



## Randomized Trial to Prevent Vascular Events in HIV

### Site Newsletter 01/22/2018

#### Table of Contents

- [REPRIEVE Trial Status](#)
- [Full Speed to 1500 Challenge Standings!](#)
- [Did you Miss the Last Monthly Site Call?](#)
- [Don't Forget to Transmit ECGs!\\*](#)
- [February 2018 is American Heart Month!](#)
- [Check Out the Retention Survey Results!](#)
- [WebLDMS for REPRIEVE Training Dates](#)
- [Save the Date! REPRIEVE Investigators' Meeting at CROI](#)
- [REPRIEVE \(A5332\): Are you up to date?](#)
- [REPRIEVE Mechanistic Substudy \(A5333s\): Are you up to date?](#)

## REPRIEVE Trial Status: January 22nd

**5552** participants are enrolled

**70** participants enrolled last week!

**383** participants are in screening

**118** sites are open for enrollment

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

**36** sites screened at least 1 participant in the past week

During the week of January 8th, **90 participants** were enrolled! This is an incredible accomplishment. Thank you for your excellent work!

## Substudy Updates

### Mechanistic Substudy of REPRIEVE (A5333s)

**776** participants are enrolled (only **24** participants left to enroll!)

**PREPARE Substudy (A5361s)**

**571** participants are enrolled (only **29** participants left to enroll!)

## Thank You to All Sites Enrolling Participants Week of 01/15/2018!

Johns Hopkins University CRS  
University of Washington AIDS CRS  
Washington University Therapeutics (WT) CRS  
Puerto Rico AIDS Clinical Trials Unit CRS  
Weill Cornell Uptown CRS  
Family Clinical Research Unit  
Barranco CRS  
Chennai Antiviral Research and Treatment (CART) CRS  
Joint Clinical Research Centre (JCRC)/Kampala CRS  
Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS  
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS  
Denver Public Health  
Houston AIDS Research Team CRS  
GHESKIO Institute of Infectious Diseases and Reproductive Health  
Chiang Mai University HIV Treatment CRS  
New Jersey Medical School-Clinical Research Ctr. CRS  
Whitman-Walker Health CRS  
Thai Red Cross AIDS Research Center  
UT Southwestern  
Mount Sinai Downtown CRS  
Mount Sinai Beth Israel CRS  
Chronic Viral Illness Service of McGill University  
Toronto General Hospital  
School of Medicine, Federal University of Minas Gerais CRS  
Instituto de Infectologia Emilio Ribas CRS  
Hospital Escola Sao Francisco de Assis  
HGNI HIV Family Care Clinic HHFCC  
Tropical Medicine Foundation  
Centro de Referencia e Treinamento



## Full Speed to 1500



### Full Speed to 1500 Challenge Standings!

We know you haven't forgotten that we need every site's help to **enroll 1500 participants between December 4th, 2017 and April 30th, 2018**. 429 participants have already been enrolled.

The goal is to enroll at least 15 participants per site through the last week in April.

#### Many sites will win!

- 1st place site wins \$500
- 2nd place site wins \$250
- All other sites that enroll 15 participants by May 1st will win \$100

**Some sites have already met the challenge, while others are on track, is your site listed below????**

Site #	Site name	# Enrolled
11701	Chennai Antiviral Research and Treatment (CART) CRS	73
31441	Byramjee Jeejeebhoy Government Medical College	51
31924	Instituto de Infectologia Emilio Ribas CRS	28
31946	Tropical Medicine Foundation	25
12401	Joint Clinical Research Centre (JCRC)/Kampala CRS	19
31802	Thai Red Cross AIDS Research Center	18
31954	Centro de Referencia e Treinamento	17
11301	Barranco CRS	14
30022	Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS	13
31879	Mount Sinai Downtown CRS	12
31864	UT Southwestern	10
31927	HGNI HIV Family Care Clinic HHFCC	10
31925	Hospital Escola Sao Francisco de Assis	9
12701	Gaborone CRS	8
31915	School of Medicine, Federal University of Minas Gerais CRS	8
31784	Chiang Mai University HIV Treatment CRS	7
31730	GHESKIO Institute of Infectious Diseases and Reproductive Health	6
6101	University of Colorado Hospital CRS	5

## Did you Miss the Last Monthly Site Call?

If so, please take a moment to read the [call summary](#) and you can [review the slides here](#).

Topics covered include:

- **Important: The DSMB Recommendations to cease enrollment of people with a risk score less than 2.5% were discussed.** A Letter of Amendment (LOA) is being issued as quickly as possible to formalize this change. Sites are asked to limit screening of this population to the extent possible until the LOA is distributed. The slides from the Monthly Site Call have more details and FAQs about this recommendation.
- Transmitting ECGs
- Retention
- New content on the DAIDS RSC website
- Important lab tips
- Mechanistic substudy updates



**Save the date: the next team site call is February 20**

# Don't Forget to Transmit ECGs!\*

There are some very important steps about ECGs we want to remind you of:

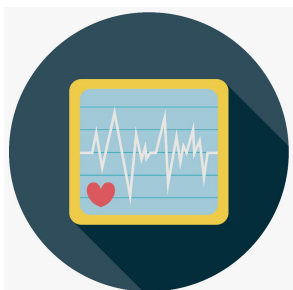


Remember to transmit ECGs to IQVIA (formerly Quintiles). For detailed transmission instructions see the Investigator's Manual, section 4.2 that was included with your ECG machine. The manual is also located on the A5332 PSWP, Training Folder.

- Document on the CRF (DGW0105) that the ECG recording has been performed.
- Keep the ECG printout with the PI or PI designees signature with the source document.

**Section 3.2 of the REPRIEVE MOPS has additional details about the ECG performed at entry.**

\*For the majority of sites in Brazil, please follow the instructions in the REPRIEVE MOPS, APPENDIX IV



**Transmit ECGs after the ECG is performed by either:**

1. Batch Transmission
2. Individual ECG Transmission

It is recommended to do a Batch Transmission as this saves time and ensures that all ECGs are transmitted.

For batch transmissions, please determine a regular schedule to transmit ECGs to IQVIA so that **ALL** ECGs are received in a timely fashion.

We have been reaching out to sites that have entered that an ECG was performed on the DGW0105 CRF in OpenClinica but for which an ECG has not been transmitted. Thank you to sites who have responded to these emails, if you have received an email about missing ECGs and have not yet responded please do so!

If you have an ECG related question please do not hesitate to email:

[gecg.helpdesk@quintiles.com](mailto:gecg.helpdesk@quintiles.com), if your email make sure to include your site ID and PI.



# American Heart Month

## Create a REPRIEVE Heart Health Awareness Table at Your Site

February 2018 is American Heart Month!



To help improve consumer education about HIV-associated heart disease and the REPRIEVE trial, we invite you to create a **"REPRIEVE Heart Health Awareness"** table at your clinic or research site during the month of February!

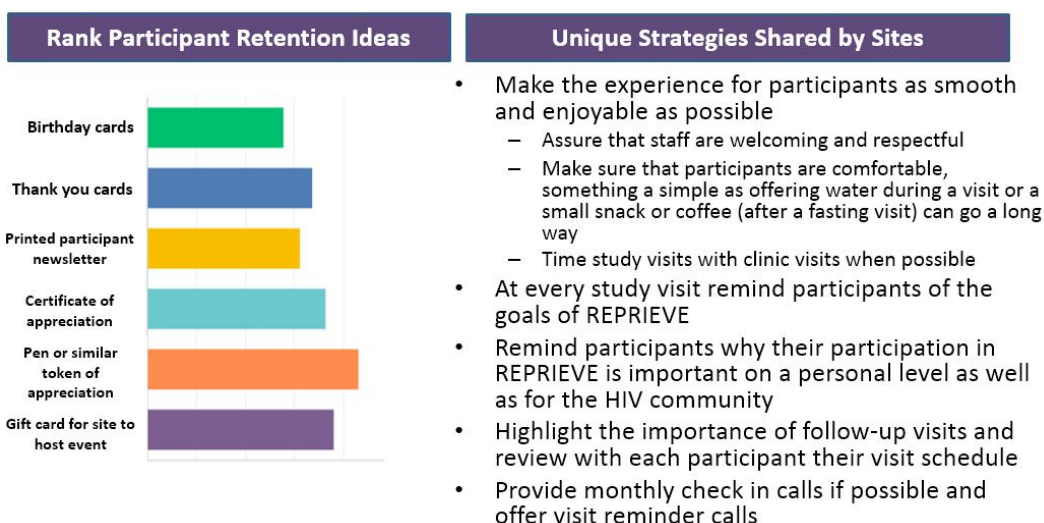
### Steps to Creating a Heart Health Awareness Table

1. Designate a space for a table in your waiting room or clinical research site.
  - Can be self-service or staffed with a team member.
2. Download Educational Materials about HIV and Heart Health
  - **FREE** materials from the REPRIEVE website [here](#).
  - **FREE** materials from the Follow YOUR Heart website [here](#)
  - **FREE** materials from the FDA Office of Women's Health website [here](#).
  - **FREE** general heart health educational materials from the [NHLBI](#).
  - **FREE** heart-healthy recipes [here](#).
3. Find additional ideas and materials from the REPRIEVE Outreach Toolkit [here](#)



## Check Out the Retention Survey Results!

Thank you to everyone who completed the survey about retention!  
We have compiled the results below



The Clinical Coordinating Center is working on some of the ideas you shared so stay tuned...

And don't forget, the annual Participant Newsletter will be out in April! Sites have shared that this is an excellent retention tool. [Click here](#) for previous newsletters.

If you have ideas for the newsletter or know of a REPRIEVE participant who might want to be interviewed for the next newsletter, please email Katie Fitch, CCC Project Manager at [kfitch@partners.org](mailto:kfitch@partners.org)

## Retention-related FAQ:

**Q: A participant told us a while ago that they no longer wanted to be on study medication, so we completed the Premature Treatment Discontinuation Visit and**

**have been following the participant on-study/off-study treatment per protocol. Now the participant wants to re-initiate study medication. How do we proceed?**

The specific criteria for premature and permanent termination of study treatment are listed in the protocol section 8.1. If the participant expresses a desire to stop study medication permanently for other reasons, please discuss their concerns and the importance of staying on study medication.

Every effort should be made to keep participants on the study medication if it is determined safe to do so. If the treatment discontinuation is going to be permanent, complete a Premature Treatment Discontinuation Visit. (Temporary stops only require an update of the study medication stop date on the TXW0295 Medication Log.)

**Even after the participant stops study treatment permanently, the team is happy to have participants re-initiate study medication unless it is otherwise prohibited (such as during and after a pregnancy).**

When the participant re-initiates study medication:

- Contact the data management team at [reprieve.dmc@fstrf.org](mailto:reprieve.dmc@fstrf.org) and request that the RP0003 Final Study Medication Status CRF be removed.
- 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.



**WebLDMS for REPRIEVE  
Training Dates**





Did you know that the Data Management Center/FSTRF now lists WebLDMS training for REPRIEVE on their website?

[Click here](#) for a list of future training dates and to register!

## Save the Date! REPRIEVE Investigators' Meeting at CROI 2018



**Tuesday, March 6th between 12:15-1:45pm**

**Boston Marriott Copley Place**

An invite via email will go out to Site PIs toward the end of this month. Please RSVP as space is limited.

### **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*

*Letter of Amendment, Version 3.0 #2, dated 04/14/17*

***MOPS:***

***MOPS Version 3.0, dated 09/20/2017***

***A5332 LPC for ACTG Sites:***

*Version 3.0 dated 09/21/2017*

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

*Version 3.0 dated 09/21/2017*

*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 06/05/2017  
**A5333s LPC:** Version 3.0, dated 09/21/2017

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



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## 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](mailto:reprieve.news@fstrf.org).

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