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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

The REPRIEVE Leadership Team would like to wish all of you a healthy and safe holiday season

This year, as we continue to combat not one, but two viruses – HIV and SARS-CoV-2 – we want to thank our community of site investigators, staff, and participants, who have remained dedicated to the safety of one another and the important research we are doing together on REPRIEVE.

While 2020 has been challenging in ways we never imagined, despite the challenges, we have achieved many great accomplishments, *together,* including:

- Follow up of participants entering into its 5th year!
- Analysis and publication of baseline data in a supplement of manuscripts published in the Journal of Infectious Diseases.
- Ongoing analysis of baseline data--9 additional manuscripts are in development.
- Over 500 attendees joined the first ever REPRIEVE site/team virtual meetings.
- 2 successful DSMB meetings were held and DSMB members commended the REPRIEVE team on study conduct and participant retention, data timeliness and quality.
- Supplemental funding was awarded from the NHLBI and ViiV to study COVID-19 in the REPRIEVE cohort.

These accomplishments would not have been possible without your hard work and our common goal to better understand how to maintain health, especially heart health, as people with HIV age. We look forward to continuing our work together in

2021 and the years to come. Thank you, and we wish you all well over the holiday season.

Holiday Closures

- **BRI will be closed** on Friday, December 25th and Friday, January 1st. Please ship ONLY on Monday and Tuesday of these weeks. If your site is scheduled to ship during this time and you are unable to ship, please contact brirepository@afbr-bri.com to make alternate shipping arrangements.
- **Frontier Science will be closed** and no user support assistance will be available on Friday, December 25th or Friday, January 1st. If you have any questions, please contact user support by email at user.support@fstrf.org.

REPRIEVE Site Teams share their tips on how to maintain participant engagement and safety during the COVID-19 public health emergency

David Klein, from Whitman-Walker Clinical Research Site (31791), shares that he has been taking the time to try and reengage participants who may be lost to follow-up or chronically difficult to contact. Since participants are more likely to be at home during the pandemic, it may be easier to reach them.

And the good news is, is this effort has been fruitful. David had success in connecting with a participant who has been historically difficult to reach. The participant responded very positively to the remote visit format, but mostly was just extremely happy to have someone to chat with while isolating during the pandemic. David chatted with the participant about REPRIEVE and how they were managing during these difficult times.

"I think a lot of REPRIEVE participants are probably isolated at the moment, and just a little bit of conversation can really help them feel connected!"

The **Houston AIDS Research Clinical Research Site (31473)**, share their tips for successful long-term engagement in REPRIEVE:

- Establish a strong relationship based on empathy with each participant.
- Help participants to solve any problems at the clinic, including those not research-related, for instance, managing clinical appointments, non-study related medication issues, non-study related laboratory appointments, etc. It is important that the participants know they can count on the research coordinator!
- Provide tokens of appreciation (provided by the REPRIEVE CCC), such as birthday cards, face masks, calendars, pens, REPRIEVE bags, REPRIEVE newsletters, etc.
- Remind the participants, *at each visit*, the importance of their participation and commitment to the study.

Thank you to David and the Whitman Walker site team, and to Maria and Romina and the Houston AIDS Research site team, for sharing your engagement and safety tips and for all your efforts on REPRIEVE!

If you have an engagement tip you would like to share in a future newsletter, please email Katie Fitch at kfitch@mgh.harvard.edu.

- The **COVID-19 Medications List has been updated** on the REPRIEVE (A5332) Protocol Specific Web Page on the ACTG website (Current Study-Specific Support Documents folder). The updated list now includes vaccines for SARS-CoV-2 and Influenza.
- Before shipping specimens, **ensure that each cryovial label is CLEARLY printed and LEGIBLE**.
    - If BRI cannot read a cryovial label you will be asked to send replacement labels. If you need assistance contact the LDMS helpdesk by emailing: ldmshelp@fstrf.org
- If a participant misses the annual specimen collection, **there is guidance in the REPRIEVE (A5332) MOPS, section 4.3 about missed specimen collection**.

For participants who are off study complete the Vital Status and Endpoint Assessment CRF (VSW0025)

The Vital Status and Endpoint Assessment CRF (VSW0025) is intended to capture vital status and major adverse cardiovascular events (MACE) ***ONLY for a participant who is off study*** *for reasons other than withdrawal of consent or death.*

The VSW0025 CRF is to be completed annually beginning one year after the Date of Off-Study, as indicated on the Off-Study Form ***or*** at any time the site becomes aware of a potential MACE event or death for a participant who is off study.

Keying of the form is based on the attempt of contacting a participant who is off study in an effort to obtain vital status or endpoint information. **Even if contact is not obtained, the attempt and date of attempt should be recorded in Section A of the log.** However, do not enter on-study data (i.e. contacts, attempts at contact or events) from PRIOR to off study date on the VSW0025 CRF.

Should contact be made, additional information about the participant's vital status should be recorded in Section A of the log.

If it is discovered that a participant had a change in vital status or experienced a REPRIEVE MACE, additional information will be required in Section B of the log.

Please see **section 12.6 of the A5332 MOPs** for more information about Vital Status Assessment.

For participants who remain on study, please refer to section 6.0 of the A5332 MOPS for guidance about reporting potential MACE events, including deaths.

If you have any questions you can email the core team at actg.corea5332@fstrf.org.

Please complete a short survey to tell us about *Remote Source Document Verification* abilities at your site

Onsite monitoring continues to present challenges due to the COVID-19 public health emergency. The FDA is encouraging sponsors to consider optimizing the use of central and remote monitoring programs to maintain oversight of clinical sites. Guidance suggests the sponsor and monitors may consider multiple options to facilitate remote source document verification (rSDV).

To support DAIDS, REPRIEVE's regulatory sponsor in this effort, the REPRIEVE Clinical Coordinating Center is trying to better understand what rSDV systems may already be in place at clinical sites. Therefore, please take a minute to complete this brief survey by clicking here or scanning the QR code!

Thank you in advance for you help with this effort.

Update from the December 1st DSMB Meeting

We are pleased to share that **the REPRIEVE Data and Safety Monitoring Board (DSMB) unanimously approved the continuation of the trial.** The DSMB noted no safety concerns and praised the clinical research sites and trial leadership on the conduct of the trial in the midst of the COVID-19 pandemic.

We look forward to sharing updates from the meeting and the formal memo with you when available. Thank you to all site staff for your data entry efforts in preparing for this important meeting!

NIH and Dr. Anthony Fauci recognize REPRIEVE in World AIDS Day Statement

Last week, we recognized World AIDS Day – a day to reflect on the progress we have made over the course of the HIV epidemic and acknowledge the challenges the HIV community continues to face. Every year, this day reinforces the important work we continue to do together on REPRIEVE. In fact, in the NIH World AIDS Day Statement, Dr. Anthony Fauci echoes just that by specifically mentioning the REPRIEVE trial and how the results will "teach us about the many long-term health effects of HIV".

Who's Who on the REPRIEVE Team?

Meet Amy Kantor, MS, Biostatistician

Amy is a biostatistician at the Center for Biostatistics in AIDS Research (CBAR). In this role, Amy works with other biostatisticians on the team to prepare the DSMB reports and analyses of the Women's and Kidney ancillary studies. At CBAR, Amy also works on other ACTG studies including A5336 and A5371.

In her free time, Amy has been taking a photography class and has started needlepointing. She lives in Boston with her cat Eli.

Next Team/Site Site Call
January 19th, 2021 at 1PM ET

Details will be sent prior to the call via email.
If there are any topics you would like to be discussed please email Katie Fitch at kfitch@mgh.harvard.edu.

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 09/15/2020*
LPC for ACTG Sites *Version 5.0 dated 05/04/2020*

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

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