



## Randomized Trial to Prevent Vascular Events in HIV

### Site Newsletter 02/27/2017

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### REPRIEVE Trial Status: February 27th

**2871** participants are enrolled

**232** participants are in screening

**108** sites are open for enrollment

**29** sites have enrolled at least 1 participant in the past week

**33** sites have screened at least 1 participant in the past week

### REPRIEVE Announcements



As April approaches, **don't forget our important goal of reaching 50% of REPRIEVE's total enrollment.**

Less than 500 participants need to be enrolled to reach this goal, if at least 50 participants are enrolled each week we will reach this major milestone by mid-April!

**Welcome!!!**

**A warm welcome to the newest site open for enrollment**

Durban International Clinical Research Site

## Thank You to REPRIEVE Super Sites!

**These sites are enrolling at least 10 participants per month**

Family Clinical Research Unit

WITS Helen Joseph Hospital CRS

Instituto de Pesquisa Clinica Evendor Chagas

Soweto

Thai Red Cross AIDS Research Center

School of Medicine, Federal University of Minas Gerais CRS

## Thank You to All Sites Enrolling Participants Week of 02/20/2017!

Massachusetts General Hospital (MGH) CRS

Boston Medical Center

Johns Hopkins University CRS

UCLA CARE Center CRS

UCSF HIV/AIDS CRS

Cincinnati CRS

Case CRS

Chapel Hill CRS

Puerto Rico AIDS Clinical Trials Unit CRS

The Ponce de Leon Ctr. CRS

University of Colorado Hospital CRS

Family Clinical Research Unit

Wits Helen Joseph Hospital CRS (Wits HJH CRS)

Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS

SOWETO

Gaborone CRS

Columbia Physicians and Surgeons CRS

UIC Project WISH CRS

Orlando Immunology Center CRS

University of Cape Town Lung Institute

Thai Red Cross AIDS Research Center

Kinder Medical Group

UT Southwestern

Mount Sinai Downtown CRS

Mount Sinai St. Luke's CRS

Postive Health Clinic

Eisenhower Health Center at Rimrock

Abbott Northwestern Hospital

Inova Heart and Vascular Institute



**Q. A participant came in for their 12 month visit and reported they are taking fish oil. How do I proceed?**

- Fish oil/omega 3 is not exclusionary at entry nor is it prohibited or precautionary during study participation.
- Please document use on the Medications Log.

**Q. We recently discovered that a participant is incarcerated. How do we proceed?**

- Keep trying to get in touch with the participant on a regular basis.
- If the participant has remained incarcerated, keep reporting the missed visits at the time points noted in the protocol until one year has passed.
- If one year has passed and the participant is still incarcerated/missing, inform the protocol team and consult the REPRIEVE site PI to see whether or not she/he would like to keep the participant in the study.

**The REPRIEVE (A5332) MOPS provides guidance on this topic:**

**Incarceration/involuntary confinement**

If a participant returns to care after incarceration/involuntary confinement and would like to resume study participation, it is at the discretion of the site PI whether or not to allow the participant to resume study participation. That individual will be required to provide written informed consent at time of re-entry into the study.

NOTE: No study procedures may be completed and no study medications may be dispensed while the participant is incarcerated.

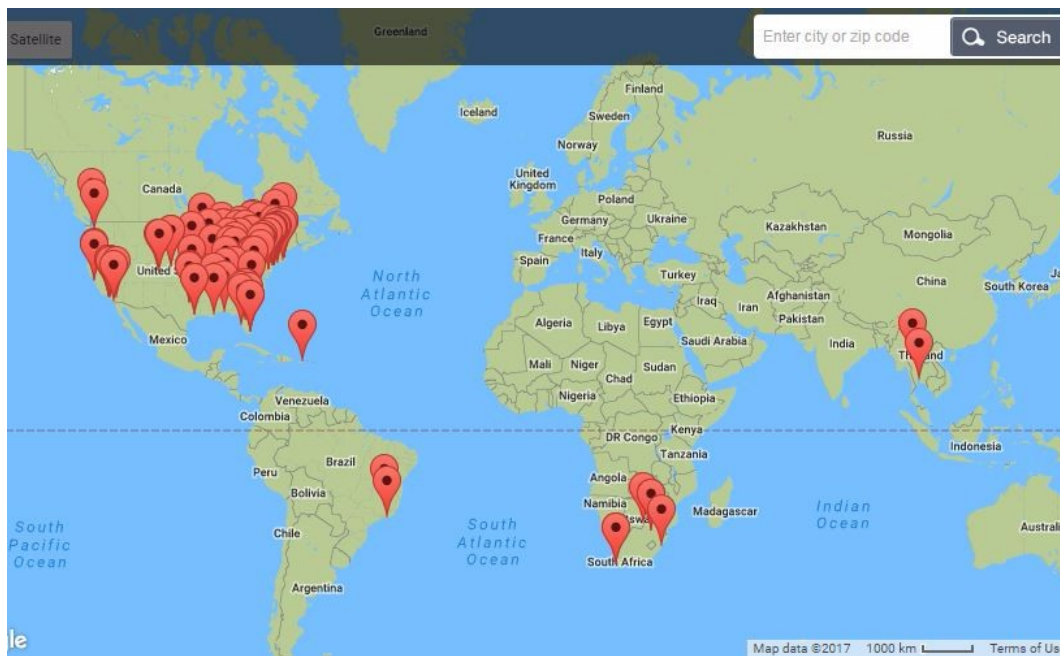
**Return to care**

If a participant returns to care after >1 year and would like to resume study participation, it is at the discretion of the site PI whether or not to discontinue the subject from study participation.

**Is Your REPRIEVE Contact Info Correct?**

The site map on the REPRIEVE website is updated every few months, but sometimes the CRS coordinator is not always the REPRIEVE coordinator, or coordinators have changed and we have not received the updated information.

To ensure that the right person and phone number is listed, please [click this link](#) and locate your site. If there are any updates or corrections required, please email Laura Sanchez at [lsanchez12@partners.org](mailto:lsanchez12@partners.org) with the correct info.



**Check Out the Latest REPRIEVE Video**

A Conversation About REPRIEVE at the UW ACTU featuring REPRIEVE volunteers and Dr. Carl Dieffenbach, the Director of the Division of AIDS, NIAID.

**RECRUITMENT**

**Read About the University of Cincinnati's Approach to Enrollment**

•According to the team at UC, this approach has been superior to giving providers lists of names, talking with providers one on one, and even giving presentations.

### •UC's approach:

- Accrual goal is set for each month – 3 participants.
- Query is done every 2 weeks for upcoming appointments. [Click here](#) for instructions on how to do this in Epic.
- Research nurses review query and confirm potentially eligible participants.
- Send Epic message on day of visit to their doctor indicating that one or more of their patients are eligible (by name and MRN).
- IRB-approved printed material is put in sealed envelope with the patient's name on it. This invites them to think about REPRIEVE and talk with their doctor or call us.
- Research nurses make contact when the participant is there to give them a copy of the consent and arrange follow up if they are interested. For some we call them in follow up.

**This will be discussed in more detail during the Monthly Site Call on Tuesday, March 21st at 1:00 PM ET, so please join us!**



## Investigator's Meeting at CROI

Thank you to everyone who was able to join the REPRIEVE Investigator's Meeting at CROI 2017, over 75 people attended this event!

If you were unable to attend, [click here](#) to download the slides for the meeting, and also [click here](#) to download the slides from Dr. Heidi Crane's keynote presentation on Type 1 and Type 2 MIs in the setting of HIV.

## REPRIEVE in the News



### REPRIEVE was recently featured in:

- **Vital Updates**, [Campaign Launched to Get More Women into HIV Heart Health Study](#). Author David Heitz features REPRIEVE's unique Follow YOUR Heart Campaign led by Drs. Sara Looby and Markella Zanni.
- **Blog.aids.gov**, [This February Take Heart: NIH is Committed to Preventing HIV-Related Heart Attacks and Strokes](#). A recent blog by Dr. Carl Dieffenbach, Director of DAIDS, NIAID.

**REPRIEVE (A5332): Are you up to date?**

*For A5332 please use*

**Protocol:**

Version 3.0 dated 01/28/2016

Clarification Memo #1 dated 04/04/2016

Clarification Memo #2 dated 04/12/2016 (corrects an error in CM #1)

Clarification Memo #3 dated 12/27/2016

Letter of Amendment, Version 3.0 #1 dated 08/17/16

**MOPS:**

Version 3.0, revision 1, dated 09/09/16, **watch your email, an updated version will be distributed to the field very soon!**

**A5332 LPC for ACTG Sites:**

Version 3.0 dated 01/04/2017

**A5332 LPC for Non-ACTG Sites:**

Version 3.0 dated 01/04/2017

These documents are on the [A5332 PSWP](#)

## REPRIEVE Mechanistic Substudy (A5333s): Are you up to date?

**For A5333s please use****Protocol:** Version 3.0 dated 01/28/2016**MOPS:** Version 3.0 dated 09/02/2016**A5333s LPC :** Version 3.0 dated 01/04/2017

These documents are on the [A5333s PSWP](#)

### For future reference, all newsletters are available on the [REPRIEVE Website](#)

We welcome suggestions and ideas for upcoming newsletters. Please submit any comments or suggestions to the REPRIEVE News Team at [reprieve.news@fstf.org](mailto:reprieve.news@fstf.org).



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