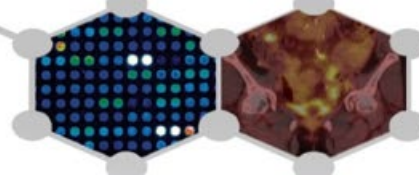

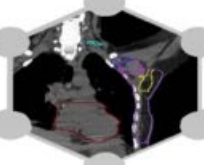

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NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

September 19, 2024

Practice Personnel Update

Presenters:

Jamillah Gross-Caldwell, Grey Freylersythe

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).

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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	

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See protocol for complete contact details

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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, MSU** 517-884-7662 **Grey Freylersythe, UMiami** 305-243-9832 **Shared Inbox:** symon@miami.edu

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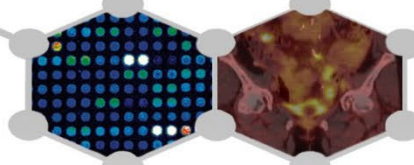
See protocol for complete contact details



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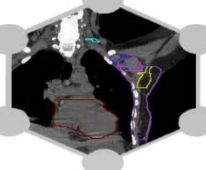

Brief Study Overview

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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 or urgent care visits, hospitalizations, and treatment interruptions

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Study Rationale

- Testing the implementation of the following conditions in real world of community-based oncology practices:

ATSM + TIPC (Automated Telephone Symptom Monitoring & Handbook +/- Telephone Interpersonal Counseling)	IVR Control (Telephone Symptom Monitoring only)

- 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.

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Symptom Monitoring (both arms)

- 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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Symptom Management (ATSM+TIPC arm only)

- Patients will be directed to a symptom management handbook in weeks 1-12, to contact their healthcare provider and/or to contact emergency services depending on their symptoms.

- Patients reported elevating psychosocial symptoms in weeks 1-4 will be referred to TIPC (telephone interpersonal counseling) for 8 weeks.

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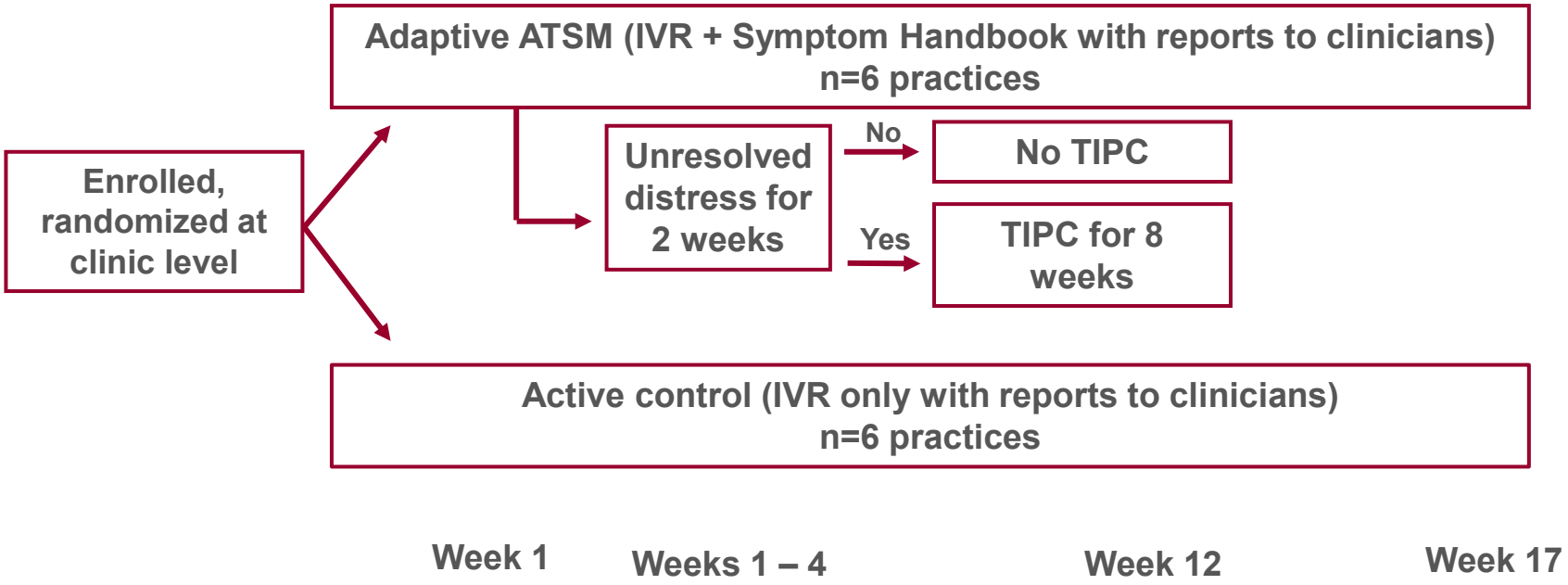
Participant Intervention



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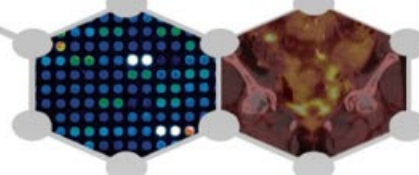
IVR = Interactive Voice Response
ATSM = Automated Telephone System Management
TIPC = Telephone Interpersonal Counseling



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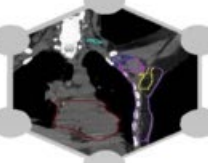

Study Updates

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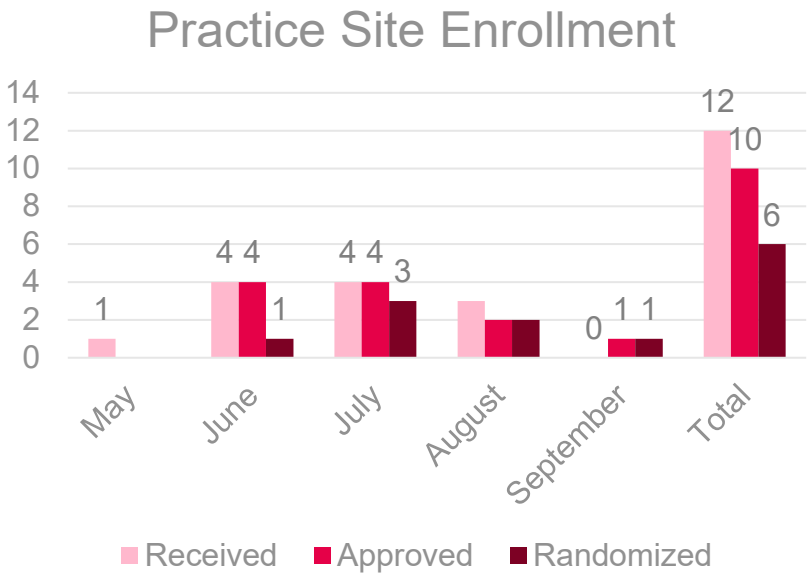
Progress



Approved Sites

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Progress

- 3 sites pending randomization
  - complete training certificate in CTSU
- 2 sites with enrolled practice personnel
  - Lake Regional MO200
  - GA CaRes GA020
  - Other sites can begin enrolling practice personnel

- CIRB Updates
  - UMiami and UArizona completed CIRB approval
  - MSU pending final local IRB reliance -> when approved, patient recruitment can begin

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Training Certificate

Training certificate on CTSU must be completed and submitted to the CTSU prior to enrollment of first participant.

NRG-CC012CD Web-based training
Confirmation of Completion

Instructions: Sumit the completed via the CTSU Regulatory Submission Portal

This verifies that you have completed viewing the NRG-CC012CD Training slides.

- Name _____
  (Please type/print)

  Your Individual NCI CTEP ID Code: _____

  Check one *(you are)*:
  ☐ Investigator on IRB Approval
  ☐ Research Associate

- Institution Name _____

- Institution NCI CTEP ID Code: _____
  (list additional institution CTEP ID Codes if you are the Qualified Investigator for additional sites and the sites are also listed on the IRB/REB approval)

- Date completed _____

Signature: _____

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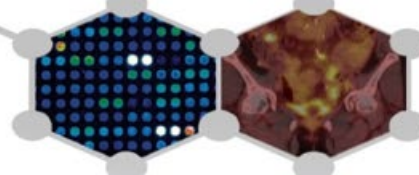

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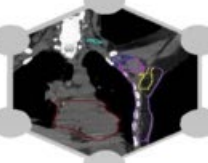

Review of Practice Study Activities

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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.

Eligible: physicians, nurses, nurse practitioners, advanced practice providers, physician assistants, medical assistants, pharmacists and are involved in symptom management of patients on trial.

- 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)

If applicable – if site has behavioral health professional who will deliver TIPC intervention, they must have licensure or eligibility for licensure in behavioral counseling if required by the State or Territory.

Can be as few as **one** person or as many as applicable, ideally ~4

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Patient Key Eligibility Criteria

- Must be starting a new course of an oral anti-cancer agent (the list of agents is always posted to the CTSU website), within 4 weeks of registration.
  - Can be receiving sex hormone inhibitor in *conjunction* with other oral anti-cancer agent
  - **Cannot** be receiving treatment with immune checkpoint inhibitor at enrollment
  - All concomitant medications and supportive care treatments are acceptable.
- Cannot be receiving competing supportive care treatments:
  - Cannot be in any other symptom monitoring/management programs or studies
  - Cannot have had 2+ counseling/therapy sessions in past month for mood/psychosocial wellbeing
- Cannot be in hospice at time of enrollment
- Must be able to speak and understand English or Spanish.
- Must have access to a telephone with a touchpad and ability to hear a recording

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Patient Enrollment

Plan to enroll 2 patients per month on average

Process:

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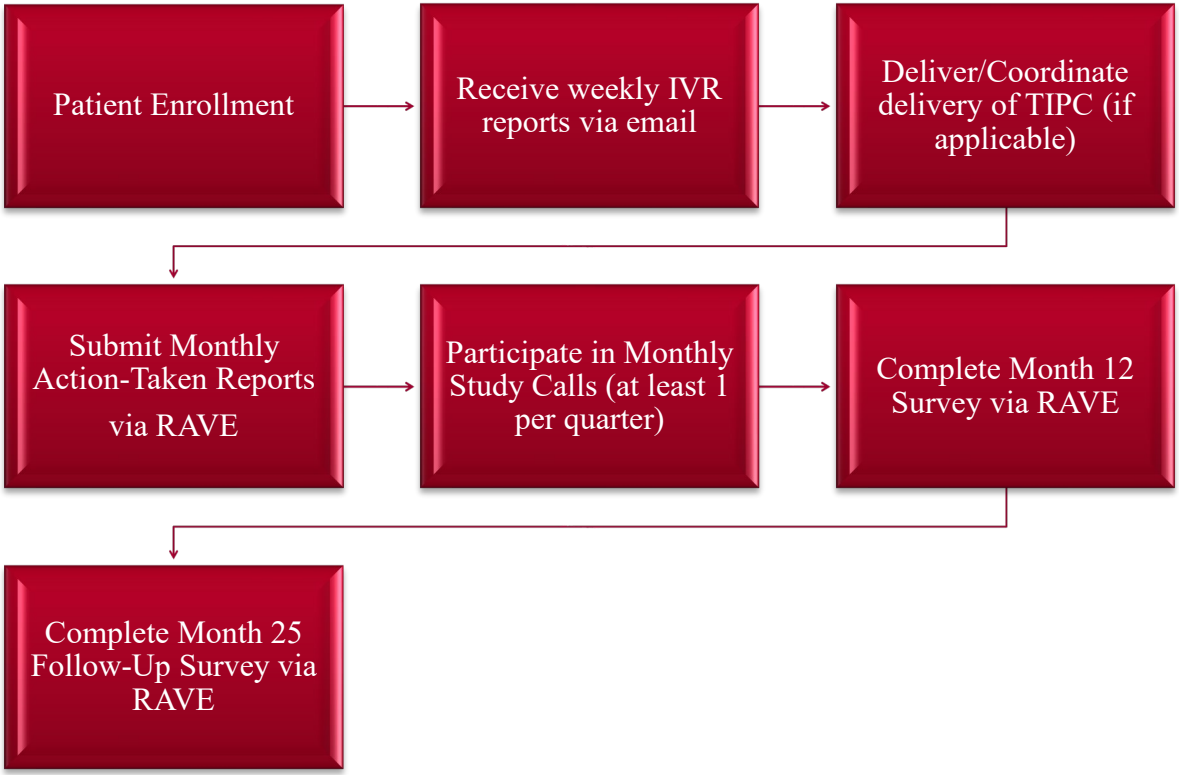
Practice Personnel Activities

- Consented practice personnel will have additional surveys to complete



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Example Weekly IVR Report

- Will be sent within ~24hrs of symptom monitoring telephone call, after each weekly call
- Can be sent to as many people as preferred

Record ID CC012CD-00001

Provider Report

Patient Name: Elle Example
MRN: 1234567
Study Start Date: 06/28/2024
Below is a summary of your patient's symptoms reported on 06/29/2024

Severe Symptoms
Cough: 4
Arm or leg swelling: 3
Pain: 4
Vomiting: 4

Moderate Symptoms
Pounding or racing heartbeat (Palpitations): 2
Hand-foot syndrome: 2
Headache: 1

No Symptoms Reported
Shortness of breath: 0
Tingling in Hands or Feet: 0
Dizziness: 0
Problems with concentration: 0
Insomnia: 0
Fatigue: 0
Anxiety: 0
Feeling that nothing could cheer you up: 0
Sad or unhappy feelings: 0
Shivering or shaking chills: 0
Unexpected or excessive sweating: 0
Dry mouth: 0
Mouth or throat sores: 0
Decreased appetite: 0
Nausea: 0
Constipation: 0
Diarrhea: 9 (Refused to answer)

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Data Management

CTSU

- Practice IRB approval
- Protocol-specific training
- Site registration documents

OPEN

- Practice Enrollment
- Practice Personnel Enrollment
- Patient Enrollment

RAVE

- Practice Personnel Demographics Questionnaire
- Patient Screening Data
- Monthly "Action Taken" Reports
- Patient health record review
- Feasibility and Acceptability questionnaires (months 12 and 25 only)

SYMON@miami.edu

- LOI (retrieve from CTSU)
- Patient Contact Form (within 1 business day – use encryption)

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

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Key Points

- 10 of 12 sites are now approved
- Approved sites should move forward with IRB approval as soon as possible, contact us for support if needed
- Open sites should begin recruitment and consent of practice personnel
- Study team will contact all sites when patient recruitment can begin, anticipated within next 1-2 weeks

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Learn More

- **Contact us!**
  - Jamillah Gross-Caldwell & Grey Freylersythe

  SYMON@miami.edu

- **Resources**
  - General information:
    - www.craneresearchlab.org/cc012cd
    - www.nrgoncology.org/Clinical-Trials/Protocol/nrg--cc012cd?filter=nrg--cc012cd
  - NRG Meeting Kick-Off Training
    - nrg2024winter.s3.amazonaws.com/RG-CC012CD+Workshop.mp4

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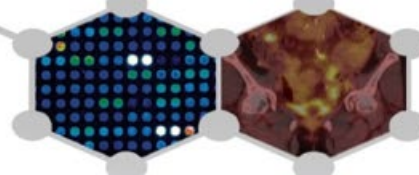

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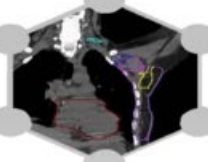

Questions?

UNIVERSITY OF MIAMI

MICHIGAN STATE UNIVERSITY

THE UNIVERSITY OF ARIZONA