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Randomized Trial to Prevent Vascular Events in HIV

Trial Status

June 25, 2018

6764 participants are enrolled

22 participants enrolled last week

259 participants are in screening

117 sites are open for enrollment

17 sites enrolled at least 1 participant in the past week

20 sites screened at least 1 participant in the past week

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 June 18th, 2018!**

Brigham and Women's Hospital Therapeutics CRS
 Duke University Medical Center
 Penn Therapeutics CRS
 Family Clinical Research Unit
 Wits Helen Joseph Hospital CRS (Wits HJH CRS)
 San Miguel CRS
 Chennai Antiviral Research and Treatment (CART) CRS
 Joint Clinical Research Centre (JCRC)/Kampala CRS
 Les Centres GHESKIO Clinical Research Site (GHESKIO-INLR) CRS
 Columbia Physicians and Surgeons CRS
 Chiang Mai University HIV Treatment CRS
 Centro de Pesquisas Clinicas ICHCFMUSP CRS
 Instituto de Infectologia Emilio Ribas CRS
 HGNI HIV Family Care Clinic HHFCC
 Tropical Medicine Foundation
 University of Toledo Medical Center
 Palmetto Health Clinical Trial Department

**Push to the Finish
Line!**



If you were unable to join the Monthly Site Call on June 19th the new target enrollment timeline was discussed. The new date to reach target accrual is April 2019.

- While REPRIEVE continues to move forward at a steady pace, we need YOUR help getting to the finish line!
- We are less than 1000 participants away from the trial's accrual target.
- How can we reach target accrual?
 - **Site Goal:** We ask that sites continue to actively recruit participants and attempt to maintain an accrual rate of at least 2 participants/month.
 - **Trial Goal:** Overall trial weekly accrual goal is 20 participants/week.



REPRIEVE

<http://followyourheart.reprievetrial.org/news/>

Join the Study »
Women's Health Info
Printable Advertisement Materials
My Heart Matters: Blog

NEW *My Heart Matters* Blog by Follow YOUR Heart

The REPRIEVE **Follow YOUR Heart Campaign** invites you to read the latest **My Heart Matters Blog**, [The Patient's Voice](#). This blog addresses wellness visits are essential to having important conversations with healthcare providers.

In case you haven't checked it out, the **My Heart Matters Blog** is a great resource to help facilitate communication between REPRIEVE investigators and women with HIV who are interested in learning more about health, research participation, and the REPRIEVE trial. Please share this [webpage](#) with your participants. The blog is updated every other month.



Q: Are people with diabetes eligible to participate in REPRIEVE?

People with diabetes (defined below) with an LDL <70 mg/dL *may* be eligible for REPRIEVE. There is no HbA1c cutoff.

For REPRIEVE, current diabetes is defined by patient report of physician diagnosis. It is important to know that potential participants with a history of diabetes that has resolved and who no longer require therapy are not considered to have current diabetes, eg, history of gestational diabetes, steroid-induced or medication-induced diabetes.

Candidates who have diet-controlled diabetes and otherwise qualify for REPRIEVE may also be eligible.

People on oral medications for diabetes may qualify with lifestyle intervention to improve blood glucose, if they are able to come off these medications, they may be eligible to participate in REPRIEVE. This is an excellent opportunity to encourage lifestyle modification to improve blood glucose!

Other Conditions That are NOT Exclusionary
(This list is not exhaustive but the team is frequently asked about them)

Condition	Comment
Chest pain of unknown etiology, or of non-cardiac nature, eg, cocaine-induced vasospastic event	Criterion 4.2.1 is intended to exclude from participation those individuals who have experienced clinical atherosclerotic cardiovascular disease, including TIA and stroke presumed to be of atherosclerotic origin.
Congenital AV block	
Fibromyalgia	This is not considered muscle inflammatory disorder or myopathy
Self-limited bout of flu	But if hospitalization for the flu was required, the participant should be assessed for eligibility 30 days after resolution.
CIS of the anal canal/basal cell skin cancer/squamous cell skin cancer	



*****Please forward this information to the relevant laboratory personnel at your**

site***

Shipping Specimens 1st Week of July?

If you use Fed Ex to ship specimens to BRI and are planning on shipping specimens the first week of July, we recommend you ship the 4th week of June (the current week) or the 2nd week of July. This is due to the US holiday on the 4th of July.

Please make sure to email our BRI colleagues to notify them of this schedule adjustment by emailing brirepository@afbr-bri.com.

Thank you very much for your attention to this matter!



Helpful LDMS Resources!



Take a moment to explore the [Resources page](#) on the LDMS website. The [Training Materials page](#) has Quick References to help you with Quick Add/Preloads. The [Videos page](#) has 3 REPRIEVE specific videos including:

[Shipping for REPRIEVE](#)

[Specimen Management for REPRIEVE](#)

[Storage Management for REPRIEVE](#)

The LDMS team is always updating this website and adding new tools to help you! Check back periodically to make sure you aren't missing anything.



What is the Goal of the REPRIEVE Retention Champion Initiative?

Via a 30-minute, one-on-one phone call with each [Retention Champion](#), we will determine:

- Current retention practices
- How REPRIEVE leadership can best support sites in their retention efforts
- Useful resources to include in a Retention Toolkit

Members of the Clinical Coordinating Center are reaching out to [Retention Champions](#) this week to schedule calls. If you have not already identified a Champion, email Emma Kileel at the CCC ekileel@mgh.harvard.edu



Miss the Monthly Site Call on June 19th?

[Click here](#) to download and review the slides if you haven't done so already.

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 4.0 dated 03/28/2018

V4 LOA #1 dated 05/16/2018

MOPS Version 4.0 dated 04/10/2018

A5332 LPC for ACTG Sites Version 4.0 dated 03/22/2018

A5332 LPC for Non-ACTG Sites Version 4.0 dated 03/22/2018

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

Mechanistic Substudy of REPRIEVE (A5333s): Are you up to date?

For A5333s please use

Protocol Version 4.0 dated 03/28/2018

MOPS Version 4.0 dated 04/10/2018

A5333s LPC Version 4.0 dated 03/23/2018

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



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