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Randomized Trial to Prevent Vascular Events in HIV

REPRIEVE in the Context of COVID-19

REPRIEVE leadership is fully aware of the fast-moving situation related to COVID-19 and values first and foremost the health and safety of our participants as well as study staff. **An email containing guidance about the study conduct of REPRIEVE in the context of COVID-19 was distributed earlier today by Laura Moran.**

[Click here](#) if you did not receive the email.

As always, questions can be emailed to the REPRIEVE Core Team at actg.corea5332@fstrf.org.



Know Your Site's Retention Metrics

Retention metrics are included in the Biannual Evaluation Letters, distributed via email to each Site PI and Study Coordinator every 6 months.

The purpose of the evaluations is to provide sites with a detailed overview of their performance in REPRIEVE and to ensure efficient conduct of the trial overall.

The Site Selection and Performance Committee (SSPC) evaluates Participant Retention, Data Management, Laboratory Data Management, and Expedited Adverse Event Reporting.

[Here is how the SSPC evaluates Participant Retention:](#)

- The SSPC looks at a site's overall treatment discontinuation rate and study discontinuation rate.
- The trial standard is that these **rates remain below 5/100 person-years at each site.**
- The SSPC also looks at the change in absolute (%) treatment discontinuation and study discontinuation over the past 6 months.

If your site's retention is above 5/100 person-years please discuss as a team how you can improve retention.

Several tools are available to help you with participant retention and include:

- A participant friendly website
- Annual participant newsletter--the 2020 newsletter will be distributed soon, [click here](#) to order hard copies.
- REPRIEVE branded tokens of appreciation (i.e. "swag")
- Retention Toolkit

Tools are available at: www.reprievetrial.org.



This year due to concerns about COVID-19, CROI is taking place virtually, therefore the REPRIEVE Investigator Meeting was cancelled.

While this is disappointing, taking measures to maintain health and safety is essential. The good news is that these presentations, which featured data collected at baseline, will be presented during the next two site calls!

On the April 21st site call, the following will be presented:

- ***Patterns of Antiretroviral Therapy Use and Immunologic Profiles at Enrollment in REPRIEVE.*** Carl Fichtenbaum, MD, Protocol Vice Chair, University of Cincinnati
- ***An Evaluation of Baseline Kidney Function in the REPRIEVE Trial.*** Turner Overton, MD, Protocol Vice Chair, Kidney Ancillary Objective Principal Investigator, University of Alabama

On the July 21st site call, the following will be presented:

- *Physical Function Impairment and Frailty in Middle-aged People Living with HIV in the REPRIEVE Trial (PREPARE)*. Kristine Erlandson, MD, PREPARE Co-Principal Investigator, University of Colorado.

Please make every effort to join the site calls to hear these important presentations. Email communications with call details are forthcoming so stay tuned...



Great news!

The manuscript describing the recruitment methods used to recruit REPRIEVE participants has been accepted for publication!

REPRIEVE Leadership would like to congratulate the entire REPRIEVE team including Clinical Research Sites, REPRIEVE participants and the Clinical Coordinating Center on the acceptance of the manuscript titled “Successful recruitment of a multi-site international randomized placebo-controlled trial in people with HIV with attention to diversity of race and ethnicity: Critical role of central coordination” in [HIV Research and Clinical Practice](#)!

- This manuscript highlights the enormous recruitment efforts undertaken by the Clinical Coordinating Center and Clinical Research Sites and outlines how REPRIEVE successfully recruited over 7,500 participants and became the largest randomized placebo-controlled clinical trial in HIV/CVD to date!



REPRIEVE (A5332) **contract modifications** are forthcoming to extend the Period of Performance to April 30th, 2021. Should you have any questions please contact REPRIEVE.finance@mgh.harvard.edu.



Q: I have been notified about 3 ER visits for intermittent chest pain for one of our REPRIEVE participants. This participant has missed a few study visits including study treatment dispensation. We hope the participant will return for a study visit and therefore we have not completed a premature study discontinuation visit for the participant. Do I report the intermittent chest pain as a potential adjudicated event and if so, should the 3 instances of chest pain be keyed as 1 event or 3 separate events?

A: The chest pain reported by the participant at 3 ER visits should be keyed on the following in OpenClinica:

- ADE0001 – Adverse Event Log
- TRK0150 – Adjudicated Event Tracking CRF
- EVW0337 – Cardiac Ischemia or MI Event CRF

It is up to the Site PI or designate to determine if the events should be keyed as 1 event or 3 separate events. Based on that determination, 1 or 3 events will be keyed into the AE Log, and 1 or 3 EVW0337 forms will be keyed. If there are questions at the site regarding how best to key the chest pain, email the REPRIEVE (A5332) core team at actg.corea5332@fstrf.org.

Section 6.0 of the REPRIEVE (A5332) MOPS provides guidance on the process to submit potential events for adjudication.



A Reminder About Laboratory Queries

Laboratories may receive queries for a variety of reasons, including: missing assay results, duplicate assay results, date or time discrepancies, visit discrepancies, specimens not shipped, or specimens not logged into LDMS.

Your laboratory's responsibility: If your lab receives a query, it will be sent via email. *Do not respond to the email notification.* This is an indication that you need to log into the [DMC Portal](#) under the REPRIEVE project and review the laboratory query in the Query System. Recipients of queries are expected to provide an adequate response to the query within two weeks.

Getting Help: If you encounter a problem or need help using Laboratory Query System, contact User Support at ldmshelp@fstrf.org or +1 716 834-0900 x7311.

[Click here](#) to download more detailed guidance about Laboratory Queries.

Who's Who on the REPRIEVE Team?

Meet Francoise Giguel and Joan Dragavon, REPRIEVE Laboratory Technologists!

The REPRIEVE Team is so lucky to have 2 amazing Lab Techs as part of the team. Joan and Francoise assist sites and labs to maintain a smooth flow of participant

specimens, preserving their integrity through training, team work, and assisting sites with questions about specimen collection, processing and shipping. Their ultimate goal is to ensure the quality of the specimens that REPRIEVE participants so graciously provide. To that end, the details of processing, documentation, storage and shipping are so very important.

We encourage labs to contact the REPRIEVE lab team with questions at any time: reprieve.labcom@fstrf.org the team is available to help.



Joan Dragavon is a Research Scientist in the Virology Specialty Laboratory at the University of Washington.

Joan's interest in viruses developed during high school when her neighbor, a virologist at a poultry disease research facility, hired her as a "gofer" to wash lab dishes the summer of her junior year. She learned to draw blood from mostly uncooperative chickens, aseptic technique to make cell culture media and observed the preparation and maintenance of chick embryo fibroblast cell cultures and plaque formation assays for Rous Sarcoma virus and its helper Rous-associated adenovirus (Joan was hooked!). After Joan graduated from college, she was fortunate to land a position in a growing clinical and research virology laboratory. The research was first SIDS, next Herpes, and then HIV. In the mid-90s, she moved into Retrovirology in an ACTG/PACTG laboratory working for Dr. Robert Coombs and she currently works on projects for the ACTG and for the HVTN. She is always learning new things about virology.



Francoise is a Laboratory Supervisor at Harvard Virology Specialty Lab,

she has been involved in REPRIEVE since the very beginning and it is the first time she has worked as a Laboratory Technologist on a protocol. Francoise joined Ann Gershon's WITS lab at Columbia University in the mid-90s, then Marty Hirsch's ACTG lab at Massachusetts General Hospital in 1997 and finally Dan Kuritzkes' lab in 2002. Francoise has worked as the Harvard Virology Specialty Lab supervisor since 2010. A public servant at heart, Francoise started working in clinical labs when AZT was the only treatment available for the treatment of HIV. Francoise is extremely grateful for the opportunity that was given to her during the transformation that has rendered HIV a manageable disease. She is honored to be part of REPRIEVE and hopes that the results of this important trial will ultimately be beneficial to the public at large.

Don't Forget!
The Next Team/Site Call is



Tuesday, April 21st, 2020
1:00 – 2:00 PM ET

Team/Site Call Schedule:
Tuesday, July 21st 1:00 – 2:00 PM
Tuesday, October 20th 1:00 – 2:00 PM

If you have ideas or topics you would like to see covered in these calls, please email Katie Fitch at kfitch@partners.org. We would love to hear from you!

If you missed the January site call, [click here](#) to download slides.

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 5.0 dated 04/01/2019

MOPS Version 5.0 dated 11/29/2019

A5332 LPC for ACTG Sites Version 5.0 dated 04/11/2019

A5332 LPC for Non-ACTG Sites Version 5.0 dated 04/11/2019

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



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