



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 12/12/2016

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REPRIEVE Announcements

REPRIEVE Trial Status as of December 12th

- 2440 participants are enrolled
- 254 participants are in screening
- 101 sites are open for enrollment
- 93 sites have enrolled at least 1 participant
- 97 sites have screened at least 1 participant

Important Early 2017 Target! WE CAN HIT THIS TARGET!!!



April 1st, 2017 marks the 2 year anniversary of the 1st enrollment in REPRIEVE. Let's make April 1st another important milestone, if ~50 participants are enrolled each week between now and April 1st, 2017 we will hit the target of 50% of participants enrolled (3,250 participants) in REPRIEVE on April 1st, 2017.

REPRIEVE's Fall 50 Updates

Reminder! Between October 1st and December 30th, all sites enrolling an average of 3 participants per month will receive a \$50 gift card and all sites enrolling an average of 4 or more participants per month will receive a \$100 gift card.

Check Out the Standings Below

Sites in the lead!		
#	Site Name	Participants Enrolled Since October
12101	Instituto de Pesquisa Clinica Evandro Chagas CRS	52
31802	Thai Red Cross AIDS Research Center	48
11101	University of the Witwatersrand Helen Joseph CRS	28
8950	Family Clinical Research Unit CRS	27
31784	Chiang Mai CRS	13
31470	Denver Public Health	11
2401	Cincinnati CRS	10
31864	UT Southwestern	10
31673	Orlando Immunology Center CRS	9
2701	Northwestern University CRS	9

Sites that are close to meeting the challenge:
You can do it!

#	Site Name	Participants Enrolled Since October
31871	University of Kentucky	8
31791	Whitman-Walker Health CRS	8
31845	Wake Forest University	8
3201	Chapel Hill CRS	8
6101	University of Colorado CRS	6
31834	AIDS Research Treatment Center of the Treasure Coast	6
7804	Cornell Chelsea CRS	6
1505	University of Nebraska Medical Center	6
31889	Toronto General Hospital	6
30347	University of Illinois at Chicago	5
31788	Alabama CRS	5
3203	Greensboro CRS	5
1601	Duke University Medical	5
603	Harbor UCLA CRS	5
31880	Mt Sinai Kreuger Clinic	5
701	UCSD Antiviral Research Center CRS	5
7803	Weill Cornell Uptown CRS	5
601	UCLA CARE Center CRS	5

**Thank You to All Sites Enrolling Participants
Week of 12/05/2016!**

- UCSD Antiviral Research Center CRS
- Georgetown University CRS
- University of Nebraska Medical Center
- Ohio State University CRS
- Cincinnati CRS
- Case CRS
- University of Colorado Hospital CRS
- Penn Therapeutics CRS
- Weill Cornell Uptown CRS
- Cornell Chelsea CRS
- Family Clinical Research Unit CRS
- University of the Witwatersrand Helen Joseph CRS
- Instituto de Pesquisa Clinica Evandro Chagas CRS
- Chiang Mai University HIV Treatment CRS
- University of Rochester Adult HIV Therapeutic Network CRS
- Alabama CRS
- Whitman-Walker Health CRS
- University of Cape Town Lung Institute CRS
- Thai Red Cross AIDS Research Center
- AIDS Research Treatment Center of the Treasure Coast
- Wake Forest University
- Louisiana Community AIDS Research Program
- Toronto General Hospital
- Inova Heart and Vascular Institute CRS
- Soweto ACTG CRS

Meet the Team at Instituto de Pesquisa Clinica Evandro Chagas



The **Instituto de Pesquisa Clinica Evandro Chagas CRS** (site #12101), also known as Fiocruz, is one of our top enrolling sites. Located in Rio de Janeiro, Brazil, they have only been open for enrollment for approximately 12 weeks and have 54 participants enrolled! A huge thank you to this team for all their hard work!

When asked what helps their site successfully recruit participants for REPRIEVE, they responded:

"We do believe that our desire to give patients better quality of life inspires our work.
An enthusiastic team has more confidence in their daily work of recruiting

volunteers. We hope that our enthusiasm in conducting the study will be passed on to our volunteers whom we only have to thank for participating in this study which we hope will answer important questions for people living with HIV.” - Fiocruz team



Important Reminders

- Collect the urine specimen at entry for all participants in REPRIEVE (A5332)
- Consider re-screening any participants that may have failed due to the pre-Version 3.0 LOA1 ASCVD criteria
- The Spanish translation of the Heart-related Health Questionnaire is now available. Go to the REPRIEVE (A5332) PSWP -->Protocol Specific Support Documents --> Spanish Translations

Help Us Improve the REPRIEVE Site Newsletter



We want to hear your thoughts about the REPRIEVE Site Newsletter

THANK YOU to everyone who has completed this survey!

If you have not already done so, please take this quick, 3 question survey and let us know what you think of the site newsletter. We can only improve it with your feedback.

To complete the survey, [click here](#)

Changes for Your Site Evaluations

In an effort to provide REPRIEVE sites with helpful metrics and feedback, the Site Selection & Performance Committee (SSPC) will send comprehensive evaluations twice per year (instead of quarterly). A site's performance over the previous 6 months will be evaluated in 3 areas: enrollment, data management, and laboratory management. Letters will be sent to all sites in January and July. Sites that do not meet the standards for enrollment, data, and/or laboratory management will be required to respond with a plan to fix pertinent issues. If you have any questions about the evaluation process, please do not hesitate to reach out to Laura Sanchez (lsanchez12@partners.org).



REPRIEVE (A5332) and Mechanistic Substudy (A5333s)

Q: We have a participant that had an entry visit today for A5332 and A5333s. The local reading of the CT for A5333s showed severe 2 vessel coronary artery disease and it is the PI's opinion that the participant be started on an open label statin and ASA. The participant has yet to take the first dose of study medication. If the participant is started on an open label statin, can the participant still be followed on-study/off-treatment?

A: If the participant is required to start a statin by the provider then he/she can be followed on-study/off treatment.

- Please complete the RP0003 eCRF that is located in the PRN visit folder and document that the participant will not start study treatment with *Clinical need for statin therapy* provided as the reason for not starting study treatment.
- Details of any non-study statin therapy should subsequently be entered on Section C of the Medications Log (TXW0295) for the duration of the study.
- Please continue to complete the study visits as outlined in the protocol. It is important to collect any potential MACE on participants, even if the participant discontinues study medication.

Mechanistic Substudy (A5333s)

Q: Exclusion Criteria 4.2.8 in Appendix II Mechanistic Substudy of REPRIEVE (A5333s) Protocol states that a cardiac arrhythmia at enrollment is exclusionary. Do I assess for this?

A: The intent of this exclusion is to capture *history of cardiac arrhythmia* that may prevent a participant from undergoing the CCTA. It is not intended that sites assess for cardiac arrhythmia at enrollment. The ECG at entry is not used for screening.

Mark Your Calendars

Monthly Site Call

Tuesday, December 20th 1:00 PM ET

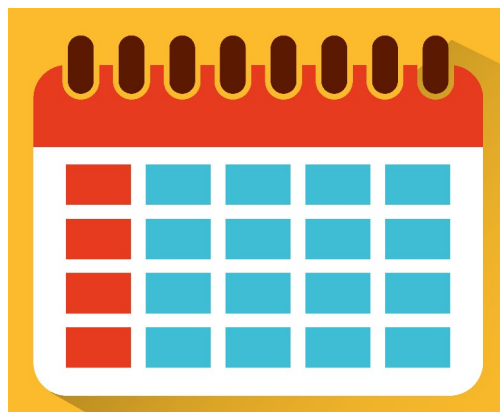
An email with call details will be sent by Barbara Bastow shortly. Please join this call and be ready to ask any questions about REPRIEVE that have come up at your site.

REPRIEVE Investigator's Meeting at CROI 2017

Wednesday, February 15th 12:15 PM - 1:45 PM PT

Grand Hyatt 721 Pine Street, adjacent to the Washington State Convention Center

An invite will go out via email in early January to all PIs



TRAINING OPPORTUNITIES

ECG Training Dates

Tuesday, 10 January 2017, 9:30 AM ET

This 30-minute training webinar includes information on the ECG machine and supplies, performing the ECG, and transmission of data to Quintiles. This training is specific to the REPRIEVE trial and at least one person from your site must attend one training to meet protocol activation requirements.

Since most sites have completed this requirement these are likely to be our last ECG Training calls, if you need a refresher, please join!

Sites still needing to complete this requirement have been contacted already, however, if you did not receive an email or if you would like to attend, please email Katie Fitch at kfitch@partners.org

Helpful Training Resources

Web LDMS Training Video

If you are a site using Web LDMS for REPRIEVE, check out the Web LDMS training video available on [FSTRF's YouTube Channel](#).

These training videos are the same training(s) that FSTRF staff have been providing REPRIEVE laboratories. We encourage lab staff to watch these videos as a means of refresher training. Please share these links with laboratory staff at your sites if they do not receive the REPRIEVE newsletter.

Data Management Videos

The REPRIEVE Data Managers have put together some excellent videos on the following topics:

- Changing Previously Saved Data
- Entering Logs
- Entering Missed Visits
- Answering Notes and Discrepancies
- Entering Out of Window Visits
- Entering Unknown or Missing Values

You can access these videos in the [ESTRF portal](#), go to -->**Site Support Tab -->REPRIEVE Training Videos**



Check Out Recent Coverage of REPRIEVE

The NIAID recently mentioned the importance of REPRIEVE in its World AIDS Day Statement, [click here](#) to read.

[Positively Aware](#) also published an overview of REPRIEVE and the importance of heart health for people living with HIV. [Click here](#) to download and share this with patients in your clinic

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)

Letter of Amendment, Version 3.0 #1 dated 08/17/16

MOPS:

Version 3.0, revision 1, dated 09/09/16

A5332 LPC for ACTG Sites:

Version 3.0 dated 09/28/2016

A5332 LPC for Non-ACTG Sites:

Version 3.0 dated 09/27/2016

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 09/29/2016

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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