Caregiver Oncology Needs Evaluation Tool

Wake Forest NCORP Research Base

WF-2300CD

Practice Survey for Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers

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No participation will occur at this site.

Participating Organizations

WAKE/Wake Forest NCORP Research Base

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Protocol History:

Initial	Version 09/05/2023	Not Activated

CONTACT INFORMATION

For regulatory requirements:	**For Practice enrollments:**	**For study data submission:**
Regulatory documentation must be submitted to the Cancer Trials Support Unity (CTSU) via the Regulatory Submission Portal. (Sign in at https://www.ctsu.org, and select the Regulatory > Regulatory Submission.) Institutions with patients waiting that are unable to use the Portal should alert the CTSU Regulatory Office immediately by phone or email: 1-866-651-CTSU (2878), or CTSURegHelp@coccg.org to receive further instruction and support. Contact the CTSU Regulatory Help Desk at 1-866-651-CTSU (2878), or CTSURegHelp@coccg.org for regulatory assistance.	Refer to the affiliate/sub-affiliate enrollment section of the protocol for instructions on using the Oncology Patient Enrollment Network (OPEN). OPEN is accessed at https://www.ctsu.org/OPEN_SYSTEM/ or https://OPEN.ctsu.org. Contact the CTSU Help Desk with any OPEN related questions by phone or email : 1-888-823-5923, or ctsucontact@westat.com.	Data collection for this study will be done through REDCap. Refer to the data submission section of the protocol for further instructions. Address: Wake Forest NCORP Research Base Wake Forest Baptist Medical Center Building 525@Vine, 4th floor Medical Center Boulevard Winston-Salem, NC 27157 Phone: (336) 716-0891 Fax: (336) 713-6476 Email: NCORP@wakehealth.edu Do **not** submit study data or forms to the CTSU. Do **not** copy the CTSU on data submissions.

The most current version of the **study protocol and all supporting documents** must be downloaded from the protocol-specific page located on the CTSU members' website (https://www.ctsu.org).

Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the Roster Maintenance application and in most cases viewable and manageable via the Roster Update Management System (RUMS) on the CTSU members' website.

For clinical questions (i.e., patient eligibility or treatment-related)
Contact Wake Forest NCORP Research Base (WF NCORP RB) at NCORP@wakehealth.edu. All correspondence will be triaged to the appropriate WF NCORP RB representative.

For non-clinical questions (i.e., unrelated to patient eligibility, treatment, or clinical data submission)
Contact the CTSU Help Desk by phone or email:
CTSU General Information Line – 1-888-823-5923, or ctsucontact@westat.com. All calls and correspondence will be triaged to the appropriate CTSU representative.

SCHEMA

Practice Survey for Multi-site Community Oncology Planning for the CONNECT Intervention Targeting Lung Cancer Caregivers

Caregiver Oncology Needs Evaluation Tool (CONNECT) is a web-based intervention that empowers and educates caregivers about the benefits of supportive care services and systematically identifies unmet needs to connect lung cancer caregivers with tailored supportive care resources.

Study Population: Practices consisting of affiliate and sub-affiliates within NCORP community and minority underserved community sites rostered with the Wake Forest NCORP Research Base.

Sample Size: 60 – 120 practices. An NCORP practice is comprised of one or more NCORP affiliate/sub-affiliate sites, that must share providers, supportive care resources for caregivers, and be willing to participate as a single unit in the future clinical trial.

Study Duration: 15-20 minutes to complete one practice survey after gathering data

Primary Objective: To determine interest and capacity of outpatient oncology practices across the broad NCORP network to test the CONNECT Intervention.

Assessments: One-time cross-sectional observational CONNECT Practice Survey

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1.0 OBJECTIVES

1.1 Primary Objective

To determine interest and capacity of outpatient oncology practices across the broad NCORP network to test the CONNECT Intervention in a future trial. CONNECT (**Caregiver Oncology Needs Evaluation Tool)** is a web-based intervention that empowers and educates caregivers about the benefits of supportive care services and systematically identifies unmet needs to connect lung cancer caregivers with tailored supportive care resources.

1.2 Secondary Objectives

- To explore potential barriers and facilitators to participation in the future trial, including the impact of study design considerations such as the proposed study comparison group, individual vs. practice randomization, and inclusion of caregiver-patient dyads vs. caregivers alone.
- To explore the association between practice characteristics (e.g., size, critical access designation, and proportion of racial/ethnic minority patients) and interest in and capacity to participate in the future trial.

2.0 BACKGROUND

The CONNECT team has demonstrated varying availability of evidence-based supportive care services in community oncology to support informal (unpaid) caregivers in caring for themselves and their care-recipient undergoing cancer treatment (e.g., psychosocial support, self-care/wellness classes, medical task training), but connection to these services is abysmal.[1] A scalable and systematic process is critically needed within oncology clinics to identify caregiver needs and connect caregivers with services, especially for lung cancer caregivers who report exceptional supportive care needs, high caregiver burden, anxiety, and depression.[2-8] Linking caregivers with supportive care services may improve outcomes for both caregivers and care recipients.

The Caregiver Oncology Needs Evaluation Tool (CONNECT), a novel, web-based intervention developed by our team and designed to be deployed in oncology practices, empowers and educates caregivers about the benefits of supportive care services and systematically identifies unmet needs to connect lung cancer caregivers with tailored supportive care resources.[9] We demonstrated strong feasibility and acceptability of CONNECT in a pilot randomized clinical trial with 40 lung cancer caregivers at one academic medical center. Caregivers in the intervention group relative to comparison group reported clinically meaningful decreases in caregiver burden, depression, and anxiety. We propose in this next step of multi-site intervention planning for community oncology practices, to supplement with navigation to address barriers that may hamper caregiver supportive care use.[10]

Rationale

CONNECT is promising, yet critical trial aspects need further investigation before proceeding with a multi-site efficacy trial in collaboration with the Wake Forest NCI Community Oncology Research Program Research Base (WF NCORP RB). Although NCORP practices have extensive experience with patient directed interventions, we need to better understand their interest and capacity to engage in caregiver research and study design preferences. This practice survey will provide us with useful and relevant data that will inform our future multi-site NCORP CONNECT study. The practice survey was developed by our inter-disciplinary investigator team that has rich expertise in cancer caregiving,

technology-based interventions, thoracic oncology, multi-site clinical trials within NCORP, and biostatistics, in collaboration with community site stakeholders. Results from this study and the subsequent study (WF-2301CD) will be synthesized and reviewed by study investigators and the Stakeholder Advisory Board and will inform all aspects of study design for the future clinical trial.

Future Trial Description (To be finalized at the conclusion of WF-2301CD).

The future clinical trial that is proposed (pending study findings from WF-2301CD) will test the CONNECT Intervention, designed to connect lung cancer caregivers (i.e., family or family-like members providing unpaid care to a care-recipient with lung cancer) with existing supportive care resources (e.g., mental health services, financial navigation, cancer education) at the practice, local community, and nationwide. Importantly, practices will **not** be asked to develop or offer new supportive care resources; rather, CONNECT is focused on connecting caregivers with existing resources that may or may not be at participating practices. CONNECT is low burden for caregivers and includes a 1.5-minute animated video, a brief survey to identify their service interests, a tailored list of supportive care resources, and navigation services provided by a Wake Forest University School of Medicine Central Caregiver Navigator by telephone. CONNECT can be completed at home or using a study tablet in the clinic.

Participants: We anticipate enrolling approximately 314 lung caregiver-patient dyads (i.e., caregiver + their care-recipient) to participate in one of 2-3 study arms. Caregiver inclusion criteria includes: (1) Provides the majority of the unpaid care during cancer treatment for a patient meeting the criteria below; and (2) ≥18 years of age. Caregivers will be excluded if they are: (1) currently receiving cancer treatment; or (2) unable to read and communicate in English.

We anticipate patient inclusion criteria to include: (1) Must have a current diagnosis of new or recurrent stage II-IV lung cancer and must be enrolled in the study after the start of anticancer systemic therapy (+/- radiation therapy) with at least 9 weeks of any planned anticancer treatment remaining and (2) Patients must be ambulatory and up (i.e., not bedridden) more than 50% of waking hours. Patients will be excluded if they: (1) are post-treatment survivors at the time of study enrollment; (2) enrolled in hospice care; or (3) unable to read and communicate in English.

Design Considerations: The future trial may include a Usual Care (that is, care that the caregivers would be expected to receive at their practice as part of normal care) comparison group and/or a group that receives a generic, non-tailored resource list (no access to video, survey to identify interests, or navigation services). It is also possible that study findings may necessitate a practice randomized design (e.g., in the case of intervention contamination), though this is not anticipated at this current time.

Site Responsibilities: Practice staff will be responsible for identifying and enrolling eligible caregiver-patient dyads. The primary source of data collection will be REDCap (and managed by Wake Forest); however, practice staff will be responsible for following up with dyads in the case of missing data. Data collection will occur at three time points including before randomization (baseline), at 12-weeks, and at 24 weeks. Practice staff will be responsible for minimal data abstraction from the patient's electronic health record. Other data collection is self-report from caregivers and patients. Practice staff may also be responsible for overseeing study tablets when in use at the clinic.

Local Practice Referral Coordinator: Each participating practice will identify a Local Practice Referral Coordinator defined as a staff member from the NCORP practice who is knowledgeable (or able and willing to learn) about the local supportive care resources and referral processes for caregivers at their practice (e.g., social worker, navigator, therapist, nurse). This local practice staff member will

add local resource information to a CONNECT resource database (may enlist support from other local staff) and facilitate referrals to link caregivers participating in the CONNECT Intervention arm with services. They will also interface with the Central Caregiver Navigator (see description below) for caregivers randomized to the CONNECT Intervention arm and report on training and participation metrics and details and suggestions to improve the future trial.

Study Champions: Each participating practice may also be asked to identify a research or clinical champion, separate from the Local Practice Referral Coordinator. These roles are defined as research or clinical personnel with high interest and agency to support the project and able to communicate its importance to various stakeholders.

3.0 STUDY DESIGN AND PRACTICE PARTICIPATION

The ***Practice Recruitment Email*** will be sent to the NCORP Administrators and CCDR Leads at NCORP community and minority underserved community sites affiliated with the WF NCORP RB. If the affiliate(s)/sub-affiliate(s) are interested in participating, they should complete the brief ***Practice Interest Form*** by following the link in the ***Practice Recruitment Email*** to define their practice. After submitting the ***Practice Interest Form***, a Practice ID will be emailed to the Practice Contact within 2 business days. The Practice ID will be used in CTSU-OPEN at enrollment to enroll the practices affiliates and sub-affiliates. Once the practice is registered for the study in CTSU-OPEN, the practice-specific observational one-time ***CONNECT Practice Survey*** will be emailed to the Practice Contact listed on the ***Practice Interest Form.*** The ***CONNECT Practice Survey*** will include a brief description of the future CONNECT study and questions to assess practice willingness to participate, estimated caregiver-patient dyad accruals per quarter at their practice, and ability to identify practice personnel key to implementing the study (i.e., local practice referral coordinator who is knowledgeable about the local supportive care resources and referral mechanism to link caregivers with services and a clinical and research champion). Potential barriers and facilitators to participation in the future trial will also be evaluated. We are looking for at least 60 NCORP practices to complete the survey (see Table 1 and 2) from the NCORP community and minority underserved community sites affiliated with the Wake Forest NCORP Research Base. An NCORP practice may comprise one or more NCORP affiliate/sub-affiliate sites, but they must share providers, supportive care resources for caregivers, and be willing to participate as a single unit in the future clinical trial.

Survey and Participation Reminders: The Wake Forest NCORP Research Base team will execute every two-week reminders (up to five times) to non-responders who have indicated interest in the Practice Recruitment Email. For practices that have yet to respond to the Practice Recruitment Email, we anticipate that we will send a reminder approximately half-way through the study and approximately one month before closing the survey, though we will demonstrate flexibility as needed to be responsive to practice requests for reminders and to strive for robust participation. Related to this, we will also host a webinar at the start of the study and approximately half-way through the study to maximize participation.

Table 1. Expected Minimum Practice Participation Planned

Number of minority/underserved community practices	Number of community practices	Total
25	35	60

Table 2. Expected Maximum Practice Participation Planned

Number of minority/underserved community practices	Number of community practices	Total
50	70	120

Minimum Expected Practice Accrual Rate: 10 practices/month

Total Expected Practice Participation: 60 Min 120 Max

Table 3 represents the maximum number of affiliate/sub-affiliate sites expected to enroll in CTSU-OPEN as part of the practices participating in this study. These estimated maximum planned enrollment numbers are based on the 2022 Landscape Survey, which showed that approximately 25% of the practices that participated in the survey consisted of 2 or more affiliates or sub-affiliates. Of those practices consisting of 2 or more affiliates or sub-affiliates, the median number of affiliates/sub-affiliates is 4. Based on this, we anticipate that a maximum of 240 individual affiliates/sub-affiliates will be enrolled in this study.

Table 3. Expected Maximum Planned Enrollment Report for Affiliate/Sub-affiliates within the Practices

Number of minority/underserved affiliate/sub-affiliate within the practices	Number of community practice affiliate/sub-affiliate within the practices	Total
100	140	240

Accrual Rate: 10 organizations/month **Total Expected Accrual**: 60 Min 240 Max

4.0 PRACTICE ELIGIBILITY

Inclusion Criteria:

- Must be an affiliate or sub-affiliate of an NCORP community or minority underserved community site that is rostered with Wake Forest NCORP Research Base
    - Affiliate or sub-affiliate site must have a valid Cancer Therapy Evaluation Program (CTEP) Identification Number
- Must be an NCORP practice that is comprised of one or more NCORP affiliate/sub-affiliate sites, that must share providers, supportive care resources for caregivers, and be willing to participate as a single unit in the future clinical trial.
- Must provide outpatient care for adult oncology patients.

- Must have completed the ***Practice Interest Form*** found within the ***Practice Recruitment Email Letter*** and have received their Practice ID needed for CTSU-OPEN enrollment.

5.0 CONNECT PRACTICE SURVEY

To inform practice recruitment of the future trial, we are conducting a practice survey of NCORP outpatient oncology practices to assess practice interest and capacity (N=60-120), including (1) practice willingness to participate and factors that might impact willingness to participate or study feasibility, (2) estimated caregiver-patient accruals per quarter at their practice, (3) ability to identify key practice study implementers, and (4) barriers and facilitators to participation. We are also determining factors associated with interest and capacity (practice size, critical access designation, racial/ethnic minority patient proportion) to inform equity considerations.

The one-time observational survey (estimated 15-20 min to complete after gathering data) was developed in collaboration with our community site stakeholders, using REDCap as the electronic data collection platform. The REDCap survey link will be included in an email sent to the Practice Contact, who was noted on the ***Practice Interest Form*** for the practices that have enrolled in CTSU-OPEN for the study. An NCORP staff member at each practice (typically the NCORP administrator, CCDR leader, or lead study coordinator) will confer with key personnel (practice clinical staff, NCORP PI, other staff within the practice) and complete the ***CONNECT Practice Survey*** on behalf of the practice.

This ***CONNECT Practice Survey*** will only be asking for information about the practices and will not have any identifying personnel data associated with it. No consent or participant enrollment will be needed to complete this survey, since it is related solely to practice information. Practices that want to participate in this cross-sectional observational survey must enroll in CTSU-OPEN prior to receiving the survey.

6.0 REGISTRATION PROCESS

6.1 Investigator and Research Associate Registration with CTEP

Food and Drug Administration (FDA) regulations require sponsors to select qualified investigators. National Cancer Institute (NCI) policy requires all individuals contributing to NCI-sponsored trials to register with their qualifications and credentials and to renew their registration annually. To register, all individuals must obtain a Cancer Therapy Evaluation Program (CTEP) credentials necessary to access secure NCI Clinical Oncology Research Enterprise (CORE) systems Investigators and clinical site staff who are significant contributors to research must register in the Registration and Credential Repository (RCR). The RCR is a self-service online person registration application with electronic signature and document submission capability.

RCR utilizes five person registration types.

- Investigator (IVR) — MD, DO, or international equivalent;
- Non Physician Investigator (NPIVR) — advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD);
- Associate Plus (AP) — clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications such as the Roster Update Management System [RUMS], OPEN, Rave, acting as a primary site contact, or with consenting privileges;
- Associate (A) — other clinical site staff involved in the conduct of NCI-sponsored trials; and

- Associate Basic (AB) — individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems.

RCR requires the following registration documents:

Documentation Required	IVR	NPIVR	AP	A	AB
FDA Form 1572	✓	✓			
Financial Disclosure Form	✓	✓	✓		
NCI Biosketch (education, training, employment, license, and certification)	✓	✓	✓		
GCP training	✓	✓	✓		
Agent Shipment Form (if applicable)	✓				
CV (optional)	✓	✓	✓		

IVRs and NPIVRs must list all clinical practice sites and Institutional Review Boards (IRBs) covering their practice sites on the FDA Form 1572 in RCR to allow the following:

- Addition to a site roster;
- Selection as the treating, credit, or drug shipment investigator or consenting person in OPEN;
- Ability to be named as the site-protocol Principal Investigator (PI) on the IRB approval; and
- Assignment of the Clinical Investigator (CI) task on the Delegation of Tasks Log (DTL).

In addition, all investigators acting as the Site-Protocol PI (investigator listed on the IRB approval), consenting/treating/drug shipment investigator in OPEN, or as the CI on the DTL must be rostered at the enrolling site with a participating organization.

Refer to the NCI RCR page on the CTEP website for additional information. For questions, please contact the **RCR Help Desk** by email at RCRHelpDesk@nih.gov.

6.2 Cancer Trials Support Unit Registration Procedures

Permission to view and download this protocol and its supporting documents is restricted and is based on the person and site roster assignment housed in the Roster Maintenance application and in most cases viewable and manageable via the Roster Update Management System (RUMS) on the Cancer Trials Support Unit (CTSU) members' website.

Protocol documents are found on the CTSU website, but additional supplemental documents may be available on the Wake Forest NCORP Research Base website (https://wakencorp.phs.wakehealth.edu).

This study is supported by the NCI CTSU.

IRB Approval

The NCI CIRB Operations Office reviewed the WF-2300CD study and determined that the activity described in the submitted materials does not constitute Human Subjects Research as defined by 45 CFR 46, and therefore the requirements of 45 CFR 46 do not apply to this activity. Sites are not required to get CIRB approval to participate in this study.

As of March 1, 2019, all U.S.-based sites must be members of the NCI Central Institutional Review Board (NCI CIRB) in order to participate in Cancer Therapy Evaluation Program (CTEP) and Division of Cancer Prevention (DCP) studies open to the National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) Research Bases. In addition, U.S.-based sites must accept the NCI CIRB review to activate new studies at the site after March 1, 2019. Local IRB review will continue to be accepted for studies that are not reviewed by the CIRB, or if the study was previously open at the site under the local IRB. International sites should continue to submit Research Ethics Board (REB) approval to the CTSU Regulatory Office following country-specific regulations.

Sites participating with the NCI CIRB must submit the Study Specific Worksheet (SSW) for Local Context to the CIRB using IRBManager to indicate their intent to open the study locally. The NCI CIRB's approval of the SSW is automatically communicated to the CTSU Regulatory Office, but sites are required to contact the CTSU Regulatory Office at CTSURegPref@ctsu.coccg.org to establish site preferences for applying NCI CIRB approvals across their Signatory Network. Site preferences can be set at the network or protocol level. Questions about establishing site preferences can be addressed to the CTSU Regulatory Office by email or calling 1-888-651-CTSU (2878).

In addition, the Site-Protocol Principal Investigator (PI) (i.e., the investigator on the IRB/REB approval) must meet the following criteria for the site to be able to have an Approved status following processing of the IRB/REB approval record:

- Have an active CTEP status;
- Have an active status at the site(s) on the IRB/REB approval (*applies to US and Canadian sites only*) on at least one participating organization's roster;
- If using NCI CIRB, be active on the NCI CIRB roster under the applicable CIRB Signatory Institution(s) record;
- Include the IRB number of the IRB providing approval in the Form FDA 1572 in the RCR profile;
- List all sites on the IRB/REB approval as Practice Sites in the Form FDA 1572 in the RCR profile; and
- Have the appropriate CTEP registration type for the protocol.

Additional Requirements

Additional site requirements to obtain an approved site registration status include:

- An active Federal Wide Assurance (FWA) number;
- An active roster affiliation with the Lead Protocol Organization (LPO) or a Participating Organization (PO);
- An active roster affiliation with the NCI CIRB roster under at least one CIRB Signatory Institution (US sites only); and
- Compliance with all applicable protocol-specific requirements (PSRs).

Protocol Specific Requirements for WF-2300CD Site Registration

Upon site registration approval in RSS, the enrolling site(s) within the practice may access OPEN to complete enrollment(s). Practices will need to have completed the ***Practice Interest Form*** found in the ***Practice Recruitment Email*** to receive their Practice ID, which they will need for OPEN enrollment.

Practices can email NCORP@wakehealth.edu, if they did not receive the initial ***Practice Recruitment Email***.

Submitting Regulatory Documents

Submit required forms and documents to the CTSU Regulatory Office using the Regulatory Submission Portal on the CTSU members' website.

To access the Regulatory Submission Portal log in to the CTSU members' website, go to the *Regulatory* section and select *Regulatory Submission*.

Institutions with patients waiting that are unable to use the Regulatory Submission Portal should alert the CTSU Regulatory Office immediately by phone or email: 1-866-651-CTSU (2878), or CTSURegHelp@coccg.org to receive further instruction and support.

Checking Site's Registration Status

Site registration status may be verified on the CTSU members' website.

- Click on *Regulatory* at the top of the screen;
- Click on *Site Registration;* and
- Enter the sites 5-character CTEP Institution Code and click on Go:
  - Additional filters are available to sort by Protocol, Registration Status, Protocol Status, and/or IRB Type.

Note: The status shown only reflects institutional compliance with site registration requirements as outlined within the protocol. It does not reflect compliance with protocol requirements for individuals participating on the protocol or the enrolling investigator's status with NCI or their affiliated networks.

6.3 CTSU-OPEN Enrollment of NCORP Affiliate/Sub-affiliates

There will be no participant enrollments in this study, as it is a one-time practice survey completed by NCORP practice staff only about their practice. If an NCORP affiliate/sub-affiliate chooses to participate, they need to complete the ***Practice Interest Form*** found within the ***Practice Recruitment Email*** to receive their Practice ID that they need for enrollment in CTEP OPEN. If an NCORP affiliate/sub-affiliate did not receive the ***Practice Recruitment Email***, they can email NCORP@wakehealth.edu to request it.

The Oncology Patient Enrollment Network (OPEN) is a web-based registration system available on a 24/7 basis. OPEN is integrated with CTSU regulatory and roster data and with the LPOs registration/randomization systems or the Theradex Interactive Web Response System (IWRS) for retrieval of patient registration/randomization assignment. OPEN will populate the site enrollment data in WF NCORP RB's clinical data management system, REDCap.

Requirements for OPEN access:

- Active CTEP registration with the credentials necessary to access secure NCI/CTSU IT systems;
- To perform enrollments or request slot reservations: Must be on an LPO roster, ETCTN corresponding roster, or participating organization roster with the role of Registrar. Registrars must hold a minimum of an Associate Plus (AP) registration type;
- If a Delegation of Tasks Log (DTL) is required for the study, the registrars must hold the OPEN Registrar task on the DTL for the site; and

- Have an approved site registration for the protocol prior to patient enrollment.

To assign an Investigator (IVR) or Non-Physician Investigator (NPIVR) as the treating, crediting, consenting, drug shipment (IVR only), or receiving investigator for a patient transfer in OPEN, the IVR or NPIVR must list the IRB number used on the site's IRB approval on their Form FDA 1572 in RCR. If a DTL is required for the study, the IVR or NPIVR must be assigned the appropriate OPEN-related tasks on the DTL.

Practice affiliate/Sub-affiliate enrollments, for this trial will be completed using OPEN. All OPEN access requirements also apply to non-patient enrollments.

Prior to enrollment, site staff should verify the following:

- Practice affiliate/sub-affiliate has met all eligibility criteria within the protocol stated timeframes
- All patients have signed an appropriate consent form and Health Insurance Portability and Accountability Act (HIPAA) authorization form (if applicable).

In the OPEN credentialing screen, select the registration type of *Practice*. Complete the practice enrollment prerequisite questions (if applicable) and the associated eligibility checklist and submit the enrollment.

Note: The OPEN system will provide the site with a printable confirmation of registration. You may print this confirmation for your records.

Access OPEN at https://open.ctsu.org or from the OPEN link on the CTSU members' website. Further instructional information is in the OPEN section of the CTSU website at https://www.ctsu.org or https://open.ctsu.org. For any additional questions, contact the CTSU Help Desk at 1-888-823-5923 or ctsucontact@westat.com.

6.4 Data Submission / Data Reporting

REDCap is a data management system being used for data collection for this practice survey. Access to the ***CONNECT Practice Survey*** in REDCap will be granted through a link emailed to the Practice Contact provided on the ***Practice Interest Form*** after the practice has been enrolled in CTSU-OPEN.

For any additional questions on REDCap contact the Wake Forest NCORP Research Base at 336-716-0891 or NCORP@wakehealth.edu.

7.0 CRITERIA FOR EVALUATION AND ENDPOINT DEFINITION

7.1 Primary Endpoints

The primary endpoints will be interest and capacity to participate in a future trial, measured and defined as follows:

- Practice willingness to participate will be measured using a Likert response from 1 (Very Unlikely) to 5 (Very Likely), with "interest" in participating defined as an answer of "Somewhat Likely" or "Very Likely".
- "Capacity" to participate (yes vs. no) will be defined as a combination of three components. To have capacity a practice must : estimate 5 or more caregiver-patient dyad accruals per

quarter; answer "yes" (on a dichotomous question) regarding the ability to identify a local practice referral coordinator (i.e., staff member who is knowledgeable about the local supportive care resources and referral mechanism to link caregivers with services); and answer "yes" regarding the ability to identify a clinical (on a dichotomous question) and/or research study champion (on a dichotomous question).

7.2 Secondary Endpoints

- The first secondary endpoint is exploration of potential barriers and facilitators to participation in a future trial; potential barriers and facilitators assessed include: use of Usual Care as a comparison group, need for practice randomization, experience recruiting caregivers or caregiver-patient dyads, eligibility, and insufficient staff.
- The remaining secondary endpoint is examination of association between practice characteristics and interest in and capacity to participate in a future trial (yes vs. no); practice characteristics that we will measure include size, critical access designation, and proportion of racial/ethnic minority patients. Size will be defined based on the estimated number of new analytic oncology cases/ year at the practice (small: less than 100, medium: greater than or equal to 100 but less than 500, large: greater than or equal to 500).

7.3 Study Termination

NCI, DCP as the study sponsor or the Wake Forest NCORP Research Base has the right to discontinue the study at any time.

8.0 STUDY MONITORING AND REGULATORY CONSIDERATIONS

8.1 Data Management

Data management for this survey will be done electronically using REDCap.

Event	System
Practice Enrollment	CTSU-OPEN
Survey and Data Collection	REDCap

REDCap is a secure, web-based, and easy to program forms and research database platform utilized by the WF NCORP RB for many research projects. This study will be using REDCap as the electronic data collection platform for the one-time ***CONNECT Practice Survey***.

8.2 Data and Safety Monitoring Plan

This study will only involve one survey that the NCORP CCDR Lead or designee will complete about the practice. There will be no participant enrollment or collection of participant information, so a Data Safety and Monitoring Plan (DSMP) is not necessary.

8.3 Institutional Review Board

Prior to initiating this study, which involves no participant enrollment or collection of participant information, the NCI Central IRB will review the protocol, and provide documentation allowing the Investigators at the WF NCORP RB to activate the study. Should changes to the study become necessary, protocol amendments will be submitted by WF NCORP RB to the Division of Cancer

Prevention (DCP) PIO according to DCP Amendment Guidelines. The DCP-approved amended protocol must be submitted and reviewed by the CIRB prior to implementation of any changes.

9.0 STATISTICAL CONSIDERATIONS

9.1 Accrual, Feasibility, and Sample Size Justification

This is a short one-time practice survey that will be emailed to all of the NCORP community and minority underserved community sites affiliated with the Wake Forest NCORP Research Base. In the Caregivers study (conducted by members of the research team within NCORP), 111 supportive care leaders were enrolled from 36 parent NCORPs over approximately fifteen months, and it took just under 7 months to receive responses from 60 practices. The survey used in this current study is much briefer with minimal data collection and therefore we anticipate that a minimum of 60 practices will be accrued for the current study. We will not restrict the total number of practice responses, but expect a maximum of 120 practices to be accrued over the 6-month period that the survey will be open. With the minimum sample size of 60 practices, we can estimate binary survey responses (e.g., somewhat or very likely to participate; capacity) within +/- 13.2% using exact binomial 95% confidence intervals. If the sample size is 120, we can estimate binary survey responses within +/- 9.3%.

9.2 Analysis Plans

Categorical survey responses will be described using frequency and percentage. Interest will be summarized as the frequency and percent who answer they are somewhat or very likely to participate. The estimated number of caregiver-patient dyads who are eligible and estimated accruals per quarter will be described using median and interquartile range. We will quantify the number of practices able to meet our definition of capacity, where yes is defined as the ability to accrue 5 or more eligible dyads per quarter, to identify a local practice referral coordinator, and to identify a clinical and/or research study champion. We will then use logistic regression models to explore the association between practice characteristics (e.g., size, critical access designation, proportion of racial/ethnic minority patients) and the outcomes of interest (yes/no) and capacity (yes/no).

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