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# REPRIEVE

## Randomized Trial to Prevent Vascular Events in HIV

### Trial Status

January 14th, 2019

**7417** participants are enrolled

**18** participants enrolled in the past week

**123** participants are in screening

**116** sites are open for enrollment

**14** 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.

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

Massachusetts General Hospital (MGH) CRS

University of Pittsburgh CRS

Case CRS

University of Colorado Hospital CRS

Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS

Joint Clinical Research Centre (JCRC)/Kampala CRS

Thai Red Cross AIDS Research Center

Baystate Infectious Diseases Clinical Research

UT Southwestern

Vancouver ID Research and Care Centre Society

Positive Health Clinic

U of Miami Infectious Disease Research Unit Jackson Memorial Hosp

HGNI HIV Family Care Clinic HHFCC

Tropical Medicine Foundation

**DID YOU KNOW?  
Additional Screening Slots Are Available!**

Due to fluctuations in the number of participants pending enrollment over the



holidays, there are approximately 100 additional screening slots available that will be filled on a first come, first serve basis.

Participants can be registered to the REPRIEVE screening study, RS1001, for A5332 until the required number of screening slots have been filled.

For these additional screens, please make every effort to screen individuals as soon as possible who will likely qualify and enroll in the study. If the individual is a screen fail, complete and enter the screening failure form as soon as possible.

For any participants who are pending enrollment, the date to complete enrollment will be adjusted and depends on when closure to screening occurs; therefore, we will keep you updated once the additional screens are complete.

**Please be aware, enrollment cannot exceed 7575 participants.**



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 <sup>st</sup> Place	Parirenyatwa CRS 30313	54
2 <sup>nd</sup> Place	BJMC CRS 31441	24
3 <sup>rd</sup> Place	Durban International CRS 11201	23
4 <sup>th</sup> Place (tied)	HGNI HIV family Care Clinic CRS 31927	21
4 <sup>th</sup> Place (tied)	Joint Clinical Research Centre (JCRC)/Kampala CRS 12401	21
4 <sup>th</sup> Place (tied)	Thai Red Cross AIDS Research Center Site 31802	21

**Keep up the great work!!**



**Q:** I am located at a US REPRIEVE site, as part of our Continuing Review process, the IRB requested changes to the consent due to the Common Rule. Will the study team be updating the ICF to incorporate the new requirements?

**A:** Only studies approved by an IRB on or after January 21, 2019 are governed by the Common Rule. Amendments to ongoing research studies that received initial IRB approval prior to January 21st do *not* need to include new sections in the consent required by the revised rule.

### Mechanistic Substudy of REPRIEVE (A5333s)

**Q:** We have a participant whose CrCl/eGFR fluctuates and always hovers around 60 mL/min using the Cockcroft Gault calculator. I want to ensure that he is able to complete the month 24 CCTA if possible. Do you have any advice?

**A:** Any creatinine-based calculator can be used to obtain creatinine clearance or GFR. The calculators recommended are:

- CKD-Epi Equation

- MDRD Study Equation
- Cockcroft Gault

We also suggest the following:

- Make sure participants are well hydrated for several days prior to the CCTA.
- Participants should avoid diuretic agents (Lasix, HCTZ, alcohol or caffeine) prior to the CCTA.
- Ensure that the weight obtained is accurate.
- Ensure that participants are not on medications that affect kidney function such as NSAIDs or Bactrim (holding these medications, if indicated, for 1 week prior to the CCTA may be helpful).



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

The invite will go out to Site PIs next week. If you are not a Site PI but are planning on attending CROI please email [kfitch@partners.org](mailto:kfitch@partners.org) to be added to the invite.



## 2019 Goal = Retention!

By maintaining high retention we will be able to ensure the overall success and scientific merit of REPRIEVE.

High rates of retention will:

- prevent bias so that REPRIEVE's results represent the true treatment effect.
- allow for REPRIEVE's results to be generalizable to the HIV community.
- will permit statistical validity by maintaining the power to detect the true differences between treatments.

Complete follow-up visits and evaluations are essential to the success of  
REPRIEVE!

## NEW My Heart Matters Blog by Follow YOUR Heart!



<http://followyourheart.reprievetrial.org/news/>

Join the Study > Women's Health Info Printable Advertisement Materials **My Heart Matters: Blog**

The REPRIEVE **Follow YOUR Heart Campaign** invites you to read the latest *My Heart Matters Blog*, [Vaping and E-Cigarettes: How do they affect my heart health?](#) This post helps to answer what vaping is, what are the risks, and does vaping really help people quit smoking?



### NEW: REPRIEVE Finance Department

If you have a financial question related to  
REPRIEVE please email  
[REPRIEVE.finance@mgh.harvard.edu](mailto:REPRIEVE.finance@mgh.harvard.edu).



### 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 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 [reprise.news@fstrf.org](mailto:reprise.news@fstrf.org)*



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