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# REPRIEVE

# **Randomized Trial to Prevent Vascular Events in HIV**

As REPRIEVE sites begin to resume in-person visits, participant safety remains our top priority. During the current pandemic, study visits remain vital for the trial. Please make every attempt to contact study participants and perform study visits as scheduled, whether in person or remotely, within the designated visit windows. The ACTG will be sending out communications shortly about re-opening. We encourage all sites to maintain frequent communication with your participants and keep them informed of any changes to visit procedures at your site.

Please email the REPRIEVE core team at <u>actg.corea5332@fstrf.org</u> with any questions or concerns.

Thank you for all your efforts on REPRIEVE!



## Six REPRIEVE Manuscripts Available For Free Online!

In case you missed it, the supplement of articles showcasing baseline data from REPRIEVE, *Critical Comorbidities in the Modern Antiretroviral Era: Baseline Demographic, Metabolic, and Immune Characteristics of the Global REPRIEVE Trial Population,* is now available online, all articles are FREE to VIEW! <u>Click here</u> to read the full set of articles!

The REPRIEVE Clinical Coordinating Center is developing participant summaries of these articles that will be available digitally, on the REPRIEVE website, and in hard copy. Stay tuned for future communications about this!



Thank you to REPRIEVE site investigators and staff who were able to join the first virtual REPRIEVE Investigator's meeting on July 24th! Also, a big thank you to the presenters, Sandra

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Wagner Cardoso, Carl Fichtenbaum, Kristine Erlandson, and Turner Overton.

This format was a success with approximately 300 people joining the live session. If you were unable to join, you can watch the recorded session: <u>click here</u>.

*Stay tuned!* We are planning a second virtual meeting that will include 3 additional presentations on articles recently published as part of the Journal of Infectious Diseases supplement.

What's New on the REPRIEVE (A5332) Protocol Specific Webpage?



#### Current Protocol Status Announcements Folder

CMS Path » A5332 » Current Protocol Status Announcements



The A5332 MOPS has been revised as follows:

# SECTION 4.0 INSTRUCTIONS FOR DATA COLLECTION

- Instructions for assessment for COVID-19 were updated in subsection 4.2.
- The note regarding missed specimen collection was updated, and a new note was added about incomplete specimen collection in subsection 4.3.

# SECTION 6.0 ENDPOINT ASSESSMENT AND ADJUDICATED EVENTS

• The COVID-19 Assessment CRF was added as a source document requested for each adjudicated event listed in subsection 6.1.3.

Additional updates on the PSWP include a revised COVID-19 Medications List, dated 07/28/20. This list is located in the Current Protocol Specific Support Documents folder. Please refer to the MOPS, subsection 4.2 for additional details on when to use this list.

# Meet REPRIEVE CAB Member Shirley Selvage!



Shirley lives in Birmingham Alabama. She has her Master's degree in Community Health Education and a certificate in health coaching. Currently, Shirley works at the UAB 1917 Clinic as a Coordinator of Health Education and has served as chair of their Patient Advisory Board (PAB) for five years. In addition to serving as a REPRIEVE CAB member, she is a member of the Positive Leadership Council (PLC) and National CFAR Community Coalition (N3C).

In 2015, Shirley created a facilitators manual to train individuals living with HIV how to become effective speakers. She provides quarterly workshops to patients at the 1917 clinic and other HIV organizations in the community. Her work landed her a feature in the December 2016 POZ Magazine. In 2019, she shared her story at the National Prevention Conference for the CDC.

As a long time survivor - 21 years of living with HIV - Shirley understands the importance of clinical trials. She believes in not only participating in a study, but being a part of the process. Cardiovascular disease is the most common chronic disease in the African American community. As an African American female living with HIV, she recognizes the increased risk of co-morbidities compared to a person living without HIV. Her purpose for serving on REPRIEVE CAB is to bring awareness, research, prevention and education about statin drugs that could help reduce heart disease in those living with HIV.

Thank you, Shirley, for being such an important part of REPRIEVE!

# Who's Who on the REPRIEVE Team?

Meet Rochelle Louis, Clinical Research Coordinator at the MGH Data Coordinating Center!

Rochelle joined the Data Coordinating Center (DCC) in 2019 as the primary coordinator for the REPRIEVE Mechanistic Substudy (A5333s) and is now replacing Allen Jin as the primary coordinator for REPRIEVE (A5332) adjudication. She is responsible for the collection, completeness, and transfer of source documentation information between the Clinical

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Research Site (CRS) and the Clinical Events Committee (CEC). Outside of work, Rochelle enjoys ballroom dancing and learning new languages.

For any questions regarding a potential adjudication event, please don't hesitate to contact Rochelle at: <u>RLOUIS7@mgh.harvard.edu</u> or <u>MGHReprieve@partners.org</u>



#### Don't forget to submit the following to your local Institutional Review Board (IRB)/Ethics Committee!

#### DSMB Summary Report

If you missed the email with the DSMB summary, it is available on the REPRIEVE (A5332) protocol specific webpage under Study Monitoring (NHLBI DSMB Reports).

#### Protocol Version 5.0 Letter of Amendment (LOA) #1

In addition to submitting the LOA to your local IRB/ECs, please don't forget to register Protocol V5.0 LOA 1.0 with DAIDS PRO within 14 days of IRB/EC approval.



### Read the July 2020 DAIDS OCSO Newsletter!

The DAIDS Office of Clinical Site Oversight (OCSO) Monitoring Operations Branch has released the July 2020 edition of the OCSO MOB Newsletter. Read about "Benefits of Remote Monitoring", "Monitoring During Coronavirus Pandemic" and more by clicking <u>here</u>!

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Next Team/Site Call Tuesday, September 15th, 2020, 1:00 - 2:00 PM ET

Please join us to hear REPRIEVE updates. Details regarding the call will be sent closer to the date!

#### 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 <u>A5332 PSWP</u>

#### 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 <u>A5333s PSWP</u>

# 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 <u>reprieve.news@fstrf.org</u>



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