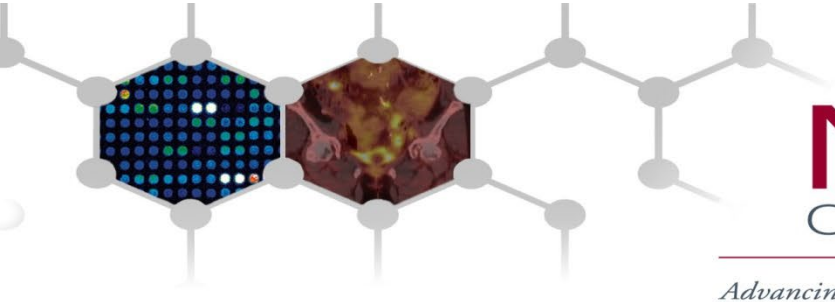

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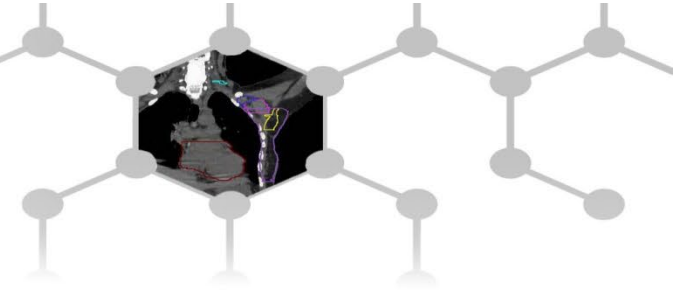

NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

Presenters:
Jamillah Gross-Caldwell, Grey Freylersythe
Project Managers

This NRG-Oncology protocol is being conducted in collaboration with NIH/NCI R01 #1R01CA279472-01 funding to Drs. Sikorskii MPI (contact), Badger (MPI) and Crane (MPI).

Study Team Contacts

Principal Investigator	Co-Chair, Health Disparities	Co-Chair, Patient Reported Outcomes
Alla Sikorskii, PhD Michigan State University	**Terry Badger, PhD, RN, PMHCNS-BC, FAPOS, FAAN** University of Arizona	**Tracy Crane, PhD, RDN** University of Miami
Co-Chair, Nursing	**NCORP Community Co-Chair**	**Statistician**
Melyssa Foust, MSN, RN Upstate Carolina NCORP	**Vamsi Krishna Vasireddy, DO** Carle Cancer Institute	**Stephanie Pugh, PhD** NRG Oncology
SWOG Champion	**Alliance Champion**	
Virginia Sun, PhD, RN City of Hope	**Kelly A. Hirko, PhD, MPH** Michigan State University	

See protocol for complete contact details

NRG Oncology Headquarters Contacts

Data Management **For questions concerning eligibility or data submission**	**Lisa Abate** abatel@nrgoncology.org **Aaron Johnson** johnsona@nrgoncology.org
Protocol Development **For questions concerning protocol and informed consent versions & amendments**	**Erica Field, MPH, MHA** fielde@nrgoncology.org
Project Managers **For questions concerning patient recruitment, data collection, and interventions.**	**Jamillah Gross-Caldwell** Michigan State University 517-884-7662 **Grey Freylersythe** University of Miami 305-243-9832 **Shared Inbox:** cc012cd@miami.edu

See protocol for complete contact details

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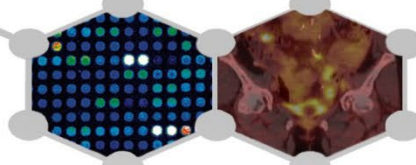

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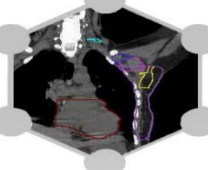

Study Background and Rationale

Study Background

- There are currently more than 50 U.S. Food and Drug Administration (FDA)-approved oral anticancer agents, and their use is increasing
- Patients on oral agents must self-manage their symptoms (e.g., fatigue, anxiety, skin rash) with less interactions with on oncology team compared to infusion treatment
- Telemonitoring and management of symptoms are key for reducing symptom burden, emergency department [ED] or urgent care visits, hospitalizations, and treatment interruptions

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Study Rationale

- This is a confirmatory trial of the adaptive Automated Telephone Symptom Management (ATSM) + Telephone Interpersonal Counseling (TIPC) in real world of community-based oncology practices
- Comparison condition: telephone interactive voice response (IVR) symptom monitoring.
- Data will inform future implementation of this telehealth symptom monitoring strategy, including acceptability, appropriateness, cost, and cost savings due to reductions in unscheduled health service use.
- Practices provide usual care and are not asked to alter their practice as part of the trial.

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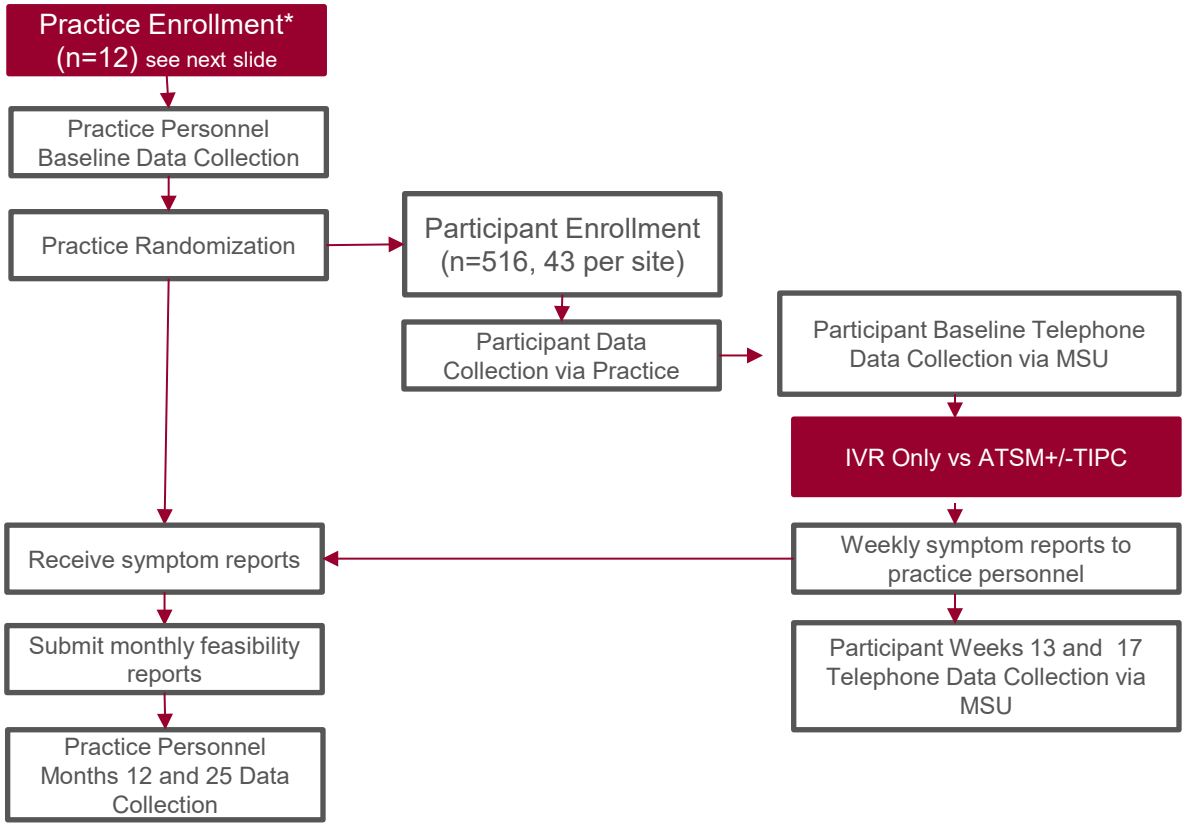
Study Schema



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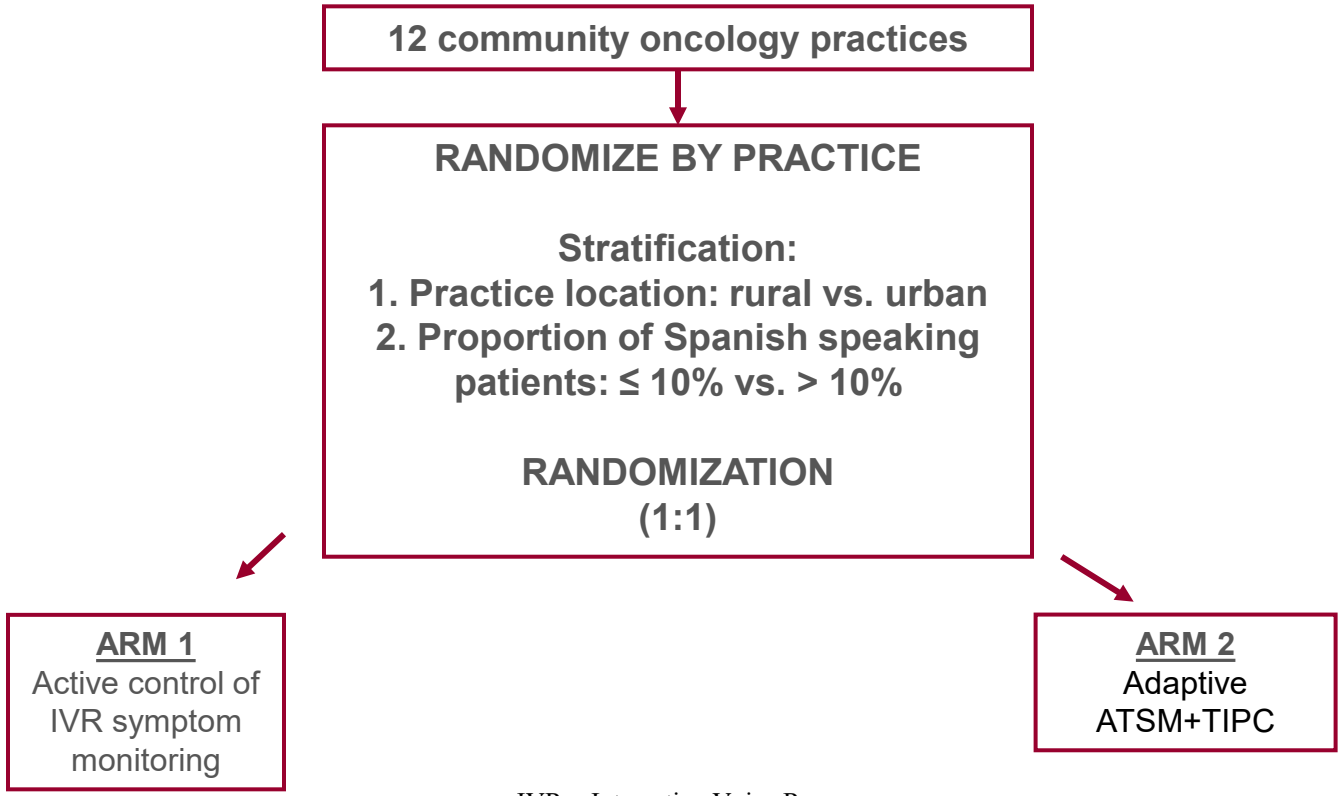
Practice Enrollment



IVR = Interactive Voice Response
ATSM = Automated Telephone System Management
TIPC = Telephone Interpersonal Counseling

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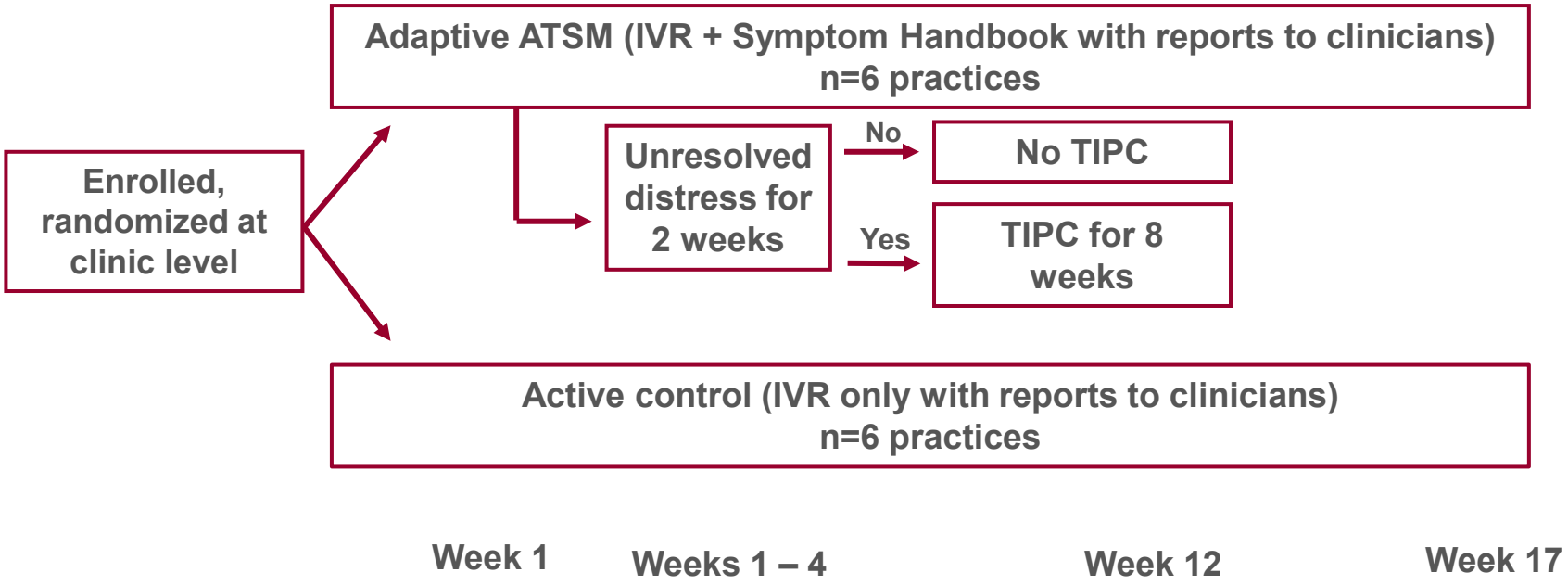
Participant Intervention



IVR = Interactive Voice Response
ATSM = Automated Telephone System Management
TIPC = Telephone Interpersonal Counseling

Symptoms

- 24 symptoms will be assessed via IVR weekly for 17 weeks using Patient-Reported Outcomes Common Terminology Criteria for Adverse Events (PRO-CTCAE)
- Symptom severity is rated as 0=none, 1=mild, 2=moderate, 3=severe, 4=very severe
- Weekly summary for each patient is sent to practice (any person or people identified by practice)
- Practice personnel are not required to do anything specific based on the report, but report recipient(s) will be asked monthly what was done

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Patient-Specific Study Flow

Patient contact information received via secure email

↓

MSU completes baseline interview

↓

Participant enrolled in IVR or ATSM+TIPC

PARTICIPANTS FROM CLINICS RANDOMIZED TO ADAPTIVE ATSM-TIPC

Any symptoms of 0-4 → Weekly report to practice personnel

Symptoms of 2-4 → Participant referred to Handbook

Psychological symptoms of 3-4 for 2 consecutive weeks (in weeks 1-4 only) → Participant receives 8-wk TIPC

Data submitted to Rave Medidata

PARTICIPANTS FROM CLINICS RANDOMIZED TO ACTIVE CONTROL (IVR)

Any Symptoms 0-4 → Weekly report sent to practice personnel

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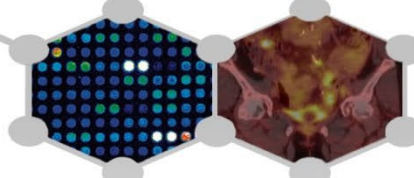

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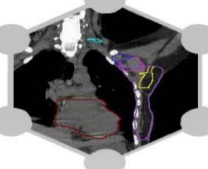
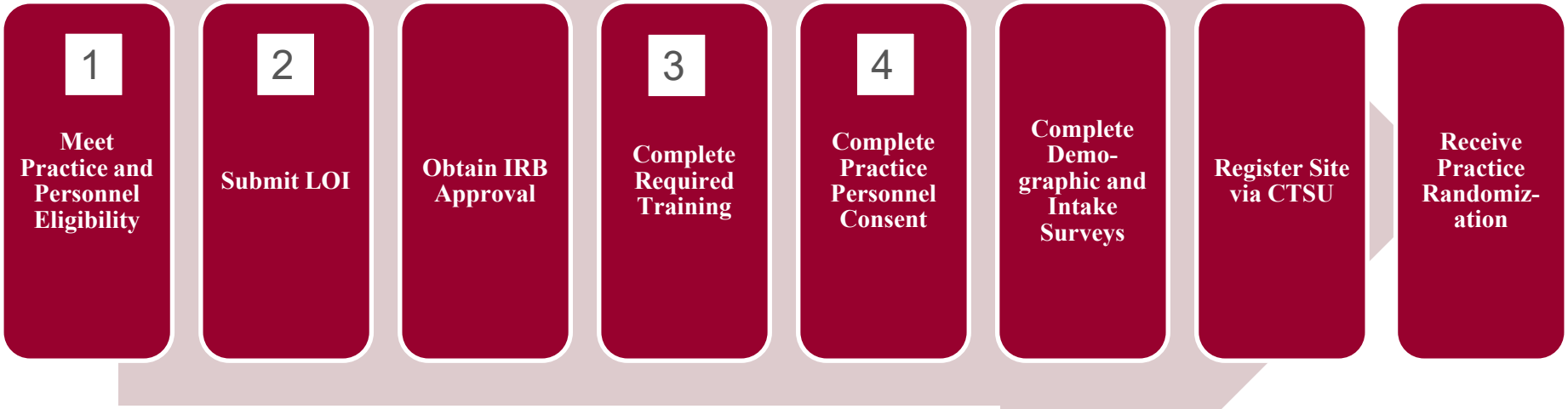


Practice Study Activities

Practice Initiation



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Practice and Staff Characteristics

- Total of 12 practices will be enrolled
  - At least 4 practices must be rural, i.e., having 1+ rural county in the catchment area. Rural county is defined as not containing a core urban area of 50,000 or more population
  - Practices serving Spanish-speaking population will be prioritized

- Approximately 4 personnel will enroll at each practice, not limited
  - Practice personnel eligible to participate are: physicians, nurses, nurse practitioners, advanced practice providers, physician assistants, medical assistants, pharmacists, social workers, and other behavioral health professionals who have the requisite education, licensure or certifications for their roles and are involved in symptom management of patients on trial.

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1

Practice Key Eligibility Criteria

- All institutions participating in the practice are NCORP affiliates or sub-affiliates.
  - Practices are defined as a single NCORP affiliate or sub-affiliate; or NCORP affiliate and/or sub-affiliates that share the same physicians/staff but are in different locations.
- Administer oral therapy (other than hormonal) to at least 40 patients per year
  - Accrual goal is 2 per month
- Practice may or may not have a behavioral health professional who is willing to be trained and deliver TIPC. If not, TIPC intervener will be hired by the study
- Able to participate for 25 months after IRB approval and start-up activities
- Able to identify a recipient(s) of weekly IVR symptom reports

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Practice Personnel Eligibility Criteria

Practice personnel will be key stakeholders in this research study, themselves consenting to participation, receiving reports, and completing brief monthly questionnaires. The practice personnel must provide study-specific informed consent prior to study entry.

- Age ≥ 18 years.
- Planned to be involved in usual care for at least one enrolled patient during patient's participation in the study.
- At least one practice personnel has to receive IVR reports and complete monthly forms (about 30 minutes)

- Social worker/ behavioral health professional who will deliver TIPC intervention, licensure, or eligibility for licensure in behavioral counseling if required by the State or Territory.

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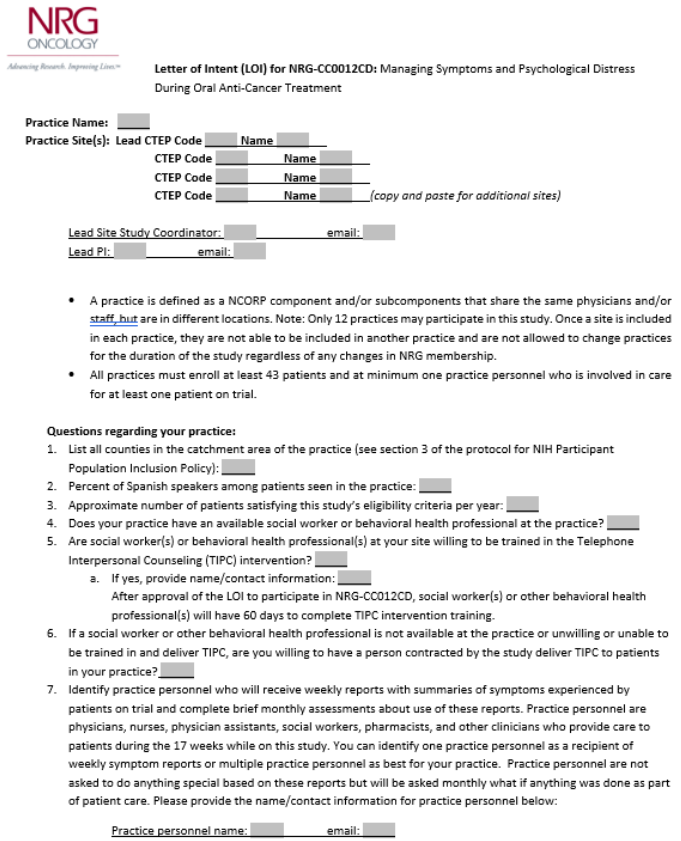
Letter of Intent

- Practices interested in participating will submit a Letter of Intent
- LOI will be posted on CTSU website
- Complete LOI and email to cc012cd@miami.edu



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Letter of Intent (LOI) for NRG-CC0012CD: Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

Practice Name: ____

Practice Site(s): Lead CTEP Code ____ **Name** ____

CTEP Code ____ **Name** ____

CTEP Code ____ **Name** ____

CTEP Code ____ **Name** ____ *(copy and paste for additional sites)*

Lead Site Study Coordinator: ____ email: ____

Lead PI: ____ email: ____

- A practice is defined as a NCORP component and/or subcomponents that share the same physicians and/or staff, but are in different locations. Note: Only 12 practices may participate in this study. Once a site is included in each practice, they are not able to be included in another practice and are not allowed to change practices for the duration of the study regardless of any changes in NRG membership.
- All practices must enroll at least 43 patients and at minimum one practice personnel who is involved in care for at least one patient on trial.

Questions regarding your practice:

1. List all counties in the catchment area of the practice (see section 3 of the protocol for NIH Participant Population Inclusion Policy): ____
2. Percent of Spanish speakers among patients seen in the practice: ____
3. Approximate number of patients satisfying this study's eligibility criteria per year: ____
4. Does your practice have an available social worker or behavioral health professional at the practice? ____
5. Are social worker(s) or behavioral health professional(s) at your site willing to be trained in the Telephone Interpersonal Counseling (TIPC) intervention? ____
   a. If yes, provide name/contact information: ____
      After approval of the LOI to participate in NRG-CC012CD, social worker(s) or other behavioral health professional(s) will have 60 days to complete TIPC intervention training.
6. If a social worker or other behavioral health professional is not available at the practice or unwilling or unable to be trained in and deliver TIPC, are you willing to have a person contracted by the study deliver TIPC to patients in your practice? ____
7. Identify practice personnel who will receive weekly reports with summaries of symptoms experienced by patients on trial and complete brief monthly assessments about use of these reports. Practice personnel are physicians, nurses, physician assistants, social workers, pharmacists, and other clinicians who provide care to patients during the 17 weeks while on this study. You can identify one practice personnel as a recipient of weekly symptom reports or multiple practice personnel as best for your practice. Practice personnel are not asked to do anything special based on these reports but will be asked monthly what if anything was done as part of patient care. Please provide the name/contact information for practice personnel below:

   Practice personnel name: ____ email: ____

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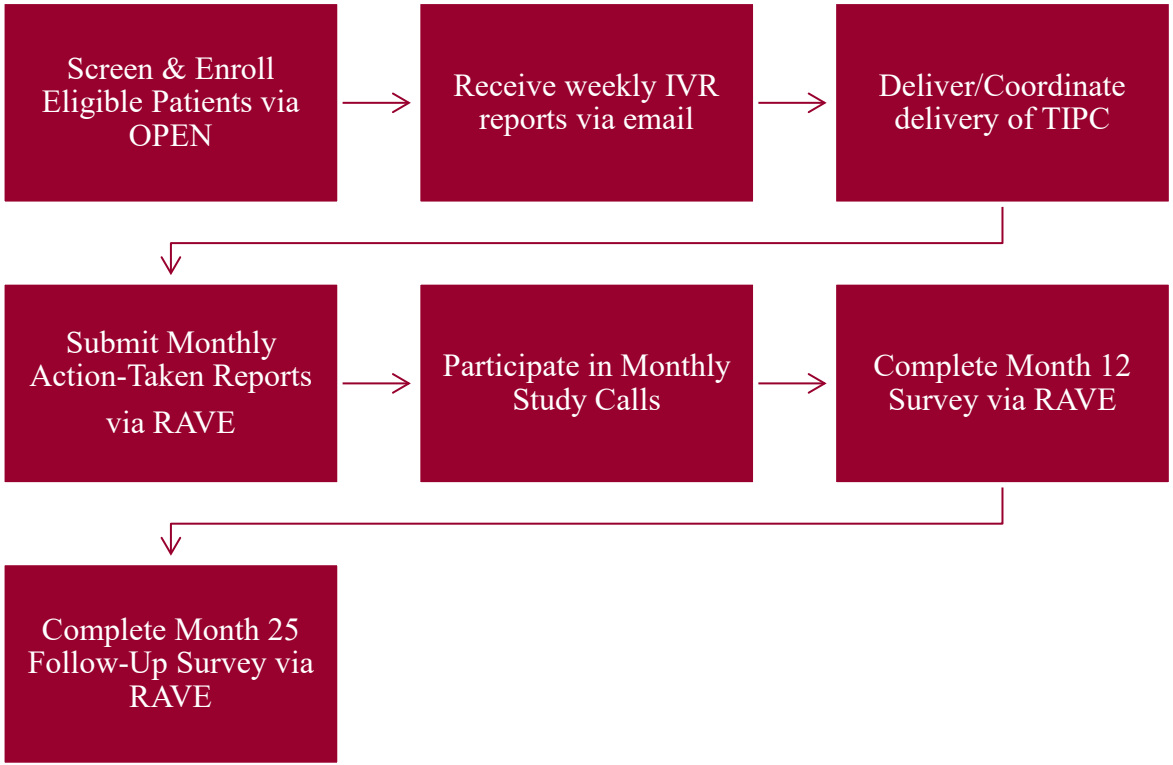
Protocol Training

- Must be completed within 90 days of approval as a participating site.
- At least one designated staff member must complete the training. If staff member leaves, another staff member must complete the training.
- Training must be completed prior to enrollment of first participant.

Training Options

- NRG Oncology Semi-Annual Meetings – 1 hour in-person training
- Web-based training available on CTSU website

Practice Study Flow



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Patient Key Eligibility Criteria

- Starting a new course of an oral anti-cancer agent (the list of agents is posted to the CTSU website) other than sex hormone inhibitors, within 4 weeks after registration or have started an oral anti-cancer agent in the past 4 weeks.
- All concomitant medications and supportive care treatments are acceptable.
- Age ≥ 18 years.
- Able to speak and understand English or Spanish.
- Access to a telephone and ability to answer questions via telephone in English or Spanish.
- The patient must provide study-specific informed consent prior to study entry and authorization permitting release of personal health information.

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Patient Key Exclusion Criteria

- Treatment with immune checkpoint inhibitor at enrollment
- Only receiving sex hormone inhibitor
- Being in the intervention arm of another symptom management trial at intake into this study. Participation in lifestyle trials with primary outcomes other than symptoms is acceptable.
- Currently receiving regular behavioral counseling for psychological symptoms (at least two counseling sessions within the past two months). Patients who completed behavioral counseling within 2 months prior to registration are eligible. Behavioral counseling for issues other than psychological symptoms (e.g., as part of weight loss or smoking cessation program) is not an exclusion criterion.
- Currently in hospice care

Targeted Patient Enrollment

- The study enrollment goal is ≥15% Spanish speakers (defined as participants who prefer information communicated in Spanish)
- The enrollment of Spanish speakers will be monitored via monthly enrollment tracking
- Enrollment of patients who are not Spanish speakers will be closed when their number reaches 85% of the target enrollment of 516 patients, i.e., no more than 438 non-Spanish speaking patients will be enrolled
- Rural determination is at the practice level (serving at least one rural county). No restriction on enrollment of patients residing in rural or urban areas

Patient Enrollment

- Patient registration can only occur after eligibility criteria confirmed, and study site is listed as ‘approved’ in the CTSU RSS.
- Complete patient contact form, patient demographics form, patient history form
- Register Patient in OPEN (See section 8.2.1 for OPEN enrollment protocol)
- Email patient contact information to cc012cd@miami.edu for UMiami/MSU to start non-practice data collection and IVR delivery.
- Planned enrollment is average of 2 patients per month over 21 months (total of 43 from practice)

Example Weekly IVR Report

Clinic ID: NRG-014
Study ID: SYM-01
Name: John Bishop
MRN:

SYMON
SYmptom Management during Oral aNti-cancer treatment

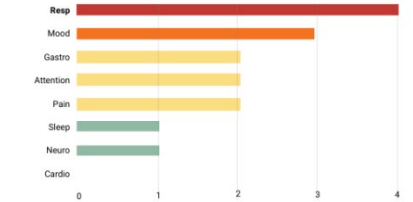
Below is a summary by system of ALL patients' symptoms reported on 1/6/24.

	Overall	Severity	Frequency	Interfere.	Gastro	Resp	Cardio	Attn.	Pain	Sleep	Mood	Other
SYM-016	2.67	2.51	2.50	3	0	2	2	2	2	2	0	0
SYM-002	2.27	1.99	1.81	3	0	0	0	0	0	0	0	0
SYM-005	2.05	1.75	1.40	3	2.75	0	0	0	05	0	2	2.05
SYM-001	0.83	1.53	0.94	1.42	3	3	3	3	2	2	1	1

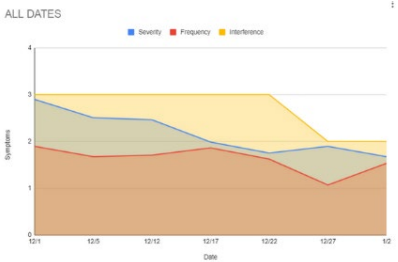
SYM-016 – Symptoms reported this week.

Prev. Week 12/31/23	1/6/24	
3	4	Shortness of Breath
2	4	Cough
2	4	Headache
1	4	Insomnia
4	4	Fatigue, Tiredness, Lack of Energy
4	3	Pain
3	3	Anxiety
1	3	Dizziness
3	2	Mouth or Throat Sores
4	2	Decreased Appetite
3	2	Nausea
0	2	Heart Palpitations
0	1	Vomiting
3	1	Constipation
0	1	Diarrhea
1	1	Arm or Leg Swelling
0	1	Rash
1	1	Numbness/Tingling in Hands or Feet
3	0	Problems with Concentration
1	0	Feelings that Nothing Could Cheer you Up
1	0	Sad or Unhappy Feelings
0	0	Shivering or Shaking Chills
1	0	Unexpected or Excessive Sweating During Day or Nighttime (not related to hot flashes/flushes)

SYM-016 – Symptoms this week by body system.



SYM-016 – Symptoms reported while on study.



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TIPC Intervention

- Practices randomized to Adaptive ATSM+TIPC will identify a TIPC intervener (social worker, behavioral health professional) who can be trained to deliver TIPC
    - If no personnel are available, the study team will work to contract someone licensed to practice in that state
- Practice TIPC intervener will complete an asynchronous online training course and will be reimbursed for their time
- Practice TIPC intervener will be compensated for delivery of TIPC intervention
- A TIPC supervisor at University of Arizona will work closely with TIPC intervener for training and delivery continuity

Monthly Study Calls

- There will be monthly calls with sites about accrual, regulatory requirements, and any issues arising during the study.
- Timing of monthly calls yet to be determined; webinar invitations will be sent to all practice personnel.
- Site PIs or designated Physician delegates (must be site co-chairs) must make every effort to attend.
- Site study team (RAs, study nurses, etc.) are required to attend at least once per quarter

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Data Management

CTSU	OPEN	RAVE	CC012CD@miami.edu
Practice IRB approval	Practice Enrollment	Practice Personnel Demographics Questionnaire	LOI (retrieve from CTSU)
Protocol-specific training	Practice Personnel Enrollment	Patient Screening Data	Patient Contact Form (within 1 business day)
Site registration documents	Patient Enrollment	Monthly “Action Taken” Reports	
		Patient health record review	
		Feasibility and Acceptability questionnaires (months 12 and 25 only)	

Blank Rave forms and Summary of Data Submission are available on the CTSU website.

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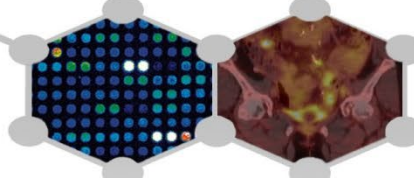

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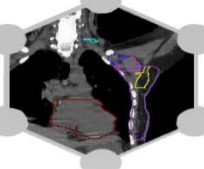

In Closing

- LOI submissions open:
- Planned activation date: April 1, 2024
- Key study contacts:
  - Jamillah Gross-Caldwell, MSU
  - Grey Freylersythe, Umiami
  - cc012cd@miami.edu

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FAQs

What oral treatments are eligible?

The list will be maintained on CTSU, as it will be updating all of the time. We recommend checking eligibility against the version in CTSU every time.

How do changes in a patient's treatment plan affect their participation?

Patients can continue in the study if they are willing to, regardless of oral agent temporary or permanent stoppages, hospitalizations, or initiation of hospice care.

How are deviations handled?

Sites can report any deviations to NRG by completing a Deviation form in Rave. Sites should also report deviations to CIRB where applicable.

What staff are eligible to participate as practice personnel?

Physicians, nurses, nurse practitioners, advanced practice providers, physician assistants, medical assistants, pharmacists, social workers, and other behavioral health professionals who have the requisite education, licensure or certifications for their roles and are involved in symptom management of patients on trial.

How are "rural" practices defined?

Having at least one rural county in their catchment area. Based on the Department of Health and Human Services, rural county is defined as county that is not part of a Metropolitan Statistical Area, i.e., does not contain a core urban area of 50,000 or more population

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