



# REPRIEVE

## Randomized Trial to Prevent Vascular Events in HIV

### Site Newsletter 09/11/2017

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## REPRIEVE Trial Status: September 11th

**4383** participants are enrolled

**254** participants are in screening

**116** sites are open for enrollment

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

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

August was REPRIEVE's best enrollment month ever, approximately 300 participants were enrolled. This huge success is directly due to your hard work and perseverance! **As we move into fall, we look forward to sustaining this successful enrollment.**

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We would like to extend a **warm welcome** to two new sites enrolling in REPRIEVE, **Site 31925 Projeto Praça Onze/Hospital Escola São Francisco de Assis/UFRJ, located in Rio de Janeiro, Brazil** and **Site 31954 Centro de Referência e Treinamento DST/AIDS, located in São Paulo, Brazil!**

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## Thank You to All Sites Enrolling Participants Week of 09/04/2017!

Univ. of Miami AIDS Clinical Research Unit(ACRU) CRS  
Washington University Therapeutics (WT) CRS  
Dallas VA Medical Center  
Penn Therapeutics CRS  
Weill Cornell Chelsea CRS  
Wits Helen Joseph Hospital CRS (Wits HJH CRS)  
Durban International CRS  
Hospital Nossa Senhora da Conceicao CRS  
Gaborone CRS  
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS  
Chiang Mai University HIV Treatment CRS  
Whitman-Walker Health CRS  
Thai Red Cross AIDS Research Center  
UT Southwestern  
Vancouver ID Research and Care Centre Society  
Mount Sinai St. Luke's CRS  
Mt Sinai West CRS  
Mount Sinai Clinical and Translational Research Center CRS  
School of Medicine, Federal University of Minas Gerais CRS  
HGNI HIV Family Care Clinic HHFCC  
Tufts Medical Center  
Center of Translational AIDS Research, Temple University

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## 1by1by1 Enrollment Challenge Standings



**Don't forget the 1by1by1 enrollment challenge! Help REPRIEVE reach 75%!**

With more sites now activated, the 1by1by1 Enrollment Challenge is heating up! **If 66 participants are enrolled each week between now and October 31<sup>st</sup>, we will achieve 75% of the 6,500 target enrollment, only 492 participants are needed to reach this goal, with 116 activated sites this is possible!**

**What's the best part? Many sites can win!**

- The site that enrolls the MOST participants during this challenge will be #1 of the 1by1by1 competition and win a \$200 gift card!
- Each site that enrolls 11 participants or more between July 1-October 31, 2017 will receive a \$100 gift card.
- Each site that enrolls 8-10 participants between July 1-October 31, 2017 will receive a \$50 gift card.

The clock started ticking on July 1st and will stop October 31st.

<b>Sites in the Lead!</b>		
		<b>Participants Enrolled Since 7/1</b>
12701	Gaborone CRS	82
31946	Tropical Medicine Foundation	51
11201	Durban International CRS	48
12201	Hospital Nossa Senhora da Conceicao CRS	43
31441	(BJMC) CRS	39
31927	HGNI HIV Family Care Clinic HHFCC	26
31802	Thai Red Cross AIDS Research Center	18
31864	UT Southwestern	17
31915	Federal University of Minas Gerais CRS	14
12101	Instituto de Pesquisa Clinica Evandro Chagas (IPEC)	11
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)	11
31792	University of Cape Town Lung Institute	10
31918	Hospital Federal dos Servidores do Estado	8
31868	Vancouver ID Research and Care Centre Society	8
2101	Washington University Therapeutics (WT) CRS	8
8950	Family Clinical Research Unit	8
31791	Whitman-Walker Health CRS	7
31784	Chiang Mai University HIV Treatment CRS	7
901	Univ. of Miami AIDS CRS	7
2401	Cincinnati CRS	6
12301	SOWETO	6
6201	Penn Therapeutics CRS	6
3752	Dallas VA Medical Center	6
5802	The Ponce de Leon Ctr. CRS	6
31963	Inova Heart and Vascular Institute	6
31470	Denver Public Health	5
31883	Mount Sinai Clinical and Translational Research Center CRS	5
31443	Trinity Health and Wellness Center	5
7804	Weill Cornell Chelsea CRS	5



Q: We have several patients with diabetes that are interested in participating in

## REPRIEVE. Are there plans to include participants with diabetes in the trial?

A: People with DM (see definition below) who also have an LDL <70 mg/dL and who are otherwise eligible can participate in REPRIEVE. Diabetics with LDL  $\geq$ 70 mg/dl are not allowed because the ADA guidelines recommend that they be on a statin.

Please remember that current diabetes is defined by patient report of physician diagnosis. Potential participants with a history of diabetes which has resolved and *no longer requires therapy* are not considered to have current diabetes, eg, women with a history of gestational diabetes, steroid-induced or medication-induced.

If you have potential participants who have diet controlled diabetes and otherwise qualify for REPRIEVE they could participate. Also, you may have patients on oral medications for diabetes but with some lifestyle modification to improve blood glucose they could come off these medications and may then be eligible to participate in REPRIEVE. This is an excellent opportunity to encourage lifestyle modification to improve blood glucose!

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## Spread the Word: REPRIEVE Presentations

Are you interested in sharing REPRIEVE with providers or the community? If so, we have template slide presentations for you to use!

Download them here:

- [Presentation for providers](#)
- [Presentation for the community](#)



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## Reminder: Data Management Contacts



For nonclinical questions about transfers, electronic case report forms (eCRFs), randomization, and other data management issues, contact the REPRIEVE data managers [reprieve.dmc@fstrf.org](mailto:reprieve.dmc@fstrf.org)  
eCRFs for download, data management training videos, and an email address lookup are available on the FSTRF website at [www.frontierscience.org](http://www.frontierscience.org).



- For transfers, reference the ACTG Study Participant Transfer SOP 119 ([click here to download](#)), and contact [reprieve.dmc@fstrf.org](mailto:reprieve.dmc@fstrf.org) directly.

## Next Monthly Site Call

**Save the date** for the next REPRIEVE monthly site call on **Tuesday, September 19th at 1:00PM ET**. Dial-in information and a slide presentation will be sent out via email in the coming days.



## Is Your Site Contact Information Correct?

Find a Research Site

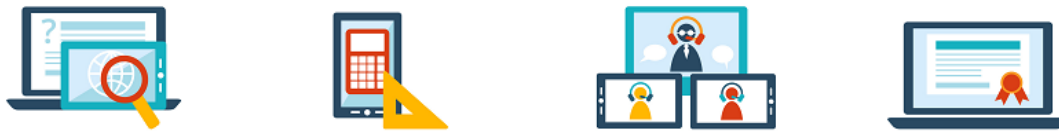
The map includes sites that are currently enrolling participants, more sites will be added as they open for enrollment.

To find a site near you, please enter your zip-code in the search box at the top of the map. Use the zoom in/zoom out functions to the top left of the map to get a better idea of where a site is in your area!

A screenshot of a Google Map of the United States. The map is filled with numerous red location pins, primarily concentrated in the eastern and central US. At the top right, there is a search bar with the text "Enter city or zip code" and a "Search" button. At the top left, there are zoom in (+) and zoom out (-) icons. The map shows state boundaries and names, and includes a scale bar at the bottom right indicating 500 km. The Google logo is visible in the bottom left corner.

The REPRIEVE website is frequently visited by individuals interested in the trial. **Please check your site contact information on the map page** to ensure that it's accurate: <http://www.reprievetrial.org/collaborating-sites/>

If your site contact info is wrong, please email Laura Sanchez, REPRIEVE Coordinator, at [lsanchez12@partners.org](mailto:lsanchez12@partners.org).



## TRAINING OPPORTUNITIES

### Next Web LDMS Training for Non-ACTG Sites

The LDMS Training Team would like to extend an invitation to all Web LDMS users on the REPRIEVE project to their next webinar. The webinar will cover the processing, storage, and shipment of specimens for the ACTG REPRIEVE study. This is a great opportunity to refresh your earlier training - and ask questions!

As a reminder, videos are available on FSTRF's 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.

### WebLDMS for REPRIEVE

Wednesday, September 27, 2017

12:00 pm | Eastern Daylight Time (New York, GMT-04:00)

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](mailto:ldms_training@fstrf.org) to request this information.

## Check Out the NEW REPRIEVE Outreach Toolkit!



[http://www.reprievetrial.org/  
outreach-toolkit/](http://www.reprievetrial.org/outreach-toolkit/)

The REPRIEVE Clinical Coordinating Center has partnered with the NIAID Communications team to compile helpful outreach resources. This "Outreach Toolkit", is an online webpage with resources to assist sites that are looking to improve outreach, increase enrollment, engage with the community, connect with local media outlets and raise awareness about HIV & heart disease and REPRIEVE!

To view the Outreach Toolkit, visit [http://www.reprievetrial.org/  
outreach-toolkit/](http://www.reprievetrial.org/outreach-toolkit/)

Included in the toolkit:

- **Print & Digital Assets:** flyers, posters, advertisement artwork, etc. that you can download and print for distribution at your facility, in community spaces, or at local events. You can also feature these digital files on your site's website, blog, or social media.
- **Guide to Participating in Community Events**
- **Guidance on How to Connect with Local Media:** in addition to written instructions, there is a media pitch template and a press release template.
- **REPRIEVE Key Messages & Fact Sheet:** these help clarify basic facts about the study and articulate ideas that will resonate with your audience. Share these messages with trial site spokespeople before media interviews and with event leaders who will engage members of the public.
- **Social Media Messaging:** templates messages in both English and Spanish

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## 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 06/23/2017

**A5332 LPC for ACTG Sites:**

Version 3.0 dated 05/04/2017

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

Version 3.0 dated 05/04/2017

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: NEW** Version 3.0 dated 06/05/2017

**A5333s LPC:** Version 3.0 dated 05/04/2017

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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