

1by1by1 FINAL COUNTDOWN!!!



## Randomized Trial to Prevent Vascular Events in HIV

### Site Newsletter 10/09/2017

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## REPRIEVE Trial Status: October 9th

Last week was another phenomenal enrollment week: **101 participants were enrolled!!!** Thank you to everyone for the tremendous effort for making last week the **highest** enrolling week to date.

**4653** participants are enrolled

**286** participants are in screening

**118** sites are open for enrollment

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

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

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# Thank You to All Sites Enrolling Participants Week of 10/02/2017!

UCSF HIV/AIDS CRS  
University of Pittsburgh CRS  
Washington University Therapeutics (WT) CRS  
Case CRS  
The Ponce de Leon Ctr. CRS  
Family Clinical Research Unit  
Durban International CRS  
SOWETO  
Gaborone CRS  
Byramjee Jeejeebhoy Government Medical College (BJMC) CRS  
Denver Public Health  
Henry Ford Hospital  
Houston AIDS Research Team CRS  
Chiang Mai University HIV Treatment CRS  
New Jersey Medical School-Clinical Research Ctr. CRS  
Thai Red Cross AIDS Research Center  
Indiana University School of Medicine  
Medical College of Wisconsin  
Florida Department of Health Hillsborough County  
UT Southwestern  
Hamilton Health Sciences  
Mount Sinai Clinical and Translational Research Center CRS  
School of Medicine, Federal University of Minas Gerais CRS  
Centro de Pesquisas Clinicas ICHCFMUSP CRS  
Hospital Federal dos Servidores do Estado  
Hospital Escola Sao Francisco de Assis  
HGNI HIV Family Care Clinic HHFCC  
Tropical Medicine Foundation  
Centro de Referencia e Treinamento  
Malcom Randall VA Medical Center  
Petersen HIV Clinic, U of Arizona

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## 1by1by1 Enrollment Challenge Standings



**It's THE FINAL COUNTDOWN, approximately 4 weeks remain in the 1by1by1 Enrollment Challenge!**

**If 56 participants are enrolled each week between now and the end of the 1by1by1 challenge, we will achieve 75% of the 6,500 target enrollment. Only 222 participants are needed to reach this goal, with 118 activated sites this is possible!**

**Remember, many sites will 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. 16 sites have already won prizes and several more sites are very close!**

## Sites in the Lead!

|       |  | <i>Participants<br/>Enrolled Since<br/>7/1</i> |
|-------|--|--|
| 12701 | Gaborone CRS                                     | 109  |
| 31946 | Tropical Medicine Foundation                     | 67   |
| 11201 | Durban International CRS                         | 64   |
| 31441 | BJMC CRS   | 62   |
| 12201 | Hospital Nossa Senhora da Conceicao CRS          | 47   |
| 31927 | HGNI HIV Family Care Clinic HHFCC                | 41   |
| 31802 | Thai Red Cross AIDS Research Center              | 27   |
| 31864 | UT Southwestern                                  | 21   |
| 31915 | Federal University of Minas Gerais CRS           | 20   |
| 31784 | Chiang Mai University HIV Treatment CRS          | 16   |
| 31917 | Centro de Pesquisas Clinicas ICHCFMUSP CRS       | 16   |
| 11101 | Wits Helen Joseph Hospital CRS (Wits HJH CRS)    | 14   |
| 8950  | Family Clinical Research Unit                    | 14   |
| 12101 | Instituto de Pesquisa Clinica Evandro Chagas CRS | 12   |
| 2101  | Washington University Therapeutics (WT) CRS      | 11   |
| 901   | Univ. of Miami AIDS Clinical Research Unit CRS   | 11   |
| 31792 | University of Cape Town Lung Institute           | 10   |
| 31868 | Vancouver ID Research and Care Centre Society    | 10   |
| 31918 | Hospital Federal dos Servidores do Estado        | 10   |
| 5802  | The Ponce de Leon Ctr. CRS                       | 10   |
| 11701 | Chennai Antiviral Research and Treatment CRS     | 10   |
| 31791 | Whitman-Walker Health CRS                        | 9  |
| 2401  | Cincinnati CRS                                   | 9  |
| 31954 | Centro de Referencia e Treinamento               | 9  |
| 6201  | Penn Therapeutics CRS                            | 8  |
| 12301 | SOWETO   | 8  |
| 31925 | Hospital Escola Sao Francisco de Assis           | 8  |
| 3752  | Dallas VA Medical Center                         | 7  |
| 31443 | Trinity Health and Wellness Center               | 7  |
| 7804  | Weill Cornell Chelsea CRS                        | 7  |
| 31470 | Denver Public Health                             | 7  |



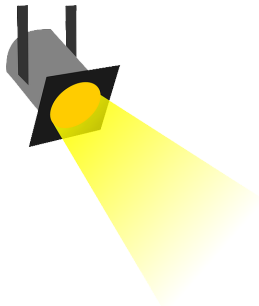
FAQ

**Q: We have a question about how to enter race in the Subject Enrollment System (screening checklist) vs. how to enter race to calculate a participant's 10-year ASCVD risk score. Must we select the same race on each?**

**A:** On the **screening checklist**, your site team may select more than one race, as you see fit for any particular participant (there is no specific guidance in the MOPS).

On the **10-year ASCVD risk calculator spreadsheet**, only one race may be selected (with guidance as per the REPRIEVE MOPS, Section 2.1, see Important Notes).

For this reason, the race entries into the screening checklist and the calculator may not be 100% concordant.



## REPRIEVE Team Spotlight: HGNI HIV Family Care Clinic 31927



The HGNI Team (some important member of the team are not present)

The **HGNI HIV Family Care Clinic #31927**, based in Rio de Janeiro, Brazil, has enrolled **77** participants in the 30 weeks that they have been activated! They shared how they achieve strong enrollment in REPRIEVE:

"We have a great clinical care team, and they are always **vigilant to possible participants every day**. Every day we remind them of the inclusion and exclusion criteria! Furthermore, the HGNI REPRIEVE team is working hard to include the most

participants we can. Our study coordinators, lab and pharmacy team, and subinvestigators **understand the magnitude of the data we are generating** and how this may impact our society. We are very proud to be part of this"

**Thank you to the HGNI Team for sharing their effective recruitment strategies!**

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## **Microsoft Bug: ACTION REQUIRED for Lab Processing Chart**

We have become aware of a Microsoft glitch that affects some Word 2016 and Outlook 2016 programs. For some of you, this means that the recently revised LPCs for REPRIEVE (A5332) – both the ACTG and Non-Network LPCs dated 9/21/17 – have some missing information and should not be used. The problem is that text in any

cells that were merged vertically disappears when viewing or printing. More information can be found here: <https://support.office.com/en-us/article/After-installing-KB-3213656-or-KB-4011039-merged-table-cells-don-t-work-correctly-in-Word-or-Outlook-8c7af9eb-9e48-4e1e-8c13-6340ede4acdc>.

**To be sure that no one uses an incomplete LPC, we have removed the Word versions of these LPCs from the PSWP for now, and we posted revised PDF files. Please download the PDF version of your LPC again, using the links below:**

- **ACTG Sites Download:**  
<https://member.actgnetwork.org/cms/dl/29042/a5332v3revlpc092117>
- **Non-ACTG Sites Download:**  
<https://member.actgnetwork.org/cms/dl/29040/a5332v3revlpc-non-network092117>

**Thank you for checking on the accuracy of your REPRIEVE LPC and for using the corrected file. If you have any questions, please email [reprieve.labcom@fstf.org](mailto:reprieve.labcom@fstf.org).**

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## **Timeline for REPRIEVE DSMB Meeting Friday, December 15th, 2017**

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 important dates in your calendar and note that **Friday, Oct 13 is**

the data entry deadline.

| Task  |   | Deadline*<br>(2017) |
|-------|---|---------------------|
|       | Latest date for the occurrence of an evaluation for which complete data will be included in this DSMB review  | Sep 30 (Sat)        |
| Sites | <ul style="list-style-type: none"><li>All data for visits through Sep 30 entered</li><li>All adjudication packets for potential MACE events with a work-up complete by Sep 30 submitted to DCC (MGH)*</li></ul> | Oct 13 (Fri)        |
| Sites | All outstanding queries resolved  | Nov 3 (Fri)         |
| Sites | Respond to last minute outstanding queries  | Nov 14 (Tue)        |
|       | <i>US holiday: Thanksgiving</i>   | <i>Nov 23-24</i>    |
| All   | DSMB Meeting  | Dec 15 (Fri)        |

\*Please make every effort to have all adjudication packets completed and submitted to the DCC by October 13th



Our REPRIEVE Lab Data Managers have written useful guides for 1) using LDMS visit codes, 2) LDMS preloads and quick add tips, 3) using the query system.

Lab Tips

In the [LDMS Visit Codes Guide](#), you'll find:

- directions on using visit codes for various visit types
- tips on how to handle unique situations in LDMS

[LDMS Preloads and Quick Add Tips](#) includes:

- Your lab's responsibility
- Benefits of Using Preloads and Quick Add

[Query System Instructions](#) includes tips on:

- accessing the query system

- your lab's responsibility
- reasons you may be receiving a query
- how to get assistance

[Click here to download](#)

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## Please Join the Next Monthly Site Call!

*Tuesday, October 17th between 1:00 - 2:00 PM Eastern Time*

Don't miss the important REPRIEVE updates, clarifications and Q&A that are shared during these calls!



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



## TRAINING OPPORTUNITIES

### Next WebLDMS 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, Oct 18, 2017 12:00 PM Eastern Standard 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](mailto:ldms_training@fstrf.org) to request this information.

Training Opportunities

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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 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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