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

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Update From the 14th REPRIEVE DSMB Meeting!



On September 21st, we held our 14th Data and Safety Monitoring Board (DSMB) meeting! We are so pleased to share that the DSMB noted no safety concerns and unanimously approved the continuation of REPRIEVE. We look forward to sharing updates from the meeting and the formal memo when available.

<u>THANK YOU to all site staff for your data entry</u> <u>efforts in preparing for this important meeting</u>.

The next DSMB meeting will take place in March 2022.

Don't Forget to Complete the Vital Status and Endpoint Assessment CRF

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We would like to remind sites to complete the Vital Status and Endpoint CRF (VSW0025) for participants who are off study but have not withdrawn consent.

The CRF is intended to capture vital status and adjudicated events for participants who discontinued the study prematurely. This CRF is to be completed annually from the Date of Off-Study that is indicated on the Off-Study or at any time the site becomes aware of a potential adjudicated event or death.

See section 12.6 of the REPRIEVE MOPS for more information. If you have questions about this CRF don't hesitate to email the core team at actg.corea5332@fstrf.org.



Schedule a REPRIEVE Ambassador Visit!

Do you have a specific question about the REPRIEVE protocol, have new site staff, or just want to speak with a member of the Clinical Coordinating Center (CCC)? If so, reach out to the CCC and schedule a (virtual) Ambassador Visit, even if your site has already had one.

These visits are an opportunity to have a *friendly informal* discussion with a member from the CCC team. We can review the new and updated COVID CRFs, vital status and endpoint assessment, adjudicated events, as well as ways the CCC can support your site's retention efforts. We can also cover other topics or questions that your team would like us to address.

If you would like to meet with a member of the CCC, even if you have already had a meeting, please email Evelynne at <u>efulda@mgh.harvard.edu</u>.



Save the Date Next Team/Site Call! October 19th 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)***

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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 <u>actg.corea5332@fstrf.org</u> and if there are slides used for a call, they are available on the PSWP in the Protocol Training >> Site Calls folder.

Spanish Translation of the Community Forum Transcription is Now Available!

<u>A Spanish translation</u> of the first annual REPRIEVE Community Forum transcription is now available.

At this virtual event, we heard trial announcements and baseline study findings from Steven Grinspoon, Michael Lu, Katie Fitch, and Emma Kileel.

Visit the <u>Community Forum webpage</u> on the REPRIEVE website for more information.

REPRIEVE TRIAL COMMUNITY FORUM

AGENDA **11:00 - 11:05 Welcome** Turner Overton, MD



11:05 – 11:10 REPRIEVE Trial Updates Steve Grinspoon, MD and Michael Lu, MD, MPH

11:10 – 11:15 Cardiovascular Risk and Health Assessments among PWH Eligible for Primary Prevention: Insights from the REPRIEVE Trial Steve Grinspoon, MD

11:15 – 11:20 Coronary Artery Disease, Traditional Risk and Inflammation Among PWH in REPRIEVE Michael Lu, MD, MPH

11:20 – 11:25 Diet Quality by Global Burden of Disease Region in PWH in the REPRIEVE Trial Katie Fitch, MSN

11:25 – 11:30 Assessment of Obesity and Metabolic Profile by Integrase Inhibitor Use in REPRIEVE Emma Kileel, MPH

11:30 – 11:50 Question and Answer



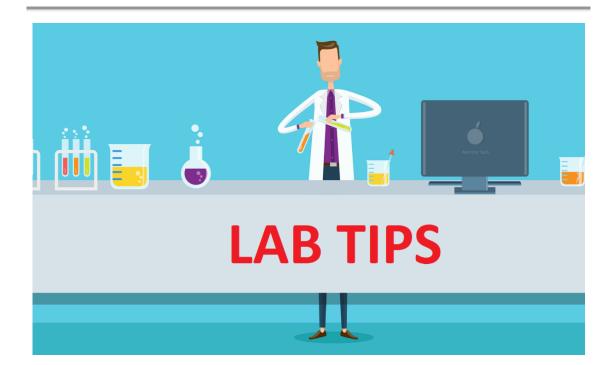


Retention Tip of the Month

• **Track your site's retention metrics** in the Monthly Score Cards and Biannual Evaluation Letters.

- If your site is at risk of or not meeting the current retention standards, consider developing a retention plan to improve retention going forward – prevention is always preferred!
- Discuss retention metrics as a team
 - Over 50% of Retention Champions we spoke with shared that team meetings to discuss participants at risk of LTFU and to discuss retention strategies were on-site strategies they used to maintain or improve retention.
- Don't forget about the retention tools developed by the REPRIEVE CCC:
 - Participant friendly website (<u>www.reprievetrial.org</u>)
 - Annual participant newsletters (available in over 8 languages)
 - REPRIEVE branded tokens of appreciation (i.e. "swag") -we have face masks, birthday cards, and thank you cards - <u>Click Here to request for</u> your site!
 - <u>Retention Toolkit</u>
 - Share <u>plain language summaries</u> of recent publications with your participants

Click Here to Order REPRIEVE Tokens of Appreciation (Swag)



Lab Tips Have questions about shipping or responding to LDMS queries?

Slides covering these topics as well as some helpful lab related FAQs are now available on the REPRIEVE (A5332) PSWP, in the Current Laboratory Documents and Memos (5.0) Folder.

Also, the LDMS support team has developed a number of <u>helpful video tutorials</u> outlining how to complete different steps in the management, storage, and shipment of specimens. Site staff have shared with us that these videos are incredibly useful. And don't forget that the REPRIEVE Lab Team is always available to answer any lab related questions, reach out by email: <u>reprieve.labcom@fstrf.org</u>.

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 (revised version!) 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 <u>REPRIEVE Website</u>

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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REPRIEVE Trial Clinical Coordinating Center

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