REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

# Site Newsletter 03/27/2017

## Table of Contents



# REPRIEVE Trial Status: March 27th

**3031** participants are enrolled

**260** participants are in screening

**102** sites are open for enrollment

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

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

# REPRIEVE Announcements


## participants are enrolled in REPRIEVE!

On Wednesday, March 22nd the 3,000th participant was enrolled in REPRIEVE! A big thank you to everyone who has worked so hard to help us reach 3,000! Also, a special thank you to the **University of Kentucky** team for enrolling the 2,999th participant and to the **Thai Red Cross AIDS Research Center** team for enrolling the 3,000th participant!!!

# REPRIEVE's Race to 50% Standings!

In order to win a prize, sites must enroll 4 or more participants from March 6 to April 28! Below are the sites that are close to 4 and already at 4!


**The current standings are as follows:**

| Enrolled 3 participants | |
|---|---|
| **Site #** | **Site Name** |
| 1504 | University of Iowa |
| 2101 | Washington University Therapeutics (WT) CRS |
| 2301 | Ohio State University CRS |
| 31787 | University of Rochester Adult HIV Therapeuitc Network CRS |
| 31792 | University of Cape Town Lung Institute |
| 31864 | UT Southwestern |
| 31879 | Mount Sinai Downtown CRS |
| 31915 | School of Medicine, Federal University of Minas Gerais CRS |

| Enrolled 4+ participants | |
|---|---|
| **Site #** | **Site Name** |
| 801 | UCSF HIV/AIDS CRS |
| 8950 | Family Clinical Research Unit |
| 11101 | Wits Helen Joseph Hospital CRS (Wits HJH CRS) |
| 12101 | Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS |
| 12701 | Gaborone CRS |
| 31784 | Chiang Mai University HIV Treatment CRS |
| 31802 | Thai Red Cross AIDS Research Center |

**As of March 27th, 219 participants need to be enrolled to reach the 50% enrolled milestone! If 50 participants are enrolled each week, we will reach this milestone by the end of April!**

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# Welcome!!!

## A warm welcome to the newest sites open for enrollment

**Fundação de Medicina Tropical, Manaus, Brazil**
**Hospital Federal dos Servidores do Estado, Rio de Janeiro, Brazil**

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## Thank You to All Sites Enrolling Participants Week of 03/20/2017!

Brigham and Women's Hospital Therapeutics CRS
Johns Hopkins University CRS
Harbor UCLA CRS
UCSF HIV/AIDS CRS

Ohio State University CRS
Case CRS
Northwestern University CRS
Family Clinical Research Unit
Wits Helen Joseph Hospital CRS (Wits HJH CRS)
Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS
Hospital Nossa Senhora da Conceicao CRS
Gaborone CRS
Denver Public Health
Houston AIDS Research Team CRS
Orlando Immunology Center CRS
University of Cape Town Lung Institute
Thai Red Cross AIDS Research Center
Drexel University
Yale University
UT Southwestern
Bluegrass Care Clinic/University of Kentucky Research FDN CRS
Mount Sinai Beth Israel CRS
HGNI HIV Family Care Clinic HHFCC


**Q: A participant had said they no longer want to be on study medication, so we completed all the requirements for the Premature Study Medication Visit to have the participant followed on-study/off-study medication. However, we have now re-engaged the participant and they would like to re-initiate study medication. How do we proceed?**

A: As per the note below, please make every effort to keep participants on study medication when possible. If a participant has to stop study medication the team is happy to have participants re-initiate study medication.

When the participant re-initiates study medication, contact the data management team at reprieve.dmc@fstrf.org and request that the RP0003 Final Study Medication Status CRF be removed. Then create a new entry on the TXW0295 Medication Log. Because the study medication discontinuation date is already in the TXW0295 Medication Log, and you will be entering the study medication re-initiation date, the team will be able to determine the total duration of study medication discontinuation.

**PLEASE NOTE:** The REPRIEVE (A5332) protocol, Section 8.0, has specific criteria to discontinue study medication. If you have a participant wishing to discontinue study medication that does not meet the criteria listed in the protocol, please have a conversation with your participant regarding their concerns and the importance of staying on study medication. Every effort should be made to keep participants on the study medication as long as it is determined safe to do so.

**Q: When I use the ASCVD calculator, I am finding some people have a total cholesterol and/or HDL too low or too high for the calculation.**

**When this occurs how should this be handled? Are they automatically excluded, or do we change the total cholesterol and/or HDL numbers to the lowest or highest number allowed to calculate the 10-year ASCVD risk score?**

A: There is guidance about this in the REPRIEVE (A5332) MOPS, in the Instructions for Calculators section:

For participants whose values of HDL cholesterol, total cholesterol, and/or systolic blood pressure fall below or above the acceptable calculator bounds for those parameters, values at the lower or upper bounds, respectively, will be entered.

## Important Update Regarding 10-year ASCVD Risk Calculator

It has come to our attention that the link below to calculate the 10-year ASCVD risk score is not working properly: https://my.americanheart.org/professional/GuidelinesStatements/PreventionGuidelines/UCM_457698_Prevention-Guidelines.jsp **(do not use, not working properly)**

Therefore, please use the direct link https://tools.acc.org/ASCVD-Risk-Estimator/ to calculate the 10-year ASCVD risk score.

It is very important that you use only the 10-Year ASCVD Risk Score results, not the "risk with optimal risk factors" and not the "Lifetime ASCVD Risk calculator"!

For more details about the ASCVD Tool used to calculate the 10-year ASCVD risk score, please refer to section 2.1 of the REPRIEVE (A5332) MOPS, Version 3.0 09/09/2016.


## HIGH RETENTION of REPRIEVE Participants is Essential!

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

- Retention will prevent bias so that REPRIEVE's results represent the true treatment effect.
- Retaining a high number of participants allows for REPRIEVE's results to be generalizable to the HIV community.
- High retention in REPRIEVE will permit statistical validity by maintaining the power to detect the true differences between treatments.

Retention strategies will be shared in future newsletters and on monthly site calls.

If your site has a successful retention strategy that you would like to share with other sites in a future newsletter or on a site call, please email Katie Fitch, MSN/Project Manager REPRIEVE CCC at kfitch@partners.org.

## Women Describe Best Methods for Learning About a Research Study

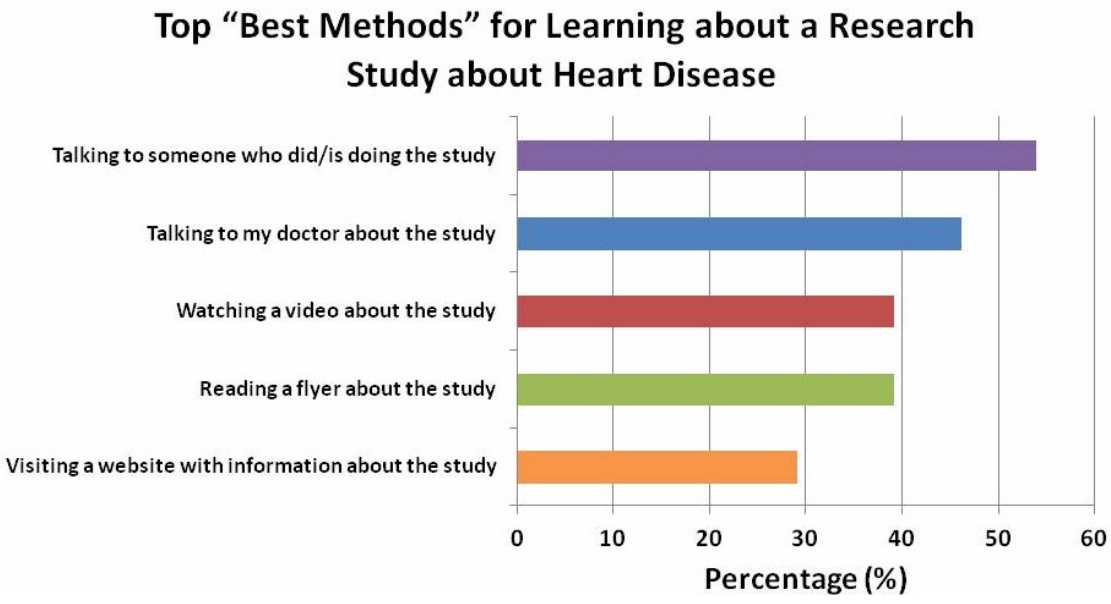
A recent publication details how the **REPRIEVE Follow YOUR Heart campaign** was developed with input from women from the community. The paper, published in ***HIV Clinical Trials***, is accessible by clicking here.

Top identified "best methods" for learning about a research study included: 1. Talking to someone who did/is doing the study, 2. Talking to my doctor about the study, and tied for 3rd place, Watching a video and reading a flyer about the study.

Are you using methods such as these to engage women with HIV about participating in research studies, like REPRIEVE?

Learn more about barriers and facilitators to research participation identified in this study, and how the **Follow YOUR Heart campaign** was developed! If you haven't visited the **Follow YOUR Heart** website, click here. There are lots of great resources about HIV, women and heart disease, including the **Follow YOUR Heart** video!

**Thank you for your ongoing support of REPRIEVE and the Follow YOUR Heart campaign.**



**Zanni, et al. Follow YOUR Heart: development of an evidence-based campaign empowering older women with HIV to participate in a large-scale cardiovascular disease prevention trial. HIV Clinical Trials 2017; 18 (2):83-91**

## The following content has been updated on the DAIDS RSC Website:

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**Clinical Research Sites – Protocol Registration – Forms:**
**The most current version of the DAIDS Investigator of Record (IoR) Form is posted.**

The DAIDS IoR Form has been updated as of March 3, 2017 to add the statement "I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug" to the Commitment section of the document.

Sites do not need to update the DAIDS IoR Form for existing submissions. However, if/when a new or updated DAIDS IoR Form is required, as of March 3, 2017 please use the updated version (version date of 3/2017) when completing this form.

The document can be viewed at: http://rsc.tech-res.com/clinical-research-sites/protocol-registration/form

Here is a link to the DAIDS RSC website: http://rsc.tech-res.com/

If you were linking directly to any file on the DAIDS RSC website, you will have to update your links since some files are archived and new files are renamed.

To view a list of recent updates to the website, go to http://rsc.tech-res.com/news/web-update-log.

# Have You Heard about the REPRIEVE Community Advisory Board?

- The REPRIEVE Clinical Coordinating Center (CCC) is seeking REPRIEVE participants interested in serving on a REPRIEVE Community Advisory Board (CAB).
- The purpose is to ensure that community concerns and suggestions are heard and carefully considered.
- The REPRIEVE CAB is currently being developed, meetings will likely take place quarterly via teleconference.

**If you have interested participants, please have them contact Katie Fitch, MSN/Project Manager REPRIEVE CCC at** kfitch@partners.org


## 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@fstrf.org.

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