

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 01/08/2018

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REPRIEVE Trial Status: January 8th

5392 participants are enrolled

301 participants are in screening

118 sites are open for enrollment

18 sites enrolled at least 1 participant in the past week

18 sites screened at least 1 participant in the past week

Substudy Updates

Mechanistic Substudy of REPRIEVE (A5333s)

763 participants are enrolled (only **37** participants left to enroll!)

PREPARE Substudy (A5361s)

552 participants are enrolled (only **48** participants left to enroll!)

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

Case CRS
The Miriam Hosp (TMH) CRS
Durban International CRS
Barranco CRS

Chennai Antiviral Research and Treatment (CART) CRS
Joint Clinical Research Centre (JCRC)/Kampala CRS
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
Thai Red Cross AIDS Research Center

Wake Forest University
UT Southwestern
Mount Sinai Downtown CRS
Toronto General Hospital

School of Medicine, Federal University of Minas Gerais CRS
Instituto de Infectologia Emilio Ribas CRS
HGNI HIV Family Care Clinic HHFCC
Capital Medical Associates
Tropical Medicine Foundation
Center of Translational AIDS Research, Temple University

Welcome to New Sites!

We would like to extend a warm welcome to the newest sites enrolling in REPRIEVE:

Site 11701 Chennai Antiviral Research and Treatment (CART) Chennai, India; Site 31972 University of Florida Clinical Research Center CRS, Gainesville, FL, USA; Site 11301 Barranco CRS, Lima, Peru; Site 11302 San Miguel CRS, Lima, Peru; Site 12401 Joint Clinical Research Centre (JCRC), Kampala, Uganda; Site 30022 Les Centres GHESKIO CRS, Port-au-Prince, Haiti; Site 31730 GHESKIO Institute of Infectious Diseases and Reproductive Health CRS, Port-au-Prince, Haiti.



Full Speed to 1500



Full Speed to 1500 Challenge Standings

Don't forget! We need everyone's help to **enroll 1500 participants between December 4th, 2017 and April 30th, 2018.** 269 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	55
31441	Byramjee Jeejeebhoy Government Medical College (BJMC) CRS	32
31924	Instituto de Infectologia Emilio Ribas CRS	22
31946	Tropical Medicine Foundation	14
31954	Centro de Referencia e Treinamento	11
31802	Thai Red Cross AIDS Research Center	10
31864	UT Southwestern	8
31927	HGNI HIV Family Care Clinic HHFCC	8
31879	Mount Sinai Downtown CRS	7
31925	Hospital Escola Sao Francisco de Assis	7
12701	Gaborone CRS	6
31915	School of Medicine, Federal University of Minas Gerais CRS	6
6101	University of Colorado Hospital CRS	4
31917	Centro de Pesquisas Clinicas ICHCFMUSP CRS	4



Q: I am having trouble finding the right person at OpenClinica to answer questions about REPRIEVE, can you please let me know who to contact?

A: If you try to contact someone from OpenClinica they will not be able to help you. FSTRF, the Data Management Center, licenses the OpenClinica software from OpenClinica, the company. For this reason, the only contact for issues regarding the OpenClinica software is FSTRF.

If you are having issues with your username or password for either REPRIEVE in OpenClinica, or the REPRIEVE FSTRF Portal, contact user.support@fstrf.org

Phone: 716 834 0900 x 7302

If you are having **issues regarding data entry or forms**, you can contact a data manager at reprieve.dmc@fstrf.org

Phone: 716 834 0900 x 7429

If you are having issues with the screening or randomization checklists, you can

contact <u>rando.support@fstrf.org</u> Phone: 716 834 0900 x 7301



Mechanistic Substudy of REPRIEVE (A5333s) Important Reminders

For sites participating in the Mechanistic Substudy of REPRIEVE (A5333s), please remember to schedule the Month 24 follow up CCTAs. This CCTA should be performed using the same CT protocol parameters as

the baseline scan. These parameters include:

- Scanner
- Tube potential for coronary angiogram (kvp)
- Slice thickness
- Field of view

Email reminders will be sent to site coordinators every 3 months from the MGH CT Core Lab.

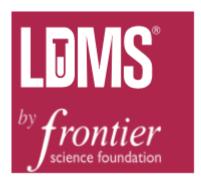
After the CCTA is completed, transfer the image to the MGH CT Core Lab as per instructions in the A5333s MOPS.



Important Reminders About Shipping

- All sites/laboratories must fax or e-mail the Shipping Notice for Ambient, Refrigerated, and Frozen Shipment form to the Repository (BRI) prior to shipping. <u>Click here</u> to download.
- All non-US sites/laboratories need to complete and fax or e-mail an "ACTG International Shipping Checklist" to BRI prior to shipping specimens. This document can be found on the ACTG website.
- Include the LDMS-generated Shipping Manifest and LDMS-generated Shipping Container Report (box map) in every shipment to BRI
- All documents above must be emailed to BRI the day of the shipment. Email to: brirepository@afbr-bri.com
- Before you ship, do a 100% QA/QC of your storage box prior to shipping!
 - Check the Global Specimen ID on your vials (the global ID is specific to each aliquot and ends with -001, -002, etc...).
 - Each vial location in the physical box should perfectly match your
 Shipping Manifest and Shipping Container Report (box map)
- For sites using FedEx to ship to BRI, ship PRIORITY OVERNIGHT this will assure that your shipments arrive on time and during BRI's business hours.

BRI receives many shipments each day, following the reminders above makes their job much easier, ensures the samples move from the shipping container to freezers with ease and helps to prevent issues you will need to respond to in your Shipment Evaluation.



WebLDMS for REPRIEVE Training Dates

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

<u>Click here</u> for a list of future training dates and to register!

REPRIEVE in the News

"Exploring Barriers for Women in HIV Clinical Research
With REPRIEVE"

The Body PRO published an excellent article on **Follow YOUR Heart**, the Women's Objective within REPRIEVE. Read it here!



TheBodyPro is the internet's premier online publication for HIV specialists, so we hope this will serve as meaningful outreach to referring clinicians.

Please Join the Next Monthly Site Call!

Tuesday, January 16th between 1:00 - 2:00
PM Eastern Time



Watch your inbox for the announcement from Barbara Bastow with dial-in details.

Save the Date! REPRIEVE Investigators' Meeting at CROI 2018



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

Boston Marriot 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





Tweet



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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