



REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 07/10/2017

Table of Contents

- [REPRIEVE Trial Status](#)
- [1by1by1 Enrollment Challenge Standings](#)
- [REPRIEVE in the News](#)
- [Welcome to Our New International Sites!](#)
- [Team Spotlight](#)
- [A Reminder about Urine Collection](#)
- [FAQ](#)
- [REPRIEVE \(A5332\): Are you up to date?](#)
- [REPRIEVE Mechanistic Substudy \(A5333s\): Are you up to date?](#)

REPRIEVE Trial Status: July 10th

3842 participants are enrolled

201 participants are in screening

112 sites are open for enrollment

24 sites have enrolled at least 1 participant in the past week

20 sites have screened at least 1 participant in the past week

**Thank You to All Sites Enrolling
Participants Week of 07/03/2017!**

Massachusetts General Hospital (MGH) CRS
Harbor UCLA CRS
UCSF HIV/AIDS CRS
Univ. of Miami AIDS Clinical Research Unit(ACRU) CRS
Cincinnati CRS

Northwestern University CRS
 Wits Helen Joseph Hospital CRS (Wits HJH CRS)
 Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS
 Hospital Nossa Senhora da Conceicao CRS
 SOWETO
 Gaborone CRS
 Chiang Mai University HIV Treatment CRS
 Whitman-Walker Health CRS
 Thai Red Cross AIDS Research Center
 AIDS Research Treatment Center of the Treasure Coast
 Los Angeles LGBT Center
 Kinder Medical Group
 UT Southwestern
 James J Peters VA Medical Center
 Chronic Viral Illness Service of McGill University
 School of Medicine, Federal University of Minas Gerais CRS
 HGNI HIV Family Care Clinic HHFCC
 Tropical Medicine Foundation
 Palmetto Health Clinical Trial Department

1by1by1 Enrollment Challenge Standings



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

If **ALL** activated sites enroll **11 participants (per site)** between July 1st and October 31st we will achieve **75% of the 6,500** enrollment target!!!

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.

Sites that are in the lead!		
		Participants Enrolled Since 7/1
31946	Tropical Medicine Foundation	8
12201	Hospital Nossa Senhora da Conceicao CRS	7
12701	Gaborone CRS	5
31802	Thai Red Cross AIDS Research Center	3
31927	HGNI HIV Family Care Clinic HHFCC	3
2401	Cincinnati CRS	2
11101	Wits Helen Joseph Hospital CRS (Wits HJH CRS)	2
12101	Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS	2
31864	UT Southwestern	2
31915	School of Medicine, Federal University of Minas Gerais CRS	2

REPRIEVE in the News



Steve Grinspoon, MD and Udo Hoffman, MD, both REPRIEVE PIs, recently wrote an editorial, ["Cardiovascular Imaging in HIV: Novel Phenotypes and New Targets for Risk Reduction"](#). They provide a nice overview of REPRIEVE while discussing the value of cardiovascular imaging in HIV.

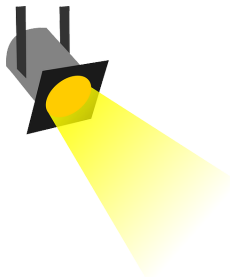
The Journal of the American College of Cardiology published an extensive [review](#) of atherosclerosis in HIV and mentions REPRIEVE.

[A new article](#) in POZ Magazine examines the promising future of HIV treatment, highlighting the REPRIEVE Trial as an important study "that may improve the health of people with HIV on numerous fronts". This is a great article to alert your participants to.

Welcome to Our New International Sites!

If your site is newly enrolling participants and is outside of the US, please see below for some tips that may be helpful as you begin screening and enrolling:

- There is information about converting SI units to conventional units in the MOPS section 2.0, Instructions for Calculators.
- There are several links to the ASCVD Risk Assessment Tool found on the web. For REPRIEVE, only use the link found in the MOPS section 2.1. Also, be sure to use the 10-Year Calculated Risk score for eligibility. Do not use the “Lifetime Risk” or “Risk With Optimal Risk Factors” or any other score that you may see on this website. The MOPS has illustrations to help you.
- It is permissible for the participant’s race entered on the enrollment checklist to be discordant from the race entered for the ASCVD risk score:
 - On the 10-year ASCVD risk calculator, only one race may be selected (with guidance per MOPS section 2.1, including what to do for participants of mixed race).
 - On the demographics section of the enrollment checklist, you may select more than one race, as you see fit for any particular participant (with no special instructions in the MOPS).
 - Ethnicity and race should be self-reported and not determined by the interviewer.
- Estimates of kidney function can be obtained using calculators other than Cockcroft-Gault. Links to the specific calculators, ie, MDRD, CKD-Epi, and Cockcroft-Gault, are in MOPS section 2.3.



Team Spotlight: Lab Data

Managers



Left to right: Kaitley Wozer, Heather Sprenger, Andee Fox

As Lab Data Managers, Kaitley and Andee track sample collections and storage while communicating with labs about discrepancies and missing items. They coordinate specimen shipment to testing labs and act as a liaison between testing labs and statisticians for incoming data. Both have been working at Frontier Science since May 2016.

Heather Sprenger is the Laboratory Data Division Chief at Frontier Science, where she has worked since June 2002. Heather provides instruction and oversight to the laboratory data managers and collaborates with other departments at Frontier Science to make sure the REPRIEVE laboratory data needs are met.

Kaitley, Heather and Andee all participate on the REPRIEVE Laboratory Committee.



A Reminder about Urine Collection

Correction from newsletter, June 26th, 2017:

For all sites participating in REPRIEVE (ACTG and non-ACTG), please collect urine at entry.

- ACTG sites are to collect urine and aliquot to **(2)** 1.0mL cryovials.
- non-ACTG sites are to collect urine and aliquot to **(1)** 1.0mL cryovial.

For all ACTG sites, please also collect urine at month 12, 24, and 48 and aliquot to **(1)** 1.0mL cryovial.



We just had our first Month 12 visit and there is a little bit of confusion between what is required as per the protocol and what is being collected in OpenClinica. Below are my questions.

Q: OpenClinica asks about urine collected under study samples but I thought that urine for alb/creat should be collected at ACTG sites only and I work at a non-ACTG site. Is this for the same urine?

A: You are right, because you are at a non-ACTG site you are not required to collect urine after Entry to send to the repository, this additional collection is only done at ACTG sites. We cannot modify the content of a form to change per visit, or per site network. All sites have one version of

the form, with the same content, and can answer the questions per the collection done at that site at that visit. Indicate "No" for Urine specimens obtained at this visit if it isn't collected for your site at this visit per the protocol.

Q: OpenClinica requests a waist circumference measurement at the Month 12 visit however as per the protocol it doesn't appear that this is collected after Screening until Month 72. Please clarify.

A: You are correct that waist circumference measurements are only collected at Screening and Month 72. To complete the eCRF, click on "Mark the CRF Complete" box before you save the form. We cannot modify the content of a form to change per visit. All possible vital signs collected for the study are listed on the form. You only have to enter values into fields due at the visit the form appears in, leave the fields not due at that visit blank if you did not collect them, or they can optionally be entered.

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:

New! 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](#)



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@fstf.org.

REPRIEVE Trial Clinical Coordinating Center
Massachusetts General Hospital
55 Fruit Street, LON 207
Boston, MA 02114

Want to change how you receive these emails?
You can [update your preferences](#) or [unsubscribe from this list](#)

This email was sent to <<Email Address>>
[why did I get this?](#) [unsubscribe from this list](#) [update subscription preferences](#)
Massachusetts General Hospital · 5 Longfellow Place · Boston, MA 02214 · USA

