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NRG-CC012CD "SYMON"

Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment

March 2025

Practice Personnel Update

Presenters:

Dr. Alla Sikorskii, 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).

Study Team

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

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See protocol for complete contact details

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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 **intervention delivery.**	**Jamillah Gross-Caldwell, MSU** 517-353-6534 **Grey Freylersythe, UMiami** 305-243-9832 **Shared Inbox:** symon@miami.edu

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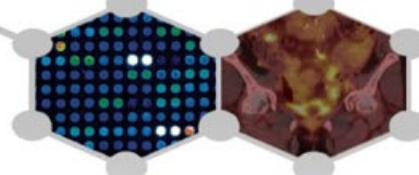
See protocol for complete contact details



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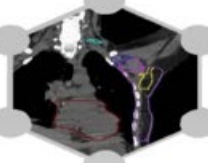

Study Updates

Protocol Amendment

Anticipated next month – minor changes to improve recruitment feasibility and eligibility

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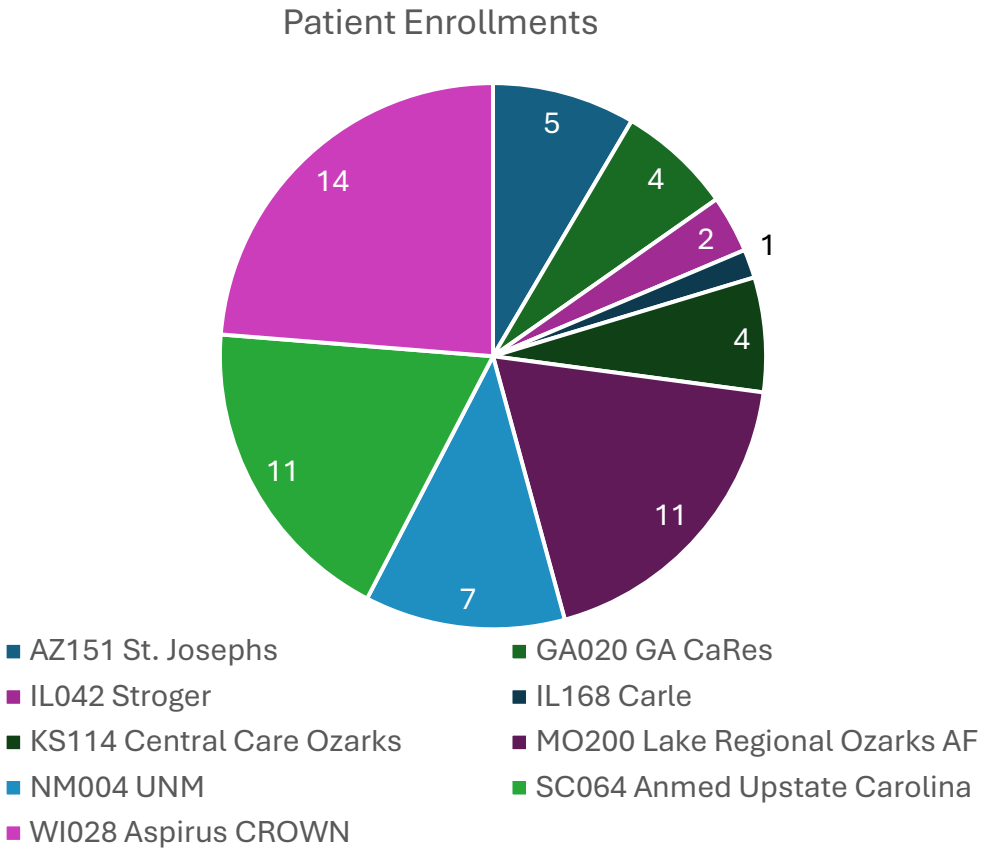
Progress

- Opened to patient accrual 10/4/2024
  - N=62 patients enrolled (3/20/25)
- 13 sites enrolled
  - 1 replacement site
  - 9 sites enrolling patients
  - 12 sites enrolling practice personnel n=38 (3/20/25)



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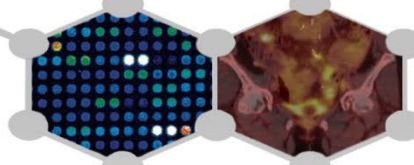

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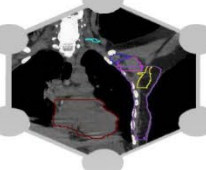

Brief Study Overview

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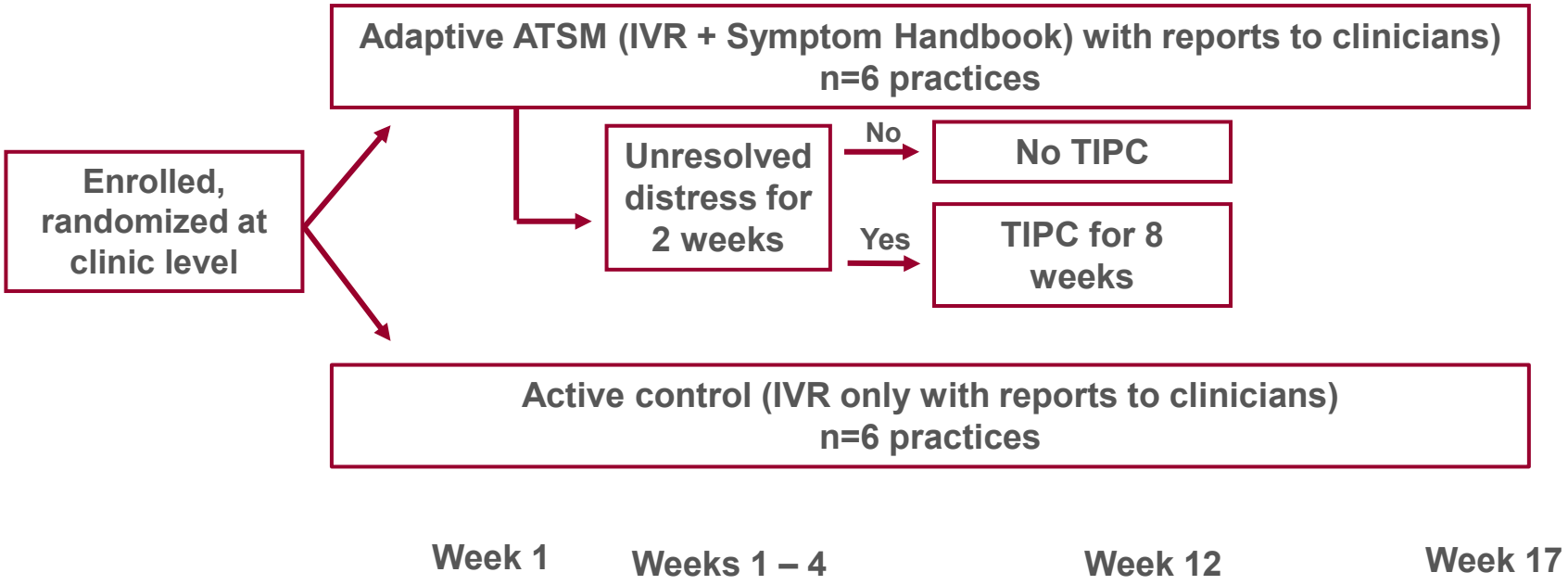
Participant Intervention



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

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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Key Recruitment Notes

- Patients will participate for 17 weeks
- Patients will:
  - Receive 3 phone calls for interviews by study staff (baseline, week 13, and week 17)
  - Receive weekly *automated* phone calls for all 17 weeks to report their symptoms using their keypad

- Some patients may also receive TIPC with a behavioral health specialist for 8 weeks if:
  1) they are enrolled by an ATSM+IVR site and
  2) they report elevated emotional distress for two consecutive weeks in the first 4 weeks of the study

- Calls will be coming from: 888-602-8325 (Caller ID: MWR UMIAMI SYLV)

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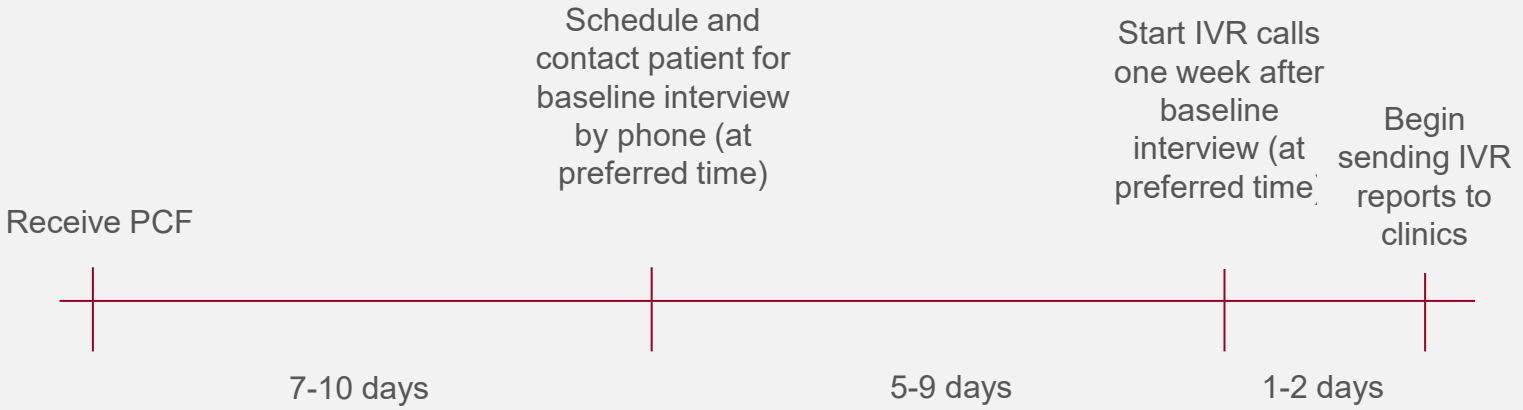
What happens between patient enrollment and beginning to receive IVR reports each week for your patients?



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Monthly FAQs

- **Does a drug need to be on the list in CTSU for the patient to be eligible?**
  - No! If you're not sure if the drug is eligible, don't hesitate to reach out to confirm, but no need to wait for it to be added to the official list.

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FAQ - continued

- **End of Study Date**
  - You will receive an email notification when the participant finishes their week 17 interview.
    - For the Patient History form, you should report the Week 17 interview date. If the week 17 interview is missed, then report the date of last contact for Week 17.
    - For the End of study form, you should use the date of last contact or date of week 17 interview, whichever is later.
  - For both forms, if the patient is unable to be contacted and the interview is missed, simply report the expected end date of study participation (the end of Week 17).

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Learn More

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

SYMON@miami.edu

- **Resources**
  - General information:
    - www.craneresearchlab.org/cc012cd
      - Monthly Update slides will be posted here after each monthly meeting
      - Sample recording of symptom monitoring call uploaded now
    - 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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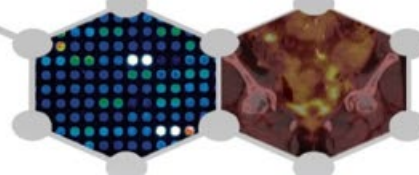

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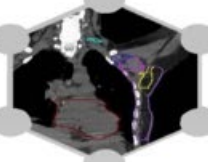

Questions?

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THE UNIVERSITY OF ARIZONA