL CANCER PREVENTION TRIAL

Identifying Patients to Enroll

Retrospective

Prospective

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# Information Technology

FIVE FORT EN
A COLORECTAL CANCER PREVENTION TRIAL

## Retrospective:

- Colonoscopy report – 1 or 2 <1cm polyps
- Pathology report – tubular or serrated adenomas
- Age 50-69
- ~ Diagnosed in up to 4.0 yrs ago
- No prior adenomas – first time diagnosis
- No other cancer in previous 5 years
- No Family history of CRC <60, no IBD, etc.

## Prospective:

- Active colonoscopy practices

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# Participants

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## How Am I Going to Find Participants?

- Establish GI/Endoscopy contacts to partner with

ESSENTIAL

- Patient acceptance

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# DRAFT Budget

FIVE FORT TEN E
A COLORECTAL CANCER PREVENTION TRIAL

## NCTN Standard/LAPS/NCORP

| | | | |
|---|---|---|---|
| **Federal (DCP)** | **Baseline** | **Required** | **$1500** |
| **Federal (DCP)** | Plasma Sample within 12 months of randomization | Optional to Participant | 150 |
| **Federal (DCP)** | Stool Sample within 12 months of randomization | Optional to Participant | 150 |
| **Federal (DCP)** | **Annual Follow-up** | **Required** | 150 |

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# DRAFT Budget

| | | |
|---|---|---|
| **“Network Establishment”** | **ONE time** | **5,000** |

LOI, application, roster, approved recruitment and adherence plans, endoscopic practice letters of support and IRB approval

# DRAFT Budget

FiveFORTenE
A COLORECTAL CANCER PREVENTION TRIAL

## Incentive Funding

| # Accrued/Year/Site | Amount/Pt |
|---|---|
| Level 1: 1 - 10 Pts | $ 0 |
| Level 2: 10 - 25 Pts | $ 100 |
| Level 3: 26 - 40 Pts | $ 125 |
| Level 4: 41 - 50 Pts | $ 150 |
| Level 5: 51 - 150 Pts | $ 200 |
| Level 6: >150 | $ 0 |

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# NRG-CC008: Non-randomized Prospective Clinical Trial Comparing the Non-inferiority of Salpingectomy to Salpingo-oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [SOROCk]


**Douglas Levine, MD**

**Director of Gynecologic Oncology Division**

**Perlmutter Cancer Center**

**New York University Langone Health**


**NRG-CC008/SOROCk Study Chair**

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# NRG-CC008: 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 [SOROCk]

# Study Team

| | |
|---|---|
| **Douglas A. Levine, MD, Perlmutter Cancer Center, NYU Langone Health** | Study Chair |
| **Joan Walker, MD, University of Oklahoma Health Sciences Center** | Study Co-Chair |
| **Stephanie Pugh, PhD, NRG Oncology SDMC** | Statistician |
| **Jeanne Carter, PhD, Memorial Sloan Kettering Cancer Center** | QOL Co-Chair |
| **Laura Havrilesky, MD, Duke University Medical Center** | CEA Co-Chair |
| **Elizabeth Jewell, MD, Memorial Sloan Kettering Cancer Center** | CEA Co-Chair |
| **Carolyn Muller, MD, Univ. of New Mexico Comprehensive Cancer Center** | Community Co-Chair |
| **Ronny Drapkin, MD, University of Pennsylvania** | Pathologist |
| **Heather Lankes, PhD, MPH, NRG Oncology** | Translational Science |
| **Kathryn P. Pennington, MD, University of Washington** | New Investigator |

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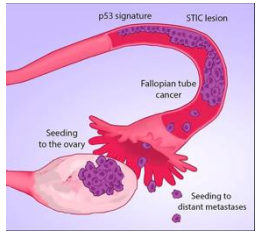
# The fallopian tube hypothesis



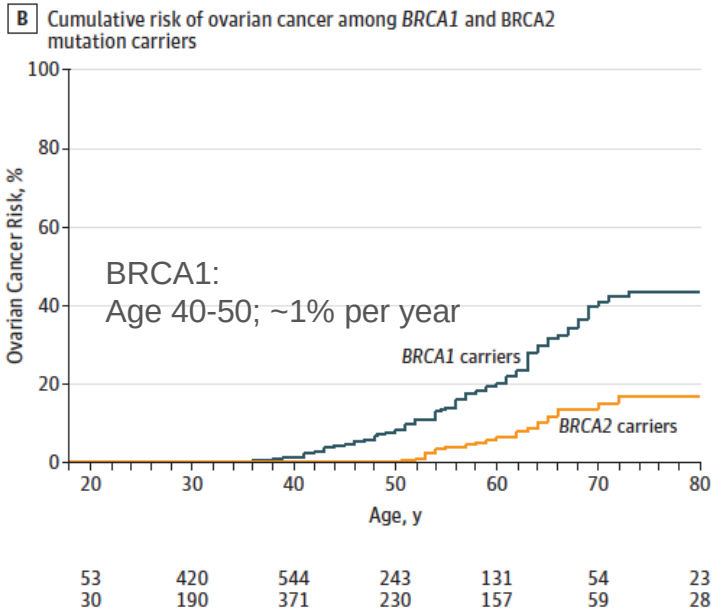

- In the early to mid-2000's, precursor lesions, termed serous tubal intraepithelial carcinoma (STIC), and early invasive cancers were found in the distal fallopian tube and fimbrial epithelium from BRCA1/2 carriers having RRSO.
- This lead to a closer evaluation of the distal fallopian and fimbrial epithelium using a method referred to as sectioning and extensively examining the fimbriated end (SEE-FIM) of the fallopian tube.
- STIC lesions have been found in 2-5% of BRCA1/2 carriers having RRSO.
- STIC lesions have been found in ~50% of women with advanced stage ovarian cancers when the fallopian tube can be identified.
    - Reasons for not identifying STIC lesions in all tubes include overgrowth of STIC lesion by invasive disease, imperceptibly small lesions, and sampling errors.

# Role of salpingectomy

- Multiple lines of evidence suggest that the fallopian tube is the likely site of origin for many/most high grade serous carcinomas.
- Removal of only the fallopian tubes may be an effective method for ovarian cancer risk reduction.
- **The efficacy of this approach is unproven and untested.**
- Risk-reducing bilateral salpingectomy (RRBS) would prevent the induction of surgical menopause and may be a viable option for women who refuse/decline the risk-reducing bilateral salpingo-oophorectomy (RRSO), which is the standard of care.
    - A 2019 analysis found that more than 40% of *BRCA1* carriers in the US have not had RRSO and the mean age of those who did have RRSO was 45 years. (PMID:30971774)

# Background

- This study will only include women between the age of 35 and 50 who are BRCA1 carriers because the risk of ovarian cancer in other age groups and for other mutations is extremely low prior to menopause.
- The main reason that high-risk women do not proceed with BSO at the recommended age is likely/mostly due to undesirable side effects of premature surgical menopause.




BRCA2:
Age 40-50; ~0% per year

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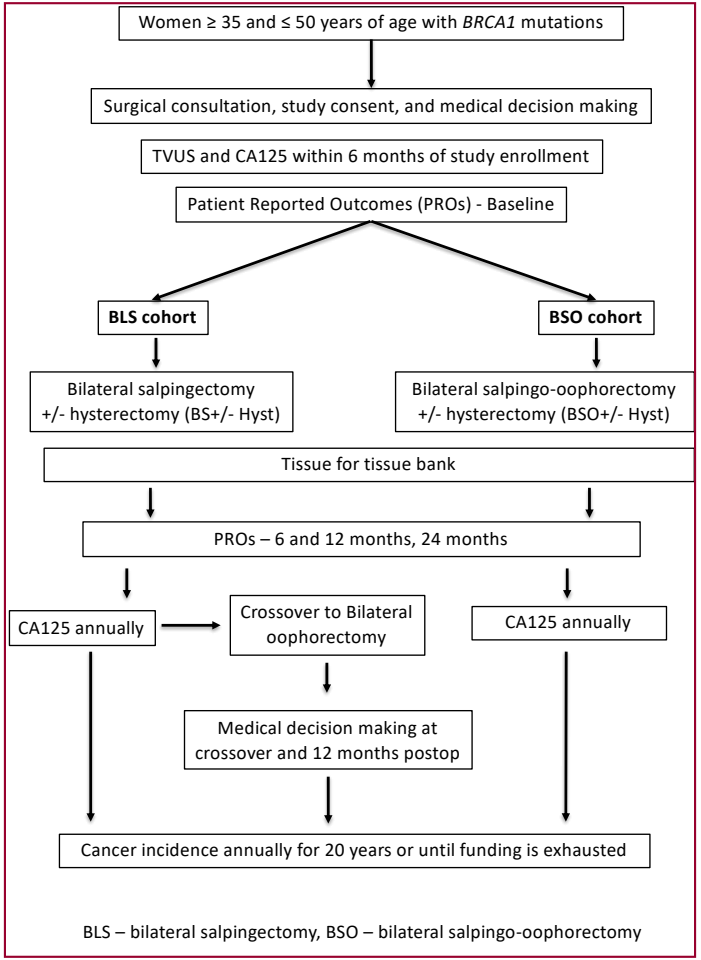
# Protocol schema

- *BRCA1* carriers will self-select surgical arm
  - Copy of genetic test report required
- Normal preoperative CA125 and TVUS required, per parameters in protocol
- Tissue will remain at local site in virtual tissue bank unless invasive cancer or precursor lesion is found at surgery
- Follow-up can be in person or remote
- Annual CA125 is required (local or remote)

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Not confidential – Please post!

# Target Accrual and Activation

- Target accrual: 2262 patients
- Study activation date: June 23, 2020
  - 24 sites already have CIRB approval

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# Primary Objective

- To compare the non-inferiority of bilateral salpingectomy (BLS) with delayed oophorectomy to bilateral salpingo-oophorectomy (BSO) to reduce the risk of ovarian cancer among women with deleterious *BRCA1* germline mutations

# Secondary Objectives

- To prospectively assess estrogen deprivation symptoms in BLS patients as measured by the FACT-ES subscale compared to women in the BSO arm
- To determine if health-related QOL (FACT) is negatively impacted by sexual dysfunction (FSFI) and cancer distress (IES) in women who have undergone BLS, in comparison to normative data (MSCL/FACT-ES) and data from BSO patients
- To assess medical decision making, as measured by the Shared Decision Making Questionnaire (SDM-Q-9) and Decision Regret Scale (DRS), and determine factors associated with the risk of reducing surgical treatment choice
- To assess adverse events, graded using CTCAE v5.0

# Exploratory Objectives

- Sexual dysfunction, as measured by selected PROMIS screener and external sexual function items
- To estimate the cost-effectiveness of BLS compared to BSO for ovarian cancer risk reduction
- To determine the association between HR-QOL with menopausal symptoms, as measured by the FACT-ES, sexual dysfunction, as measured by FSFI/ PROMIS screener and external sexual function items, and cancer distress as measured by the IES
- To assess medical decision making, as measured by the Risk-Reducing Medical Decision Making (RR-MDM) survey, a targeted set of questions on risk reducing surgical treatment choice.

# Key Eligibility Criteria

- Women 35-50 years of age, inclusive
- Patients who have declined or elected to defer RRSO after proper counselling to clearly explain the standard of care for BRCA1 mutation carriers (for the BLS with delayed oophorectomy arms) or patients who are undergoing RRSO (for the RRSO arm)
- At least one intact ovary and fallopian tube; and premenopausal
- Positive CLIA-approved test results for pathogenic or likely pathogenic germline *BRCA1* mutation in the patient herself. Documentation of the result is required.

**See Section 3.0 of the Protocol for Complete Criteria**



Not confidential – Please post!

# Key Exclusion Criteria

- Women with a history of any prior cancer who have received chemotherapy within the past 12 months, hormonal therapy in the past 90 days, or radiotherapy to abdomen or pelvis at any prior time
- Prior history of ovarian cancer, including low malignant potential neoplasms (LMP), primary peritoneal carcinoma, or fallopian tube carcinoma
- Patients medically unfit for the planned surgical procedure
- Patients with abnormal screening tests (TVUS, CA-125) suspicious for occult or gross pelvic malignancy or neoplasm within the past 180 days
- Women who are pregnant or plan to become pregnant

**See Section 3.0 of the Protocol for Complete Criteria**

Not confidential – Please post!

# Sample Size

- **Primary endpoint**: time to development of ovarian, primary peritoneal, or fallopian tube cancers
- BSO group expected to be 99% cancer-free during study period
- Hypothesize that BLS group will remain 98% cancer-free during study period
- 10 years of accrual + 6 years of additional follow-up
- 1-sided type I error=0.05, 5% loss to follow-up, 80% statistical power
- 2 interim analyses
  - Efficacy & futility
  - At 50% and 75% of events
- **53 events from 2262 patients**

# Treatment Overview

# Pre-treatment Assessments

| Assessments | Prior to Registration (calendar days) | Prior to Treatment (calendar days) |
|---|---|---|
| Informed Consent | ≤ 28 days | |
| History and Physical | | ≤ 90 days |
| Vital Signs (Blood Pressure, Heart Rate, Temperature and Pulse Oxygen Saturation) | | ≤ 90 days |
| Height | | ≤ 90 days |
| Weight | | ≤ 90 days |
| Performance Status (ECOG) | | ≤ 180 days |
| Transvaginal sonogram | ≤ 180 days | |
| CA125 | ≤ 180 days | ≤ 28 days |
| Concurrent Medications | | ≤ 3 days |
| Pregnancy Test | ≤ 14 days | ≤ 28 days |
| FACT-G plus ES subscale, EQ-5D-5L, FSFI, MSCL, PROMIS screener and external sexual function items, IES, SDM-Q-9 [d] | | X |

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Not confidential – Please post!

# Assessments in Follow-up

| Assessments | 10-60 days post-surgery | 6 months post-surgery | 12 months post-surgery | 24 months post-surgery | Annual follow-up from 24 months post-surgery |
|---|---|---|---|---|---|
| Post-Operative Visit (clinic visit or via telephone) | X | | | | |
| Decisional Regret Scale (DRS) | | | X | | |
| FACT-ES, EQ-5D-5L, FSFI, MSCL, PROMIS screener and external sexual function items, and IES | | X | X | X | |
| CA125 | | | X | X | X |
| Patient Status Follow-up: medication use/history and cancer incidence (including upload of pathology report for cancer diagnoses) | | | X | X | X |
| RRSO education and signed acknowledgement | | | X | X | X |

Follow-up procedures do not require an in-person visit to the research site

Not confidential – Please post!

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# Assessments at Crossover

| Assessments | At time of oophorectomy | 12 months post-oophorectomy | Annual follow-up from 24 months post-oophorectomy |
|---|---|---|---|
| Shared Decision Making Survey (SDM-Q-9) | X | | |
| Medical Decision Survey | X | | |
| Decision Regret Scale (DRS) | X | X | |
| Risk-Reducing Medical Decision Making | X | | |
| CA125 | X | X | X |
| Patient Status Follow-up: medication use/history and cancer incidence | X | X | X |

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# Data Management

- Quality of Life Forms
  - FACT-ES
  - EQ-5D-5L
  - PROMIS-SF
  - Menopausal Symptom Checklist (MSCL)
  - Female Sexual Function Index (FSFI)
  - Impact of Events (IES-revised)
  - Decisional Regret Scale (DRS)
  - Risk-Reducing Medical Decision-Making Survey (RR-MDM)
  - Shared Decision Making Questionnaire (SDM-Q-9)

# Data Management: Medidata Patient Cloud ePRO

- This study will allow patients to participate in electronic data submission using their own personal device (smartphone or tablet) by downloading an app and using it to complete the forms on the previous slide
- This is optional for patients or they may choose to continue to complete these forms on paper
  - It is expected that most patients will choose to complete forms electronically
- Site staff must complete the ePRO online training in Rave prior to their first patient enrollment; **Access to NRG-CC008 will not be given until this e-learning is completed**
- Information on the Medidata Patient Cloud ePRO application is located on the CTSU website on the study protocol page under the **Education and Promotion tab**

# Biospecimen Submission

- Submission of tumor tissue is required for all patients with a STIC lesion or invasive cancer
  - Investigators should check with their site Pathology Department regarding release of tissue biospecimens before approaching patients about participation in the trial. (See Section 10 for details.) This trial requires **blocks** to be submitted by the site.
  - Slides will be fresh cut at the NRG Biospecimen Bank-Columbus and will be used for central pathology review by Ronny Drapkin, PhD

- If local diagnosis does not show a precursor lesion or invasive cancer, then the institution should hold all blocks from the BSO/BLS until requested or until termination of the protocol.
- Pathology reports are required for all patients on study.

# Acknowledgements

We thank the study team, NRG Oncology protocol development staff, NCI Division of Cancer Prevention, SU2C WISP investigators, and all the patient advocacy groups that have supported development and offered to help with enrollment.

# Questions?

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# NCI NCORP Updates


**Worta McCaskill-Stevens, MD**

**Chief, Community Oncology and Prevention Trials Research Group**

**Division of Cancer Prevention**


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

***Worta McCaskill-Stevens, M.D., M.S.***
***Chief, Community Oncology and Prevention Trials Research Group***
***Division of Cancer Prevention***

**July 17 ,2020**

NIH NATIONAL CANCER INSTITUTE

# Today's Discussion

- **Status of the NCORP Research Portfolio**
- **Research Priorities Before, During, and After COVID-19**

# STUDY CATEGORIZATION

The Funding Types are rolled up to 1 of the 3 categories listed below for reference in the Notice of Grant Award

Categorization of Funding Types

- **ACCRUAL**
- **BIOSPECIMEN**
- **SPECIAL ENTRIES**

**ACCRUALS** include:

- Base/High Performance Intervention (i.e., primary study)
- Quality of Life (embedded in Treatment Trials)
- Advanced Imaging
- Special Accrual (e.g., Initial TMIST enrollment)

**BIOSPECIMENS** includes any/all biospecimens, e.g., blood, tissue, stool, serum, etc.

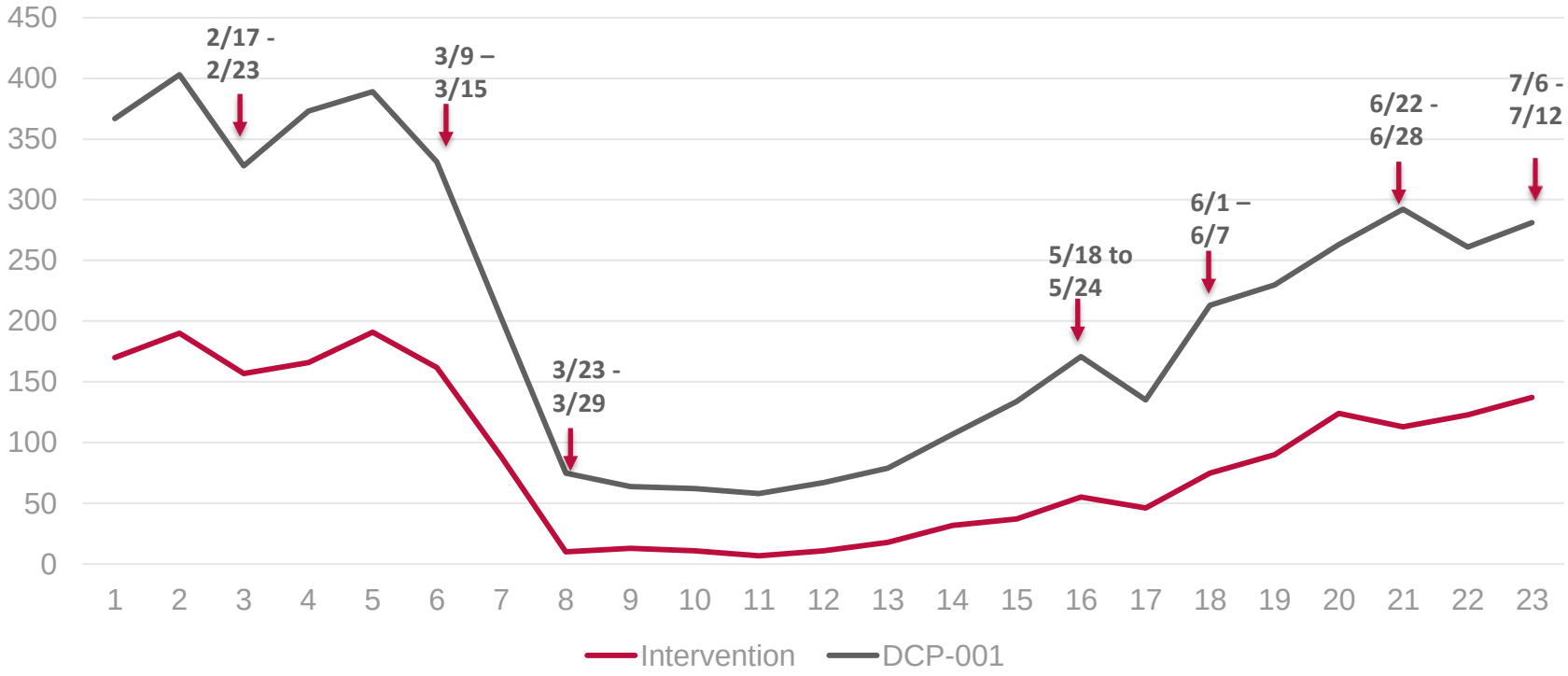
**SPECIAL ENTRIES** include:

- TMIST subsequent rounds of imaging post enrollment
- DCP-001 (Screening log)
- NHLBI-MDS (Longitudinal study cohort)
- NRG-CC004 (Forms submission)
- Screenings for Intervention (versus Screening/Base Interventions)

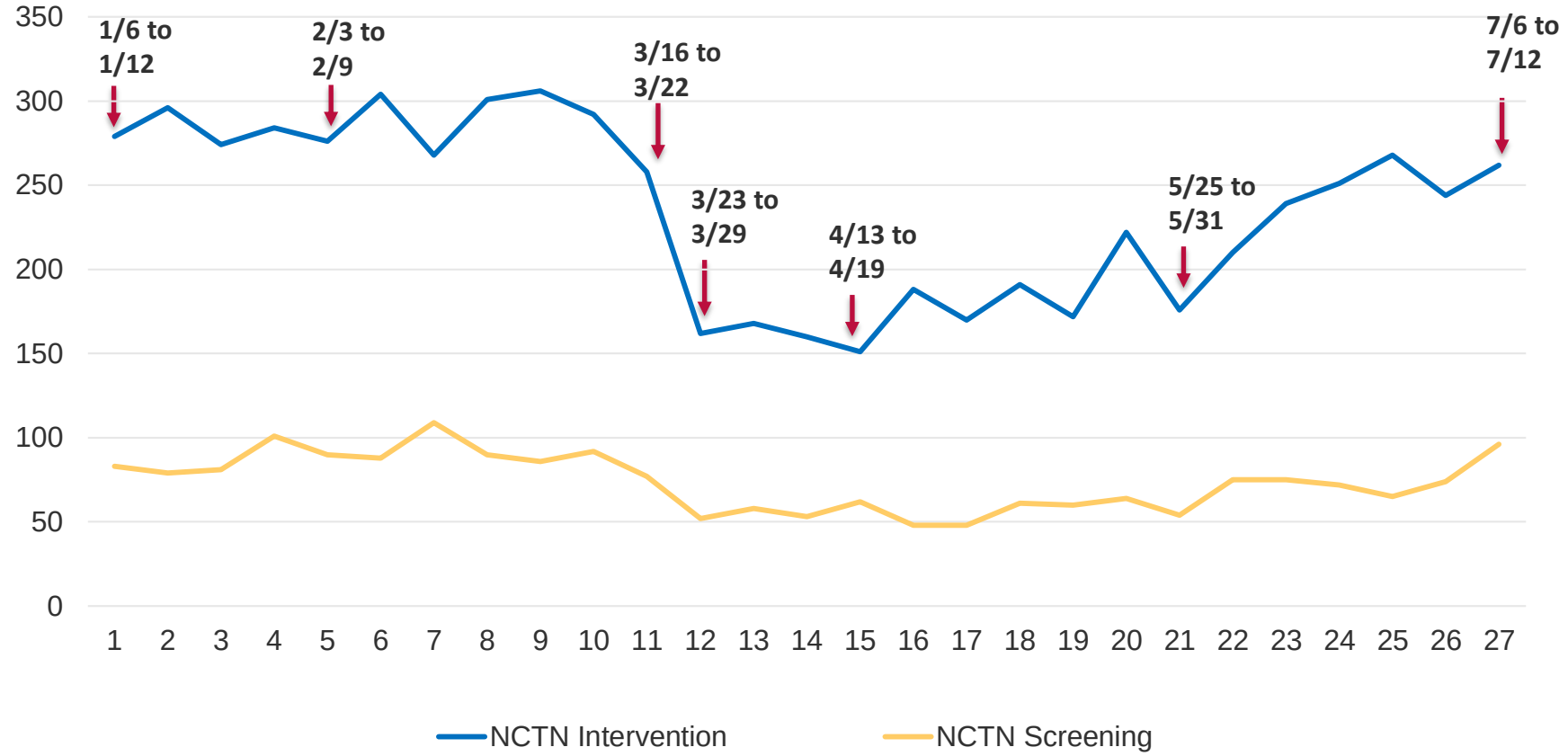
# NCORP Accrual for "Intervention" Step in NCORP Trials by Lead Research Base & Week February 3, 2020 to July 12, 2020 (CTSU OPEN Data)

| NCORP Research Base | 2/3 - 2/9 | 2/10 - 2/16 | 2/17 - 2/23 | 2/24 - 3/1 | 3/2 - 3/8 | 3/9 - 3/15 | 3/16 - 3/22 | 3/23 - 3/29 | 3/30 - 4/3 | 4/6 - 4/10 | 4/13 - 4/17 | 4/20 - 4/23 | 4/27 - 5/1 | 5/4 - 5/8 | 5/11 – 5/17 | 5/18 – 5/24 | 5/25 – 5/31 | 6/1 – 6/7 | 6/8 – 6/14 | 6/15 – 6/21 | 6/22 – 6/28 | 6/29 – 7/3 | 7/4 – 7/12 | % Change Last Week vs Weekly Avg 2/3 – 3/15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ALLIANCE | 16 | 15 | 4 | 24 | 9 | 18 | 8 | 4 | 2 | 0 | 1 | 5 | 3 | 3 | 3 | 4 | 2 | 4 | 4 | 7 | 11 | 9 | 12 | -16% |
| COG | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | -0% |
| ECOG-ACRIN | 115 | 140 | 116 | 118 | 144 | 124 | 68 | 3 | 2 | 5 | 0 | 1 | 5 | 19 | 26 | 39 | 34 | 60 | 81 | 106 | 91 | 94 | 105 | -17% |
| NRG | 4 | 3 | 4 | 1 | 9 | 4 | 3 | 0 | 2 | 1 | 1 | 1 | 2 | 3 | 3 | 3 | 6 | 3 | 1 | 2 | 3 | 11 | 3 | -29% |
| SWOG | 10 | 5 | 2 | 7 | 5 | 2 | 3 | 2 | 1 | 1 | 3 | 2 | 1 | 3 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | 4 | 8 | +53% |
| URCC | 10 | 6 | 12 | 5 | 9 | 3 | 4 | 1 | 4 | 2 | 1 | 2 | 5 | 3 | 3 | 7 | 1 | 5 | 2 | 7 | 3 | 3 | 6 | -27% |
| WAKE | 15 | 21 | 19 | 10 | 14 | 10 | 2 | 0 | 2 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 2 | 1 | 1 | 0 | 3 | 2 | 2 | -86% |
| TOTAL | 170 | 190 | 157 | 166 | 191 | 162 | 88 | 10 | 13 | 11 | 7 | 11 | 18 | 32 | 37 | 55 | 46 | 75 | 90 | 124 | 113 | 123 | 137 | -21% |

# Weekly NCORP Intervention & DCP-001 Accrual: 2/3/2020 to 7/12/2020



# Weekly NCTN Intervention & Screening Accrual: 1/6/2020 to 7/12/2020



# NCORP Trials Activated

- **URCC 19805: Wireless Transcutaneous Electrical Nerve Stimulation for CIPN**
- **A221805: Duloxetine to Prevent Oxaliplatin-Induced CIPN: A Randomized Double-Blind Placebo-Controlled Phase II Trial**
- **SWOG S1823: A Prospective Observational Cohort Study to Assess miRNA371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors**
- **NRG CC008: 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 SOROCk**
- **EAQ172: Optimizing Immunosuppression for Steroid Refractory Anti-PD-1/PD-L1 Pneumonitis**

# NCORP Since March 2020

- **Concepts: 5 Received; 4 Reviewed**
- **Protocols: 5 Received; 4 Reviewed**
- **Amendments: 46 Reviewed**

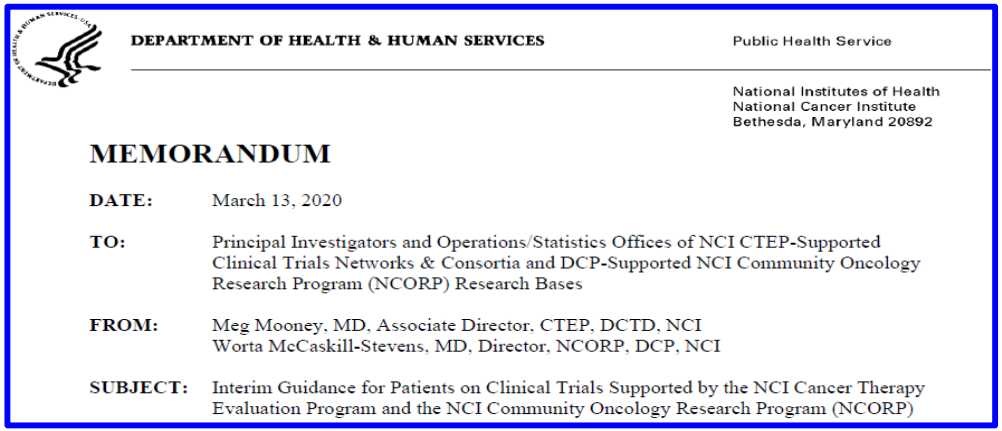
- **Biobanks Receiving Specimens: All for both NCORP and NCTN except MDA for TMIST**

# COVID-19 Related Research:

- **NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study**
- **Tocilizumab in Hospitalized Cancer Patients with Coronavirus 2019 (SARS-CoV-2) and Severe Complications of Coronavirus Disease 19 (COVID-19)**
- **COVID-19 Supplements**

# Interim Guidance for Patients During COVID-19

**NCI Advisory Boards**
**CMS**
**FDA**
**Advocacy Groups**



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

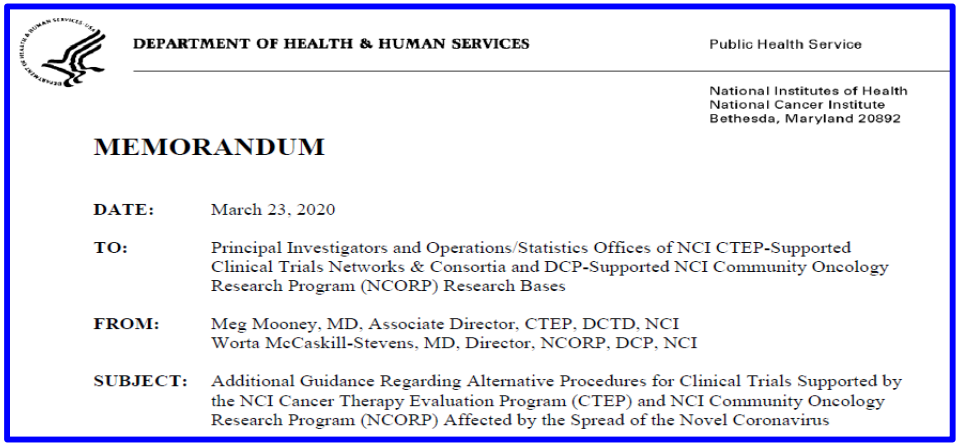
**MEMORANDUM**

**DATE:** March 13, 2020

**TO:** Principal Investigators and Operations/Statistics Offices of NCI CTEP-Supported Clinical Trials Networks & Consortia and DCP-Supported NCI Community Oncology Research Program (NCORP) Research Bases

**FROM:** Meg Mooney, MD, Associate Director, CTEP, DCTD, NCI
Worta McCaskill-Stevens, MD, Director, NCORP, DCP, NCI

**SUBJECT:** Interim Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP)



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

**MEMORANDUM**

**DATE:** March 23, 2020

**TO:** Principal Investigators and Operations/Statistics Offices of NCI CTEP-Supported Clinical Trials Networks & Consortia and DCP-Supported NCI Community Oncology Research Program (NCORP) Research Bases

**FROM:** Meg Mooney, MD, Associate Director, CTEP, DCTD, NCI
Worta McCaskill-Stevens, MD, Director, NCORP, DCP, NCI

**SUBJECT:** Additional Guidance Regarding Alternative Procedures for Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program (CTEP) and NCI Community Oncology Research Program (NCORP) Affected by the Spread of the Novel Coronavirus

# Focus on Health Disparities: Which Pandemic?

- **COVID-19:**

"***The pandemic has shone a spotlight on health disparities and created an opportunity to address the causes underlying these inequities***" -- Yancy CW, et al, JAMA, 2020

- **Systemic Racism and Racial Inequality**

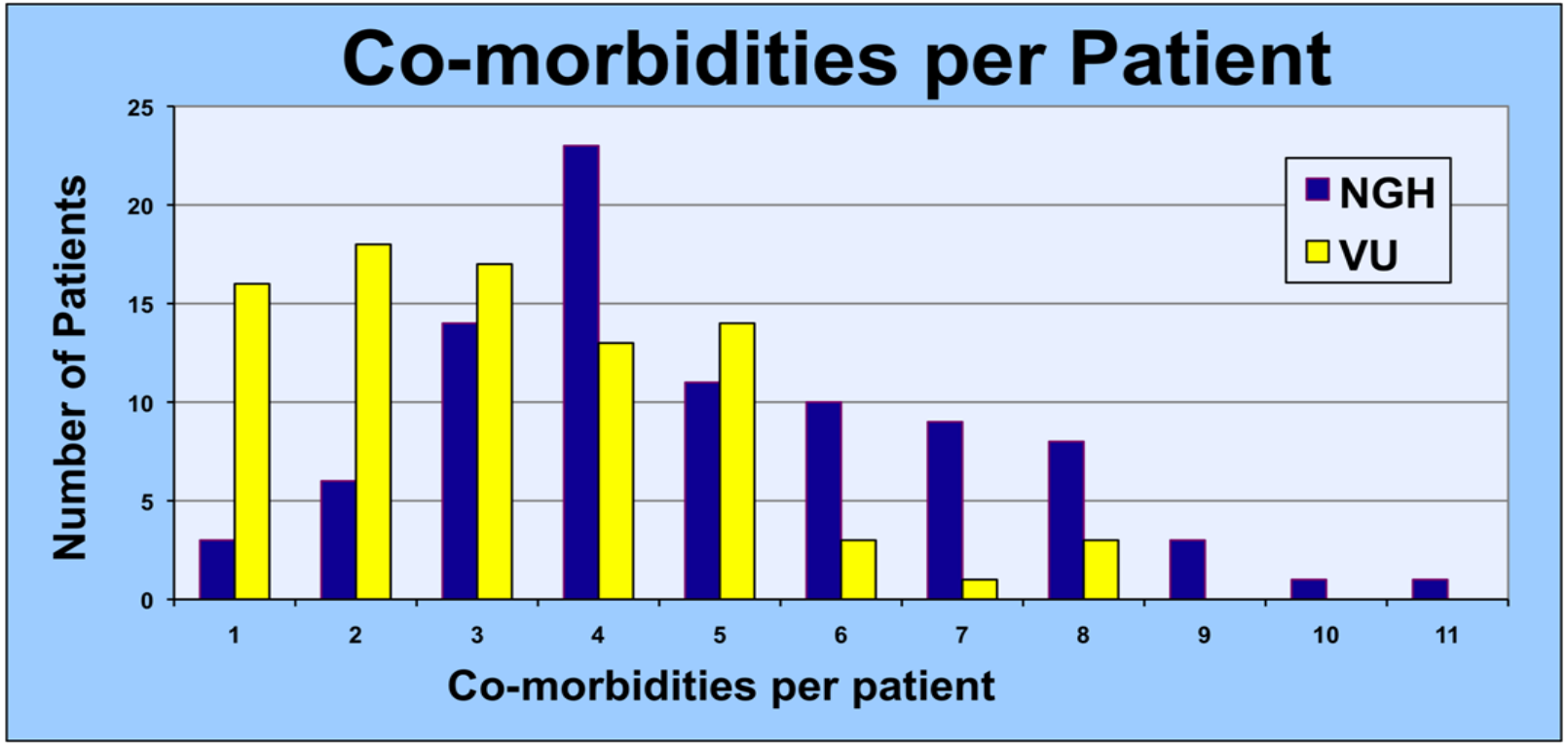
"***The oncology community must take time to reflect and begin the hard work of advancing a more equitable and just system of cancer***" -- Robert Carlson, NCCN, June 2020

# Disparities Research Approaches:

- **Integration into Trials**
  - **Pooling and sub-analyses of data from completed studies or DCP-001**
  - **Enrich data to analyze sub-groups in new studies**
  - **Add disparities research questions to existing concepts**

- **Across NCORP's scientific areas and related topics**
  - **Cancer prevention, screening and post-treatment surveillance**
  - **Symptom Science –across all of the priorities, e.g., cognitive impairment, neurotoxicity**
  - **CCDR –e.g., financial hardship, telemedicine/telehealth**

# Focus on Health Disparities: Nashville General Hospital



# Focus on Health Disparities: Which Pandemic?

"***During these unprecedented times, I do take comfort in knowing that our mission includes and benefits everyone, regardless of race, socio-economic status, education, geographic location or access to care. The events taking place today only strengthen our resolve to help eliminate these injustices."*** Ned Sharpless, NCI, June 2020

".

…**The COVID-19 pandemic has shone a bright and deeply distressing light on just how much health inequity persists in our society. We need to look at this unflinchingly, and embrace that challenge, enlisting the vision of the talent all around us**." Francis Collins, NIH, June 2020

# National Institute on Minority Health and Health Disparities Research Research Framework

| | | Levels of Influence* | | | |
|---|---|---|---|---|---|
| | | **Individual** | **Interpersonal** | **Community** | **Societal** |
| **Domains of Influence** *(Over the Lifecourse)* | **Biological** | Biological Vulnerability and Mechanisms | Caregiver–Child Interaction Family Microbiome | Community Illness Exposure Herd Immunity | Sanitation Immunization Pathogen Exposure |
| | **Behavioral** | Health Behaviors Coping Strategies | Family Functioning School/Work Functioning | Community Functioning | Policies and Laws |
| | **Physical/Built Environment** | Personal Environment | Household Environment School/Work Environment | Community Environment Community Resources | Societal Structure |
| | **Sociocultural Environment** | Sociodemographics Limited English Cultural Identity Response to Discrimination | Social Networks Family/Peer Norms Interpersonal Discrimination | Community Norms Local Structural Discrimination | Social Norms Societal Structural Discrimination |
| | **Health Care System** | Insurance Coverage Health Literacy Treatment Preferences | Patient–Clinician Relationship Medical Decision-Making | Availability of Services Safety Net Services | Quality of Care Health Care Policies |
| **Health Outcomes** | | **Individual Health** | **Family/ Organizational Health** | **Community Health** | **Population Health** |

National Institute on Minority Health and Health Disparities, 2018
*Health Disparity Populations: Race/Ethnicity, Low SES, Rural, Sexual/Gender Minority
Other Fundamental Characteristics: Sex/Gender, Disability, Geographic Region

# NCI Staff and COVID-19:


THANK YOU

# NRG NCORP Panel Discussion



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