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Randomized Trial to Prevent Vascular Events in HIV December 2021 Table of Contents

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

As 2021 comes to a close we would like to thank our community of REPRIEVE clinical

research teams and study participants who remain dedicated to REPRIEVE.

During this past year we recognize that adjustment to working in the midst of the pandemic was a common theme and we are incredibly appreciative of the continued effort by everyone to ensure participant safety and integrity of the trial. While 2021 continued to bring us new challenges, we achieved many great accomplishments, together, including:

- Follow up of participants entering into the 6th year.
- Retention of 89% of participants.
- Publication of 5 manuscripts.
- Ongoing analysis of baseline data--9 additional manuscripts are in development.
- Over 300 in attendance at the REPRIEVE Community Forum.
- 4 Science Spotlights presented at CROI 2021
- Successful DSMB meetings took place and DSMB members commended the REPRIEVE team on study conduct and participant retention, data timeliness and quality.
- Continued data collection of COVID-19 symptoms, hospitalizations and long COVID symptoms.

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 2022 and the years to come. Thank you, and we wish you all well over the holiday season.



Important Information about CROI 2022!

- We are pleased to share that REPRIEVE has had **two** abstracts selected for an oral presentation and **four** abstracts selected for a poster presentation at CROI 2022!
- REPRIEVE leadership will be hosting a REPRIEVE Meeting on Tuesday, February 15th at 1:30pm MT. We are still working out the details but we hope to be able to have this as a hybrid meeting. We will be sending out an invite shortly!



FAQ

Q: During a study visit, a participant shared that he recently had an emergency department visit for a possible seizure. After checking the REPRIEVE MOPS, it appears this should be reported as a potential adjudicated event. Can you confirm that I should use the Adjudicated Events Tracking CRF (TRK0150) to report this potential adjudicated event?

A: As mentioned on page 35 of the MOPS “certain presentations (typical and atypical) reported by a participant could indicate a possible study primary endpoint”. In the case of seizures, they could be related to a stroke or transient ischemic attack (TIA). If there is any question about the etiology of the seizure, then we would advise to submit the event for adjudication and to answer YES to question #7 “Has the subject experienced a potential cerebrovascular event (stroke or TIA) since the last evaluation or at the last evaluation?” on the Adjudicated Events Tracking CRF in OpenClinica.

Additional guidance on Reporting Potential Adjudicated Events in the EDC/OpenClinica can be found in section 6.1.1.



Site Spotlight: Barranco CRS (11301)



**The Barranco CRS, located in Lima, Peru has been a tremendous contributor to
REPRIEVE!**

This team prioritizes its retention efforts in many ways, below are a few tips they shared with us.

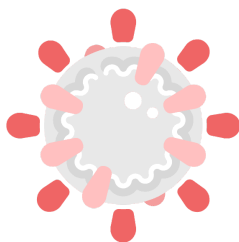
1. We treat participants with empathy and respect. Our clinical team is committed to making participants feel comfortable and cared for.
2. We have a team that is solely dedicated to participant retention. It is made up of different people with different backgrounds and professions, which helps participants feel more comfortable, building a trusting relationship with them.
3. Knowing that participants are busy, we do our best to schedule their study visits on the day they are supposed to pick up their antiretroviral medications. This helps them save time and also improves their adherence to medication.

Thank you, Barranco team, for all your efforts and for sharing your retention tips!

*Save
the
Date*

The next REPRIEVE DSMB meeting will take place on **Friday, March 25th, 2022**. The timeline for this meeting, which will be distributed shortly, will start early in January, 2022.

A Note About the COVID-19 Assessment (SSW0040) CRF



In case you missed the email, the **COVID-19 Assessment (SSW0040) CRF** was recently updated to version **1.03**.

What changed?

Question 22 'Other' and its associated 'Specify' text field was changed to a single question 'Fatigue' (Yes/No/Unknown) in version 1.03.

What are we asking you to do?

At each participant's **next** COVID-19 assessment, please complete version 1.03 of the SSW0040 form and enter the participant's response for question 22, 'Fatigue', since the last visit.

How to Obtain This Update:

- These CRF updates are installed in OpenClinica.
- Please contact reprieve.dmc@fstrf.org if you believe an incorrect version of this form is currently available for you to complete in OpenClinica for any of your on-study participants.
- The hardcopy* **SSW0040 COVID-19 Assessment v1.03** form is available in the REPRIEVE Forms Management Utility located on the Frontier REPRIEVE ePortal under the *Case Report Forms* heading. The active date for the **SSW0040 COVID-19 Assessment v1.03** is 17-November-2021.

**Please note the hardcopy form has been directly output by OpenClinica, a fully validated electronic data capture system, and is intended as a study reference document only and not for direct data capture. If your site wishes to use the hardcopy for data capture and desires revised formatting, it will need to complete that task independently by changing local printer settings and/or by manually cutting, pasting, and copying.*



Is your site scheduled to ship specimens to BRI during the holidays?

If your site is scheduled to ship during the last part of December or the beginning of January, please consider delaying your shipment to avoid issues with couriers due to increased holiday shipping.

If you anticipate delaying your shipment, please make arrangements with the Repository manager at BRI to

ship on another date by emailing brirepository@afbr-bri.com.

Who's Who on the REPRIEVE Team?



Triin Umbleja is a biostatistician at the Center for Biostatistics in AIDS Research (CBAR), located at the Harvard T. H. Chan School of Public Health at Harvard University. In her role on REPRIEVE, Triin works with other biostatisticians on the team, she supports day-to-day activities, prepares DSMB reports, and - her favorite - works on REPRIEVE's many exciting analyses. She is also the protocol statistician on the physical function substudy PREPARE (A5361s), and has worked on various other ACTG studies in coinfections and comorbidities of HIV over the past 17 years.

Outside of work, Triin enjoys spending time with her husband and two daughters, and dancing. To stay healthy, they all do chair rises together. 😊



A Reminder for Sites Participating in PREPARE (A5361s)

A5361s protocol version 2.0 added a Month 60 visit. Both participants who continue in follow-up in A5361s AND those who may have completed A5361s under protocol version 1.0 but are in follow-up in A5332 *are expected to complete a Month 60 evaluation*.

If a participant is past their Month 60 visit in A5332, the A5361s Month 60 evaluations can be performed at the next A5332 in-person visit. Refer section 6.2 of the A5361s protocol and to the A5361s Manual of Procedures (MOPS) for more details.

REPRIEVE in the News!!!

The REPRIEVE team recently published a report on



COVID-19 [vaccination rates in the REPRIEVE cohort](#).

This publication has been featured on multiple news sites, including [Healio](#), [EurekAlert](#), and [Yahoo News](#).



Next Team/Site Call! January 18th 1PM EDT

Join us for important REPRIEVE updates!

1:00 PM HAITI (EDT)
1:00 PM PERU (PET)
2:00 PM PUERTO RICO (ADT)
3:00 PM BRAZIL (BRT)
8:00 PM BOTSWANA (CAT)**
8:00 PM SOUTH AFRICA (SAST)**
8:00 PM ZIMBABWE (CAT)**
9:00 PM UGANDA (EAT)**
11:30 PM INDIA (IST)**
1:00 AM 01/20/2021 THAILAND (ICT)**

****We do not expect site staff to join these calls during their off-work hours. Instead we will update you on other scheduled calls, e.g., your calls with the ACTG NCC.**

Remember that questions are always welcome at actg.corea5332@fstrf.org and if there are slides used for a call, they are available on the PSWP in the Protocol Training >> Site Calls folder.

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
Version 5.0, Letter of Amendment 2 dated 12/14/2020
MOPS Version 5.0 dated 09/13/2021
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](#)

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@fstf.org



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