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Randomized Trial to Prevent Vascular Events in HIV



Remind REPRIEVE participants of the important contributions they are making to advance scientific knowledge about HIV and comorbidities by:

- 1. Ensuring they are aware of the recent supplement of REPRIEVE articles published in the Journal of Infectious Diseases. Access full articles by clicking here.
- 2. Ensuring they are aware of the plain language summaries of each article on the REPRIEVE website, <u>click here!</u>*
- If you would like a hard copy brochures of the plain language summaries, <u>sign</u>
 <u>up here</u>, please indicate quantity and language desired.

*Plain language summaries have been approved by the Partners IRB for the REPRIEVE CCC however, please submit to your local IRB/EC as per their requirements.



SAVE THE DATE!

The 2nd REPRIEVE Team Sites Virtual Meeting will take place on Wednesday, October 14th, 9:00 AM - 10:30 AM EDT

During this virtual meeting summaries of 3 articles in the recent Journal of Infectious Diseases supplement,

<u>Critical Comorbidities in the Modern Antiretroviral Era:</u>

<u>Baseline Demographic, Metabolic, and Immune</u>

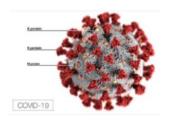
<u>Characteristics of the Global REPRIEVE Trial Population</u> will be presented.

Join us to hear from:

- Sara Looby, PhD, and Markella Zanni, MD, Correlates and Timing or Reproductive Aging Transitions Among Midlife Women in REPRIEVE
- Laura Smeaton, MS, Characteristics of REPRIEVE Participants Identifying Across the Transgender Spectrum
- Markella Zanni, MD and Tomas Neilan, MD, *Myocardial Steatosis Among ART-treated People with HIV in REPRIEVE*

Below is the link to join the live stream on October 14th http://healthcare.partners.org/streaming/Live/MGH/2020_REPRIEVE_Meeting.html

If you missed the first Virtual Meeting on July 24th, you can access the recorded presentations using the same link.



Tips for Completing the COVID-19 Assessment (SSW0040) CRF

- Complete the COVID-19 Assessment CRF at every visit.
- Question 4 on the COVID-19 Assessment CRF inquires about results of COVID-19 testing.
 - Please answer "yes" for any positive result from any of the COVID-19 testing platforms including SARS CoV2 PCR, Rapid Antigen tests and also antibody tests.
- If a participant was hospitalized for COVID-19 (primary reason for hospitalization) (response to Question 5 is "yes"), complete the following:
 - Respond "Yes" to question 9 on the Adjudicated Events Tracking CRF (TRK0150).
 - Complete the associated Heart Failure Event CRF (EVW0339) and submit the required source documents for this event as per instructions in Section 6.0 of the A5332 MOPS.
 - On the AE log, record the diagnosed event (COVID-19 diagnosis) and indicate hospitalization as the reason for the SAE. The COVID-19 hospitalization is not required to be reported in DAERS as an EAE.*

*The MOPS is being revised to include this guidance.



REPRIEVE is in the News!

Check out recent press about REPRIEVE related to the Journal of Infectious Diseases supplement.

- In Poz, Major Global Study of HIV's Ties to Heart Disease Is a Data Goldmine, click here.
- From the Massachusetts General Hospital, Initial data from the landmark REPRIEVE study on HIV and heart disease

- highlights the multiple health risks among a population that's living longer, click here.
- In the NIAID Now blog, Large NIH Clinical Trial Illuminates Long-Term Health Effects of HIV, click here.

Please share these important write-ups about REPRIEVE with your participants!

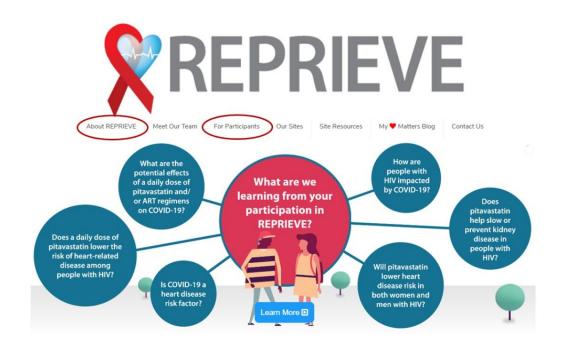


Complete the Re-Opening Attestation Form for REPRIEVE (A5332)!

On August 17th, an email with a CRS Reopening Attestation Form was distributed. If your site had paused in-person visits and is ready to resume them, or has already resumed inperson visits, click here to download and complete the reopening attestation form.

For NON-ACTG sites, please know that the ACTG Lab Center will not be providing separate approval for your site. Please make a note of this on the form, <u>click here</u> for example.

What's New on the REPRIEVE Website?



- We've added a new <u>Publications Page</u> in the About REPRIEVE section. This
 page is dedicated to REPRIEVE publications and includes plain language
 summaries of recent publications.
- The homepage includes a new animation with FAQs about REPRIEVE!
- The For Participants Page includes the 2020 Participant Newsletter!

Check out the updates at www.reprievetrial.org and make sure to let your participants know about these updates!

If you would like hard copies of the plain language summaries of recent publications for your participants, <u>click here</u> to sign up, please indicate number and language you would like to receive.

Sharing the plain language summaries with your participants (either digital or hard copy) is extremely important. This way, they will be able to see how their participation in REPRIEVE is contributing to the knowledge of HIV associated heart disease and comorbidities.



Attention: Sites in Hurricane Regions!

Please be aware that we are currently in the peak of hurricane season (late August - September). If your site is in a region that may be affected by hurricanes, please be cautious when sending specimens to BRI. If you need to send specimens to BRI out of your assigned schedule, make arrangements with the repository manager by emailing: brirepository@afbr-bri.com.

And most importantly... STAY SAFE!

Who's Who on the REPRIEVE Team?

Meet Sara McCallum, MPH, Senior Programmer Analyst



Sara is a statistical programmer with REPRIEVE's Clinical Coordinating Center at MGH. In this role, Sara prepares reports such as the Specimen Availability Report and the DSMB reports. To prepare these reports Sara works alongside the biostatisticians at the Center for Biostatistics in AIDS Research (CBAR). In the past, Sara has worked on other ACTG studies including HAILO.

A fun fact about Sara is that she just moved from Boston to Florida, she shares that "while I will miss skiing, I love taking my great dane to the beach."



Next Team/Site Call Tuesday, September 22nd, 2020, 1:00 - 2:00 PM EDT Please join us to hear REPRIEVE updates. A calendar invite with call details has been emailed, if you did not receive it please contact Jhoanna Roa by emailing Jhoanna.Roa@dlhcorp.com

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 5.0 dated 04/01/2019
Version 5.0, Clarification Memo 1 dated 04/03/2020
Version 5.0, Clarification Memo 2 dated 05/04/2020
Version 5.0, Letter of Amendment 1 dated 06/19/2020
MOPS Version 5.0 dated 07/15/2020
A5332 LPC for ACTG Sites Version 5.0 dated 05/04/2020
A5332 LPC for Non-ACTG Sites Version 5.0 dated 05/04/2020
These documents are on the A5332 PSWP

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

For A5333s please use

Protocol Version 5.0 dated 04/01/2019 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







REPRIEVE Trial Clinical Coordinating Center

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