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Randomized Trial to Prevent Vascular Events in HIV

Trial Status

January 28th, 2019

7464 participants are enrolled26 participants enrolled in the past week109 participants are in screening

116 sites are open for enrollment

16 sites enrolled at least 1 participant in the past week

19 sites screened at least 1 participant in the past week

Thank you for the excellent effort that all teams are putting forth to enroll participants in REPRIEVE.

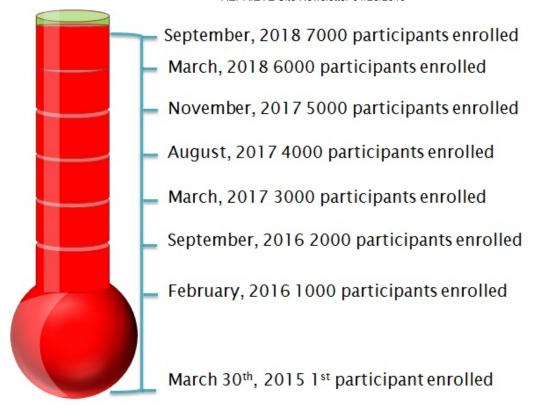
Enrollment is Approaching 7500!!!

The REPRIEVE enrollment thermometer has been taken out of retirement to show you how far we have come and how close we are to our target!

We are so pleased that enrollment is quickly approaching 7500 participants and we appreciate every effort to screen and enroll participants to achieve our target enrollment.

Watch for emails about closure to screening as well as the date of closure to accrual.

Be aware, enrollment cannot exceed 7575 participants.



Thank You to All Sites That Enrolled At Least 1 Participant in the Past Week!

UCLA CARE Center CRS

Cincinnati CRS
Barranco CRS
San Miguel CRS
SOWETO
Joint Clinical Research Centre (JCRC)/Kampala CRS
Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS
Parirenyatwa CRS
GHESKIO Institute of Infectious Diseases and Reproductive Health
University of Rochester Adult HIV Therapeutic Network CRS
Thai Red Cross AIDS Research Center
Drexel University
Vancouver ID Research and Care Centre Society
Toronto General Hospital

Tufts Medical Center Tropical Medicine Foundation



Don't forget, we are in our final push to the finish line! The REPRIEVE Leadership Team wants to recognize the *extra* effort and cost of recruiting these final participants.

We have been keeping track of enrollment since September 10th and will continue until the enrollment of the 7500th participant!

The top 3 enrolling sites over the course of the challenge, will receive \$1000 USD, \$750 USD, or \$500 USD respectively for the extra effort to enroll.

Any site that enrolls more than 5 participants during the course of the campaign will receive 100 USD.

Check out the current standings below!

Standing	Site Name and Number	Participants Enrolled Since 9/10/18
1 st Place	Parirenyatwa CRS 30313	61
2 nd Place	Thai Red Cross AIDS Research Center Site 31802	27
3 rd Place	Durban International CRS 11201	25
4 th Place	BJMC CRS 31441	24
5th Place	Joint Clinical Research Centre (JCRC)/Kampala CRS 12401	22

Keep up the great work!!

DSMB Summary Report

Don't forget to forward the DSMB summary report to your Institutional Review Board (IRB)/Ethics Committee (EC)!

If you missed the email with the DSMB summary, the summary is available on the REPRIEVE (A5332) protocol website under Study Monitoring (NHLBI DSMB Reports).

It is recommended that everyone use discretion in sharing the summary with others, since technical language may be subject to misinterpretation.





When: Wednesday, March 6th 12:00-1:15 PM Where: Grand Hyatt, 721 Pine St, Seattle, WA

This meeting will be an excellent opportunity to meet with the REPRIEVE team and to celebrate our recent successes!

If you are planning on attending CROI <u>click here</u> to register for the Investigator's Meeting by Friday, February 22nd.



A Note About ECG Machines

Once enrollment is complete the REPRIEVE CCC will be reaching out to sites to return their ECG machine. In anticipation of this <u>please do the following</u>:

- 1. Make sure your site has transmitted all ECGs to IQVIA.
- 2. Confirm the original ECG tracings are available in participant files.

Expectations of sites prior to shipping:

- Sites are expected to pack the ECG machine and accessories in the original box including all accessories (cables and power cord).
- Sites are not expected to return unused electrodes or paper.
- Sites need to return the device to the equipment warehouse as per instructions that will be provided.

The ACTG Leadership and Operations Center (LOC) has moved from Brigham and Women's Hospital (BWH) to University of California, Los Angeles (UCLA) as of December 1st, 2018.

Please know that REPRIEVE operations will remain at Massachusetts General Hospital (MGH), and payments will continue to be made from MGH. Below is a detailed table that both ACTG and REPRIEVE sites can reference for PI and contact information for their respective studies.

	Enrollment Status	Network	PI(s)	Contact Email
REPRIEVE (A5332) (U01HL123336)	Enrolling	ACTG* /REPRIEVE	Steven Grinspoon, MD, Pamela	REPRIEVE.finance@mgh.harvard.edu
Mechanistic Substudy of REPRIEVE (A5333s) (U01HL123336)	Closed to enrollment	ACTG	Douglas, MD, Udo Hoffmann, MD, Heather Ribaudo, PhD	REPRIEVE.finance@mgh.harvard.edu
Women's Ancillary Objective (R01AI123001)	Enrolling	ACTG /REPRIEVE	Markella Zanni, MD and Sara Looby, PhD	REPRIEVE.finance@mgh.harvard.edu
PREPARE (A5361s) (R01AG054366)	Closed to enrollment	ACTG	Kristine Erlandson, MD and Todd Brown, MD	Kristine.Erlandson@ucdenver.edu
Kidney Ancillary Objective (R01DK108438)	Closed to enrollment	ACTG	Turner Overton, MD	eoverton@uabmc.edu

^{*}Only applies to ACTG sites. Supplement # 1 (\$500/per participant enrolled): Sites were previously paid by the BWH LOC through their current existing ACTG PF contracts up until 11/30/18. As of 12/01/18, UCLA will disperse this supplement. Contact Meg Robles at MMRobles@mednet.ucla.edu for any payment related questions.



Save the Date! Tuesday, February 19th, 2019 1:00 - 2:00 PM ET

For the February Monthly Site Call!

Watch for the email announcement with more details.

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 4.0 dated 03/28/2018

V4.0 LOA #1 dated 05/16/2018

MOPS Version 4.0 dated 10/16/18

A5332 LPC for ACTG Sites Version 4.0 dated 03/22/2018

A5332 LPC for Non-ACTG Sites Version 4.0 dated 07/23/2018

These documents are on the A5332 PSWP

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

For A5333s please use
Protocol Version 4.0 dated 03/28/2018
MOPS Version 4.0 dated 04/10/2018
A5333s LPC Version 4.0 dated 03/23/2018
These documents are on the A5333s PSWP

For future reference, all newsletters are available on the REPRIEVE Website.

We welcome ideas and suggestions for future newsletters. Please submit any comments or suggestions to the REPRIEVE News team at reprieve.news@fstrf.org







REPRIEVE Trial Clinical Coordinating Center

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Our mailing address is: reprieve.news@fstrf.org

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