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Randomized Trial to Prevent Vascular Events in HIV

Trial Status

November 26th, 2018

7257 participants are enrolled

18 participants enrolled in the past week

212 participants are in screening

116 sites are open for enrollment

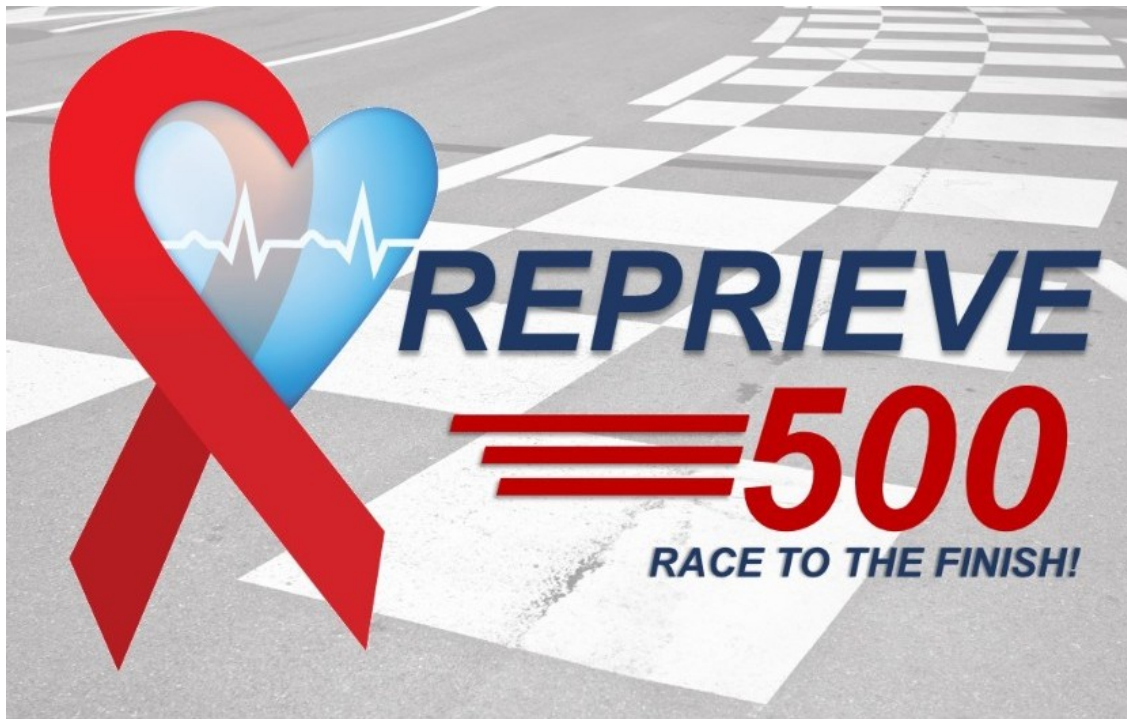
10 sites enrolled at least 1 participant in the past week

14 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.

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

University of Pittsburgh CRS
San Miguel CRS
SOWETO
Joint Clinical Research Centre (JCRC)/Kampala CRS
Parirenyatwa CRS
University of Cape Town Lung Institute
Thai Red Cross AIDS Research Center
HGNI HIV Family Care Clinic HHFCC
Tropical Medicine Foundation
Centro de Referencia e Treinamento



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 | 37 |
| 2 nd Place | Durban International CRS 11201 | 17 |
| 3 rd Place | HGNI HIV Family Care Clinic Site 31927 | 15 |
| 4 th Place (Tied) | Thai Red Cross AIDS Research Center Site 31802 | 11 |
| 4 th Place (Tied) | Joint Clinical Research Centre (JCRC)/Kampala CRS 12401 | 11 |
| 5 th Place | Tropical Medicine Foundation CRS 31946 | 9 |

Keep up the great work!!

Enrollment is Approaching 7500!

The REPRIEVE Leadership Team has developed a closure to enrollment plan so that all sites are aware of current enrollment numbers and the plan to close out enrollment as we approach our target accrual.

How this will work:

- REPRIEVE Leadership will immediately notify all sites when enrollment reaches approximately 7350 participants (anticipated around January 2019); this will serve as a notice that closure to screening will occur shortly.
- REPRIEVE Leadership will monitor enrollments and screening carefully, communicating frequently with sites, and will make a formal announcement regarding specific timing of screen closures shortly after enrollment of 7350 participants.
- After the closure of screening, enrollment of participants in screening must be completed within 45 days from the date of the announcement and not exceed the protocol defined screening period.

Sites will be notified of all the above communications via:

Direct email
Site Newsletter
Monthly Team-Site Call



Don't Forget: World AIDS Day is December 1st!

In addition to being a day to unite in the fight against HIV and show support for people living with HIV, it is also a great opportunity to recognize the great strides made in HIV treatment and **Saturday, December 1st!** on World AIDS Day Join us in recognizing research, and highlight the work your REPRIEVE teams and trial participants are doing.

You can show your support by organizing an event at your site, wearing an HIV awareness red ribbon, or by using [#WAD2018](#) on your social media platforms. [Click here](#) to visit the REPRIEVE Outreach Toolkit and select the "Social Media Messages" form for examples of messages you can use to promote REPRIEVE and HIV research on your social media platforms.

To learn more about World AIDS Day and how you can get involved [click here](#).



A5332 MOPS Version 4.0 (dated 16 Oct 2018) Updates!

[New Content Includes:](#)

Section 4.6 Inadvertent Enrollment Prior to Entry Visit

[Updated Content Includes:](#)

Section 4.3 Missed Visits

Web Links and Email Addresses have also been updated.

Please make sure you are using the most up to date version of the A5332 MOPS!



Retention Champion Results!

Thank you to all sites who participated in the Retention Champion Initiative! Members of the REPRIEVE CCC spoke with *over 50 sites* to learn about what sites are currently doing to promote retention in REPRIEVE, what are some common retention barriers sites are facing, and how WE can help sites promote retention in REPRIEVE!

We are excited to share the preliminary results below!

| SITE-IDENTIFIED BARRIERS to RETENTION | SITE-IDENTIFIED RESPONSES | TEAM RESPONSES |
|--|--|--|
| <u>Duration of trial</u> | <ul style="list-style-type: none"> Visit scheduling flexibility Coordinate study visits with clinic visits | ✓ Visit schedule template and visit calendar are posted on PSWP |
| <u>Remuneration</u> | <ul style="list-style-type: none"> Pay for transportation Pay for meals | ✓ Provision of additional funds, supplement to be reflected in 2019-2020 contracts to enable |
| SITE-IDENTIFIED PROMOTION STRATEGIES | | TEAM RESPONSES |
| <ul style="list-style-type: none"> Strategize retention of participants at risk of LTFU during designated local Site Team Meeting Discuss retention strategies at Local Site Team Meetings | | ✓ CCC supports Team Meeting efforts, thank you! |
| Distribute Participant Newsletter | | ✓ CCC develops Participant Newsletter annually! ➤ available on the PSWP or, ➤ email ekileel@partners.org to obtain hard copies |
| Provide thank you cards, birthday cards, pens, or other small tokens of appreciation | | <ul style="list-style-type: none"> Tokens can be requested from CCC! pens, magnet calendars, and bracelets <ul style="list-style-type: none"> ➤ email ekileel@partners.org Provision of tokens by local site utilizing 2019-2020 supplement |

To view distributions of site responses and more results [click here!](#)



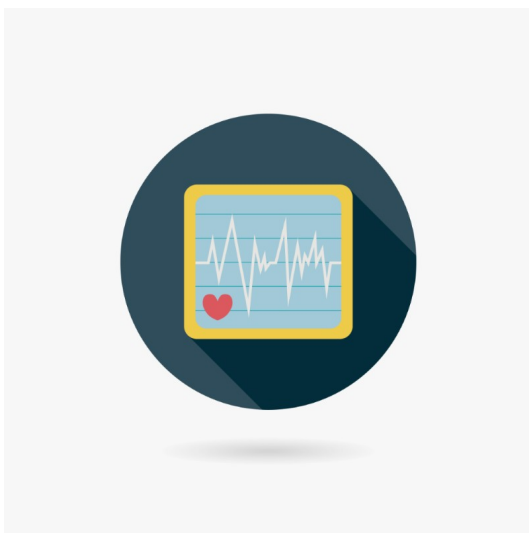
Seeking Additional REPRIEVE Community Advisory Board Members!

As follow-up for REPRIEVE continues it is important that we make sure participants feel involved and that their voices are heard. The purpose of the REPRIEVE Community Advisory Board (CAB), ongoing since 2016, is to ensure that community concerns and suggestions are brought to the attention of trial investigators and carefully considered.

The REPRIEVE Clinical Coordinating Center (CCC) is seeking additional REPRIEVE participants interested in serving on the REPRIEVE CAB.

Members of the REPRIEVE CAB receive important trial updates on a monthly basis via email and meet quarterly via teleconference.

If you have participants who may be interested, please have them contact Emma Kileel at ekileel@partners.org.



A Message About ECG Machines

The REPRIEVE Clinical Coordinating Center (CCC) is beginning to collect ECG machines from sites that are no longer enrolling participants. If you do not anticipate enrolling any additional participants into REPRIEVE please contact Emma Kileel at ekileel@partners.org to initiate the return of your site's ECG machine.



For Sites Participating in A5333s: Check PaxGene Tube Expiration Dates & Quantity

Please check your PaxGene tube expiration dates and quantity on site to ensure you have enough on hand for any end of December/first of January visits. PaxGene tubes requested between December 21st and January 2nd will be responded to on January 3rd.

To order additional PaxGene tubes please email reprievesupplies@partners.org

Save the Date!
Tuesday, December 18th 2018
1:00 – 2:00 PM ET

For the next monthly site call!



Watch for the email announcement with more details about the call.

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



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