# URCC22053 NEWSLETTER

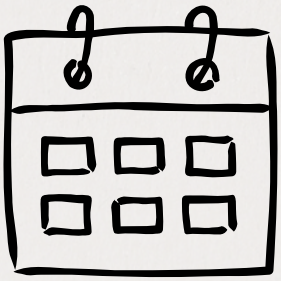
URCC_22053@URMC.ROCHESTER.EDU

## NCORP SPOTLIGHT

Top Recruiters from December:

**SCOR - 3**

**Upstate Carolina - 2**



## UPCOMING EVENTS

**ViPER Webinar**

January 07, 2026

Join our ViPER Webinar to chat with the study team, and get any clarifications! Bring your questions, or email them in advance to the study inbox.

**URCC Holiday Closure**

January 19, 2026

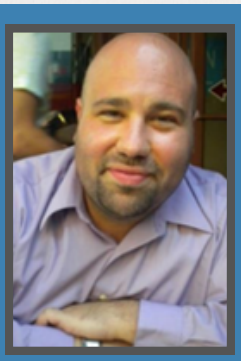
URCC Research Base will be closed in observance of Martin Luther King Jr. Day, shipments and emails may be delayed.

VIPER

## STUDY REMINDERS & UPDATES

- **Screening REDCap:**
  - Be sure to complete a screening entry for every participant screened for ViPER!
- **Project Manager Handoff**
  - Brooke Beauchemin has returned from maternity leave, and will resume her role as study PM.

## Message from the PI



Happy New Year! I hope everyone had a restful and enjoyable holiday break. As we start the new year, this is a great moment to re-energize and thoughtfully ramp up our accrual efforts. We now have about one year left in our grant accrual period, and every participant enrolled meaningfully contributes to the success of ViPER and to improving care for our patients.

Thank you for everything you are already doing: screening, following up, coordinating workflows, and troubleshooting challenges. These steady, consistent efforts truly add up.

I am also beginning to make in-person site visits. I'm happy to come meet with your team to review workflows, problem-solve barriers, and support sites that are interested in opening or starting up the protocol. Please reach out to the study inbox if a visit would be helpful — I'm glad to support however I can.

Thanks again for your partnership and dedication to ViPER!

Amendment Feature

# Protocol Amendment V 3.0

**Eligibility Criteria Widened**

^ Age to 50
^ ADT Initiation to 6 mo.
^ Vitamin D range to 10 - 32 ng/mL
V Sample size to 240
V Blood Draws; Safety draws only

**Other Changes**

DXA data transfer
TRIAD, Poweshare, or Box

***All changes approved by CIRB and reflects in the revised protocol, consents, and study materials***

## Recruitment Tips

- **Target appropriate clinics**
  - Many patients begin their ADT treatment under Urology clinics or are prescribed ADT by radiation oncologists.
  - Be sure to review these schedules / any searches available utilizing these locations and doctors.
- **EMR queries**
  - Reach out to your local EMR team, they should have training available to assist you in creating queries to pull reports that will provide you with potential participants.
- **Outreach**
  - Having APPs or research nurses reach out to clinics and regional urology groups may create new networking connections, and provide an additional source of referrals.
  - Provide clinics with outreach materials, so they are informed of the study and its requirements.

Recruitment Activity Center

## Current Accrual

36%

86 enrolled of 240

***If you would like a site visit from the PI - please reach out to the study inbox!***

# Get Involved!

Interested in opening ViPER at your site? Follow the below short checklist, or reach out to the study inbox!

- Self-Train via URCC NCORP website
- Review Documents
- Procure Training Certificate
- Obtain URMC REDCap Project Access
- Request Supplies
- Receive DXA & DXA Tech Certificates

## Start Recruiting!

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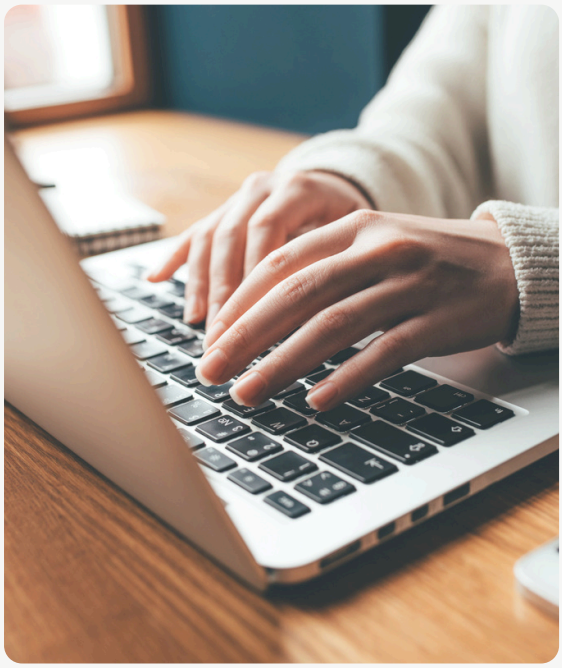
Inside the Protocol

# Know the Basics: Definitions

**HELP! To many research terms!**

- **Adverse Event (AE)**
  - Any unfavorable medical occurrence that happens during the study, regardless of its relation to study participation.
- **Attribution**
  - Assessment of the relationship between the AE and study agent/ intervention.
  - Unrelated, Unlikely, Possible, Probable, or Definite
- **Serious Adverse Event (SAE)**
  - Any adverse event that results in death, is life-threatening, requires or prolongs hospitalization, causes significant disability, results in a congenital anomaly, or requires medical intervention to prevent these outcomes.



***Section 12.0 of the protocol contains more detail.***

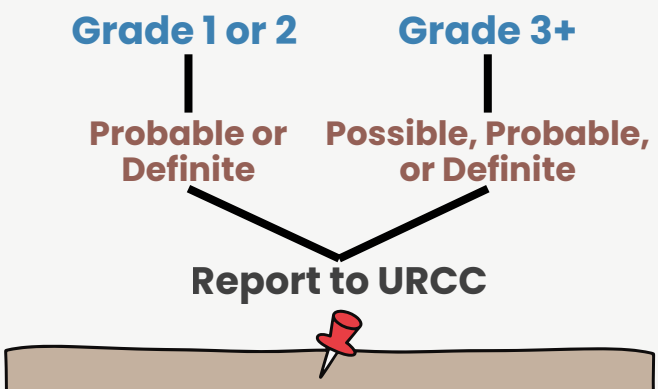
## When to Report to URCC?

- **Need a quick answer?** Use the decision tree on the right to help!
- Refer to the AE table in **section 12.4** for a more concise overview on when to report AEs to URCC.
- Reporting is completed through the Adverse Event REDCap form.

## Expedited Reporting...

- Carried out through CTEP-AERs
- Criteria are fully detailed in **section 12.5** of the protocol and must be reviewed in full.

AE Decision Tree




## Note on SAEs:

SAEs are reported to URCC if they are directly related to the study!

**Reach out to the study inbox if clarification is needed!**