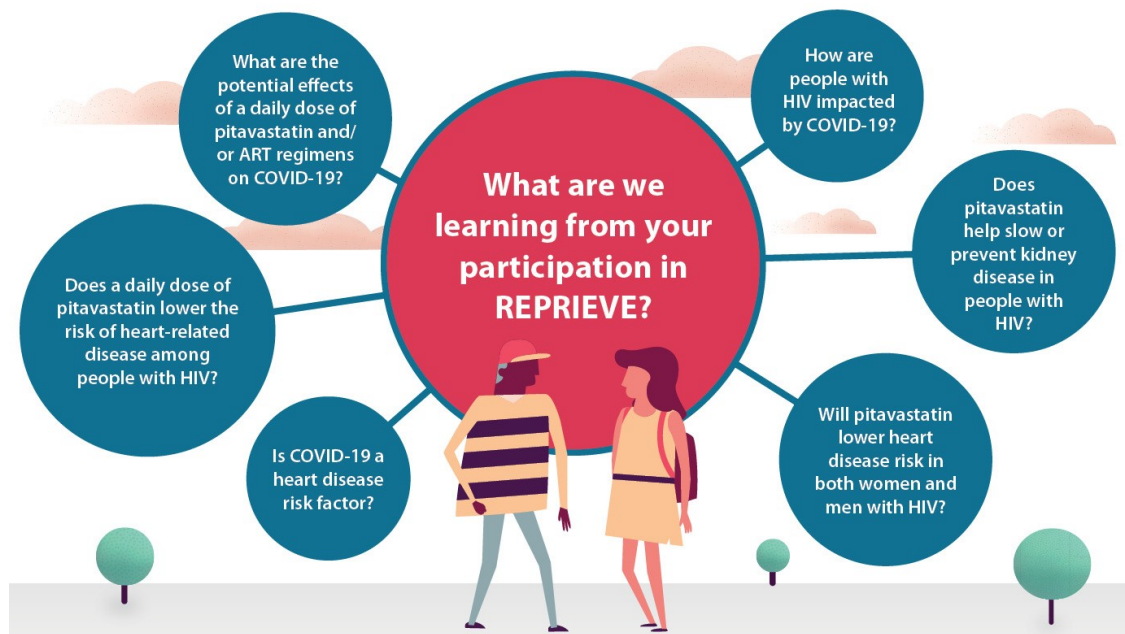


[View this email in your browser](#)



REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV



Did you know, participants who have discontinued REPRIEVE can rejoin the trial at any time?

We encourage REPRIEVE sites to use the rejoining talking points ([click here](#)) with participants who have previously discontinued but may be interested in rejoining.

If a participant chooses to rejoin, even if they have completed a premature discontinuation visit, we ask that you email the REPRIEVE Data Managers at reprieve.dmc@fstrf.org and a member of this team will advise you on the next steps.



Important Reminders from the CCC!

Register Protocol Version 5.0 LoA #2: Please remember to register REPRIEVE (A5332) Protocol Version 5.0, Letter of Amendment (LoA) #2 with DAIDS Protocol Registration. If you need instructions about how to register the LoA, please refer to Section VI, B.2 (page 44) of the Registration Manual ([click here](#) to download the

DAIDS_prmanual). If you have any questions please contact protocol@tech-res.com.

Complete the Consent/Deconsent CRF: For sites that have protocol registered Protocol Version 5.0, LoA #2, please have your participants complete the ICF addenda for sharing of de-identified genetic information obtained from a blood sample collected at the entry visit for A5332 (**ACTG sites only**), and at the entry and month 24 visits for A5333s. If you have any questions about this please contact the core team actg.corea5332@fstrf.org.



Hot Off the Press! 2021 Participant Newsletter

Sites may now request hard copies of the 6th Annual Participant Newsletter! [Click here](#) to request newsletters for your site!

The newsletter is currently pending final approval by the IRB for the CCC, once approved, electronic versions will be distributed and downloadable in over 8 languages!



Please Complete Chart Reviews for Participants Missing Visits

If a participant misses 3 or more consecutive visits, site staff should make every effort to obtain 'other' contact, including a **chart review**. Data from this chart review can be keyed in the CRFs for the missed visit in OpenClinica.

We encourage site teams to use the guidance and tracking tool provided in **Appendix V of the REPRIEVE MOPs** for remote/other contact data collection.

Additional guidance on remote data collection can be found in section 4.3 of the MOPs.



Q: I just learned that a REPRIEVE participant was newly diagnosed with Type 2 diabetes before their most recent study visit but didn't mention this during the visit. Should I enter this information in OpenClinica for the most recent study visit or should I enter it for the next study visit?

A: Our core team recommends to add this to the documentation for the participant's last/most recent study visit. Section 6.2 of the REPRIEVE MOPS provides helpful information regarding reporting incident diabetes as a non-adjudicated, non-CVD event.

Q: In Section 13.0 of the REPRIEVE MOPS, regarding COVID-19 vaccinations, the MOPS states that COVID-19 vaccines must not be given within 14 days prior to a scheduled annual blood draw for REPRIEVE. What is considered day 1, the day of the vaccine or the day after?

A: The core team considers day 1 to be the day after the vaccine. For example, if a participant received their COVID-19 vaccine on April 1st they should not have their annual REPRIEVE blood draw before April 15th.



Last week, a memo regarding the DAIDS Critical Events Policy was distributed to sites, [click here](#) to download the memo. Questions regarding the contents of the memo should be directed to the DAIDS OPCRO ProPEP Team at DAIDSProPEP@mail.nih.gov.



A note about reporting a downgraded event in DAERS as an EAE

If you are notified that you must submit a downgraded event as an EAE in DAERS, please remember that the date the email notification of the downgraded event was received by the site constitutes the "Site Awareness Date." Section 7.1 of the REPRIEVE MOPS has more details about reporting downgraded events.



For Sites Participating in PREPARE (A5361s)

PREPARE (A5361s) Protocol Version 1.0 LoA#3, incorporated instructions for alternate completion of post-entry evaluations and added instructions *for documenting missed assessments or components of the assessments required at a visit.*

Now that more visits are occurring in-person, please remember to conduct any missed PREPARE evaluation at a subsequent REPRIEVE visit so that we can improve data collection for PREPARE, which has been substantially affected by the pandemic. Missed or partially completed evaluations can be completed at any time before the next scheduled annual visit (eg, Month 40 or 44 for Month 36).



**Save the Date Next Team/Site
Call!
April 20th, 2021 1PM EST**

Join us for the next Team/Site call on April 20th, 2021 at 1:00PM EST! The call will feature five presentations highlighting the latest findings from REPRIEVE baseline data:

- Cardiovascular Risk and Health Assessments among People with HIV Eligible for Primary Prevention: Insights from the REPRIEVE Trial, *presented by Pamela Douglas*
- Coronary Artery Disease, Traditional Risk and Inflammation Among PWH in REPRIEVE *presented by Steven Grinspoon*
- Diet Quality by Global Burden of Disease Region in PWH in the REPRIEVE Trial, *presented by Katie Fitch*
- Assessment of Obesity and Metabolic Profile by Integrase Inhibitor Use in REPRIEVE, *presented by Emma Kileel*
- Factors Associated with Systemic Immune Activation in a Global HIV Cohort, *presented by Markella Zanni*

1:00 PM HAITI (EST)

1:00 PM PERU (PET)

2:00 PM PUERTO RICO (AST)

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@fstf.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 02/08/2021

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@fstrf.org



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