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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Trial Status

April 9th, 2018

6316 participants are enrolled

45 participants enrolled last week

439 participants are in screening!

119 sites are open for enrollment

28 sites enrolled at least 1 participant in the past week

30 sites screened at least 1 participant in the past week

Since the last newsletter, **106** participants have been enrolled. **Thank you for the excellent effort that all teams are putting forth to enroll participants in REPRIEVE.**

**Thank You to All Sites Enrolling Participants
Week of April 2nd, 2018!**

Massachusetts General Hospital (MGH) CRS

Specialty Care Center CRS

Northwestern University CRS

University of Colorado Hospital CRS

Weill Cornell Chelsea CRS

Wits Helen Joseph Hospital CRS (Wits HJH CRS)

Barranco CRS

San Miguel CRS

Chennai Antiviral Research and Treatment (CART) CRS

SOWETO

Joint Clinical Research Centre (JCRC)/Kampala CRS

Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS

Parirenyatwa CRS
Columbia Physicians and Surgeons CRS
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS
GHESKIO Institute of Infectious Diseases and Reproductive Health
Chiang Mai University HIV Treatment CRS
Thai Red Cross AIDS Research Center
Florida Department of Health Hillsborough County
UT Southwestern
Positive Health Clinic
Centro de Pesquisas Clinicas ICHCFMUSP CRS
Instituto de Infectologia Emilio Ribas CRS
HGNI HIV Family Care Clinic HHFCC
Tufts Medical Center
Tropical Medicine Foundation
Centro de Referencia e Treinamento
Inova Heart and Vascular Institute



Full Speed to 1500



Full Speed to 1500 Challenge Updates!

Since the Full Speed to 1500 Challenge began on December 4th, 2017, **1181 participants have been enrolled**, we are getting closer to the goal of enrolling 1500 participants! If 46 participants are enrolled each week between now and the first week of May, we will meet the challenge. Stay tuned for updates.

Don't forget prizes include:

- \$500 gift card for 1st place
- \$250 gift card for 2nd place
- All other sites that enroll 15 participants by May 1st will win a \$100 gift card

Check out the standings below!

Site #	Site name	# Enrolled
11701	Chennai Antiviral Research and Treatment (CART)	147
31441	Byramjee Jeejeebhoy Govt. Medical College	112
12401	JCRC/Kampala CRS	101
31946	Tropical Medicine Foundation	66
11301	Barranco CRS	59
31802	Thai Red Cross AIDS Research Center	47
30022	Les Centres GHESKIO Clinical Research Site	43
31924	Instituto de Infectologia Emilio Ribas CRS	38
31954	Centro de Referencia e Treinamento	36
12701	Gaborone CRS	34
31730	GHESKIO Institute of Infectious Diseases & Reproductive Health	30
11302	San Miguel CRS	23
31927	HGNI HIV Family Care Clinic HHFCC	22
31864	UT Southwestern	18
31917	Centro de Pesquisas Clinicas ICHCFMUSP CRS	17
31915	Federal University of Minas Gerais	17
31879	Mount Sinai Downtown CRS	16
31925	Hospital Escola Sao Francisco de Assis	16
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)	15
31784	Chiang Mai University HIV Treatment CRS	14
31980	Palmetto Health Clinical Trial Department	12
6101	University of Colorado Hospital CRS	12
6201	Penn Therapeutics CRS	9
12301	SOWETO	9
2501	Case CRS	8
8950	Family Clinical Research Unit	8
31788	Alabama CRS	8
30329	Columbia Physicians and Surgeons CRS	8
31918	Hospital Federal dos Servidores do Estado	8
1001	University of Pittsburgh CRS	8
1601	Duke University Medical Center	7
11201	Durban International CRS	7
31786	New Jersey Medical School-Clinical Research Ctr.	7
2401	Cincinnati CRS	7

Barbara Bastow Is Retiring!

Barbara Bastow, REPRIEVE Project Specialist within the Network Coordinating Center/AIDS Clinical Trials Group, will be retiring in April. Barbara has been a crucial member of the REPRIEVE team- the trial would not be where it's at without her hard work. While we are sorry to see her go, we are so happy that she is starting this new



chapter.

REPRIEVE Team members had the following kind words to say about Barbara:

"Barbara Bastow has been a major constant in REPRIEVE since the project's initiation. As our lead CTS, Barbara has skillfully and successfully guided the study team. Her knowledge of the ACTG process has allowed us to efficiently roll out and recruit this large multinational trial. We are grateful to Barbara for her dedication to the trial and to the mission of improving CVD health in HIV. We will sorely miss Barbara, and wish her great fun and relaxation in her retirement. We look forward to working with Laura Moran, our new lead CTS, who has also been associated with the trial for many years." - Steve Grinspoon, Co-Principal Investigator of the Clinical Coordinating Center for REPRIEVE, Chair of the REPRIEVE protocol, and Chair of the Operational Leadership Committee.

"I have had the good fortune of working with Ms. Barbara Bastow on several protocols during my time as an ACTG investigator. She has an incredible amount of knowledge about the intricacies of all aspects of protocol development, dissemination, and completion. She was always prepared for any eventuality and remained calm and organized in all circumstances. Her commitment to our work was always evident by her careful attention to detail and her professionalism and kindness in responding to all types of queries. Furthermore, she always maintained her sense of humor. I will miss collaborating with her professionally and miss talking with her on a weekly (sometimes daily) basis. Barbara has clearly earned her retirement. Please raise your glass and join me in a toast to her!" - Turner Overton, Co-Chair of the REPRIEVE protocol and Chair of the Protocol Writing and Implementation Committee

"I consider myself fortunate to have been able to work with Barbara for nearly 5 years on the REPRIEVE study. I have learned a great deal from Barbara with respect to developing and modifying a protocol and associated study documents, implementing a trial across over 130 sites, and answering site questioning. Barbara excels in every aspect of her work and her pride in her work shines through. On a personal level, I appreciate Barbara for being a kind and trusted friend – she is quick to share a laugh, warm praise for others, and a helping hand. We will all miss working with Barbara! We thank Barbara for her tremendous contributions to REPRIEVE and we hope to keep in touch in the years to come!" -Dr. Markella Zanni, Co-Chair of the REPRIEVE protocol and Co-PI of the Women's Objective

"I have felt so lucky to have had the opportunity to work with Barbara for the past 4 years. She has always been so patient while orienting me and so many others on our team to the ACTG. She taught me so much about working on a large multicenter trial. Barbara has truly been one of REPRIEVE's greatest assets, and we have all been so fortunate to have worked with her. In addition to Barbara's amazing skills, she is quick witted and always fun to have a laugh with. She will definitely be missed

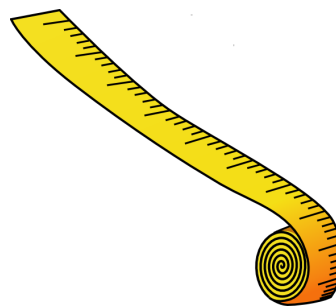
and I wish Barbara the best as she transitions to the next phase of her life." -Katie Fitch, Project

Manager, REPRIEVE CCC



Waist Circumference Reminder

Waist circumference is to be measured at entry and end of study, and entered onto the Detailed Vital Signs CRF (VSW0013). Waist circumference measurement is explained in section 3.1 of the REPRIEVE (A5332) MOPS. Please make sure to obtain this data as it is required for the study.



Q. A potential candidate for REPRIEVE who qualifies but was just diagnosed with a urinary tract infection (UTI) and is on antibiotics, do we need to wait 30 days for the entry visit?

A. If this study candidate was diagnosed and treated for an uncomplicated UTI infection, then it is considered a localized infection rather than a systemic infection and he/she may enroll in the study without further delay as long as all other inclusion/exclusion criteria are met.

However, per exclusion 4.2.14 (see below) you would have to wait until 30 days after resolution of the infection to enroll the study candidate if it was a complicated UTI such as pyelonephritis, or complicated by bacteremia, etc since it would then be considered systemic.

4.2.14 Known active or recent (not fully resolved within 30 days prior to study entry) systemic bacterial, fungal, parasitic, or viral infections (except HIV, HBV, human papillomavirus [HPV], or HCV).

Retention Champions Initiative

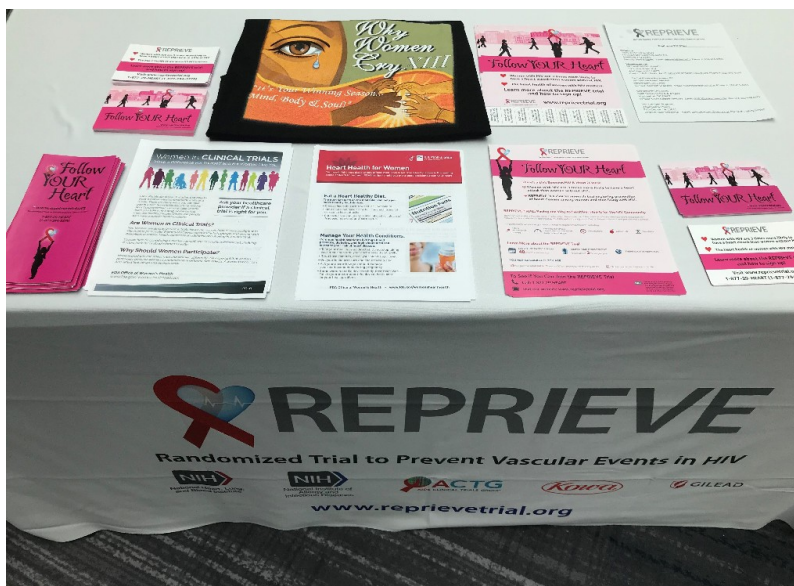
Thank you to those sites that have responded to our request to identify their Retention Champion!

If you have not sent us your site's Retention Champion contact information, please do so as soon as possible. We are planning to hold calls with Retention Champions to learn about your site's retention challenges and ideas. The goal is to create a retention toolkit to benefit all sites. Please contact Laura Sanchez, REPRIEVE Coordinator, at lsanchez12@partners.org with any questions.



Follow YOUR Heart In the Community

On April 2nd, the REPRIEVE Follow YOUR Heart outreach coordinator, Corinne Rivard, attended the **Why Women Cry Conference** hosted by [Sisters Together and Reaching \(STAR\)](#) in Baltimore, MD. STAR is a non-profit community/faith-based organization that provides spiritual support, linkages to care, direct services, and treatment and prevention education primarily for minority women at risk or living with HIV/AIDS and other illnesses. **Over 1,000 women attended** the Why Women Cry Conference, which offered a wonderful opportunity to spread the word about the



importance of heart health and clinical research participation among women with HIV. The attendees had the opportunity to ask questions, improve their understanding of heart disease, and receive educational materials about heart health and the REPRIEVE Trial.

The **Follow YOUR Heart** team, led by the Principal Investigators of the REPRIEVE Women's Objectives, Dr. Sara Looby and Dr. Markella Zanni, has conducted outreach for women at a number of HIV community organizations. To learn more, please email Corinne Rivard:

CRIVARD1@mgh.harvard.edu



Next REPRIEVE DSMB Meeting is June 4th, 2018

The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE trial.

Please mark these dates on your calendar and note that **Monday, April 13th** is the next important date. All adjudication packets for potential MACE events with a work-up completed by March 31st must be submitted to the MGH DCC.

Task		Deadline* (2018)
Sites	Latest date for the occurrence of an evaluation for which complete data will be included in this DSMB review	Mar 31 (Sat)
Sites	All data for visit through Mar 31 entered	Apr 9 (Mon)
Sites	All adjudication packets for potential MACE events with a work-up complete by Mar 31 submitted to DCC (MGH)**	Apr 13 (Fri)
Sites	All outstanding queries resolved	Apr 23 (Mon)
Sites	Respond to last minute outstanding queries	May 11 (Fri)***
All	DSMB Meeting	June 4 (Mon)

*Deadlines are Close of Business on the given date unless otherwise noted

** Please ensure that you have responded to all queries and clarifications from the DCC regarding source documents submitted for potential adjudicated events. This will ensure that the DCC is able to submit complete packets to TIMI for adjudication prior to the DSMB.

***Please note this date has been updated from the email that was distributed



TRAINING OPPORTUNITIES

The LDMS Training Team would like to extend an invitation to all Web LDMS users on the REPRIEVE project to our next webinar. The webinar will cover the processing, storage, and shipment of specimens for REPRIEVE.

As a reminder, videos are available on our website at:

<https://www.ldms.org/resources/videos/> which cover these topics. These videos are hosted on YouTube and can also be viewed through the mobile app.

Topic: WebLDMS for REPRIEVE

Time: Apr 18, 2018 12:00 PM Eastern Time (US and Canada)

If you would like to join the training session but did not receive the email with the webinar information please email ldms_training@fstrf.org to request this information.



April Monthly Site Call

The next monthly site call will take place on Tuesday, **April 17th** at 1:00PM ET. During the call, we will discuss changes in Version 4.0 of the protocol and MOPS. Therefore, **please make every effort to join this call.**

Jhoanna Roa sent out the calendar invitation and will share the slides closer to the call. If you did not receive the calendar invitation, please contact Jhoanna at JRoa@s-3.com.

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Current Protocol Documents:

Protocol Version 4.0 dated 03/28/2018 (new version!)

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

Letter of Amendment, Version 3.0 #3, dated 01/19/2018

MOPS Version 3.0: dated 09/20/2017

A5332 LPC for ACTG Sites: Version 3.0 dated 02/02/2018

A5332 LPC for Non-ACTG Sites: Version 3.0 dated 09/21/2017

These documents are on the [A5332 PSWP](#)

Mechanistic Substudy of REPRIEVE (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](#)

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



REPRIEVE Trial Clinical Coordinating Center

Massachusetts General Hospital
55 Fruit Street, 5LON 207
Boston, MA USA 02144

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reprieve.news@fstrf.org

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