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## Randomized Trial to Prevent Vascular Events in HIV March 2022 Table of Contents

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**THANK YOU** to all REPRIEVE site teams for the incredible effort to meet the data entry deadlines in preparation for the DSMB meeting on Friday, March 25th. We will provide you with updates from the meeting as soon as we are able to.

### We Want to Hear from You!

To better provide support to sites, [we have developed a brief survey](#). Completion of this survey is completely optional and anonymous; it should take ~1 minute to complete and will help the Clinical Coordinating Center develop resources that are most helpful to sites. Click [the link](#) or scan the QR code to complete the survey, thank you in advance!



### Tips from the Data Management Team



## Post-entry CD4+/CD8+ evaluations are specified in Protocol Section 6.3.6

Please ensure that your site is entering in OpenClinica CD4+/CD8+ results obtained from clinical care since the last annual study visit.

- If CD8+ cell count is not available, CD4+ cell count alone is acceptable.

The most recent values obtained since the last annual visit will be used.

If there is no new value available since the last annual visit, re-enter the value entered at the last annual visit along with the date on which the value was obtained.

**Example:** a participant is coming in for their month 48 visit, their CD4+ at month 36 was 800 cells/mm<sup>3</sup>, and there is no new value since the month 38 visit, therefore enter this same value of 800 cells/mm<sup>3</sup> at the month 48 visit along with the date it was obtained.

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### Non-Adjudicated Event CRFs Require the Signature of the Local PI

For all non-adjudicated events, **the event-specific CRFs require the signature of the local PI or designee** confirming that she or he has reviewed the documentation and agrees with the diagnosis and the level of evidence.

The signature may be electronic or on the paper CRF. If the signature is on the paper CRF, this CRF should be maintained with source documents.

It is recommended that sites are consistent with the manner in which the PI or designee signs these CRFs.



### For Sites Participating in the Mechanistic Substudy of REPRIEVE (A5333s)

In case you missed the email...

As you may recall, the last participant in A5333s received their baseline coronary CTA on

February 1st, 2018, and 688 participants successfully concluded their participation. The substudy is an essential part of REPRIEVE and has been a great success because of your strong efforts to collect data which in turn has facilitated a number of publications from baseline data collected in the substudy. Indeed a number of baseline analyses are ongoing from the substudy with additional longitudinal analyses to follow in the future.

We have received email communications that sites are being asked to de-register the protocol with DAIDS, however REPRIEVE leadership does not plan to close the substudy at this time, we are hoping to obtain additional funding to complete an identical visit to the month 24 visit at the completion of REPRIEVE (A5332). Therefore, **we ask that you do not de-register the substudy and that you do not close the study protocol with your local IRB/EC until further notice of plans for this visit.**

Thank you,  
A5333s Team



## We are Happy to Share Additional Publications from Baseline Data Collected by You!

ACCEPTED MANUSCRIPT

### Geographical Differences in the Self-Reported Functional Impairment of People with HIV and Associations with Cardiometabolic Risk [Get access >](#)

Kristine M Erlandson, MD ✉, Kathleen V Fitch, MSN, Sara A McCallum, MPH, Heather J Ribaudo, PhD, Edgar T Overton, MD, Markella V Zanni, MD, Gerald S Bloomfield, MD, Todd T Brown, MD, PhD, Carl J Fichtenbaum, MD, Sara Bares, MD ... Show more

*Clinical Infectious Diseases*, ciac098, <https://doi.org/10.1093/cid/ciac098>

Published: 15 February 2022 [Article history](#) ▼

ACCEPTED MANUSCRIPT

### Factors Associated with Systemic Immune Activation Indices in a Global Primary Cardiovascular Disease Prevention Cohort of People with HIV on Antiretroviral Therapy [Get access >](#)

Sara E Looby, PhD ✉, Amy Kantor, MS, Tricia H Burdo, PhD, Judith S Currier, MD, Carl J Fichtenbaum, MD, Edgar T Overton, MD, Judith A Aberg, MD, Carlos D Malvestutto, MD, MPH, Gerald S Bloomfield, MD, MPH, Kristine M Erlandson, M ... Show more

*Clinical Infectious Diseases*, ciac166, <https://doi.org/10.1093/cid/ciac166>

Published: 02 March 2022 [Article history](#) ▼

Don't forget to check our publications page on the REPRIEVE website for links to all publications and plain language summaries to share with participants, [click here](#).

**Clonal hematopoiesis and risk for cardiovascular disease**

Pradeep Natarajan, MD MMSc  
Director of Preventive Cardiology, MGH  
Paul & Phyllis Fireman Endowed Chair in Vascular Medicine, MGH  
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February 15, 2022  
REPRIEVE Investigator Meeting during CROI



## Recording from the REPRIEVE Meeting During CROI is Available!

On Tuesday, February 15th, we held our annual REPRIEVE Meeting during CROI. We discussed important trial updates and were fortunate to have Dr. Pradeep Natarajan, PI of the REPRIEVE Genetics Grant as our keynote speaker. If you were unable to make this meeting, you can find a recording [here](#).

REPRIEVE (A5332) **contract modifications** are forthcoming to extend the Period of Performance to April 30th, 2023.

Should you have any questions please contact [REPRIEVE.finance@mgh.harvard.edu](mailto:REPRIEVE.finance@mgh.harvard.edu).



## Next Team/Site Call!

### April 19th

1:00 PM US (EDT)  
 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 04/20/2021 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](mailto: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*  
**Updated version!** *MOPS Version 5.0 dated 2/16/2022*  
*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](mailto:reprieve.news@fstrf.org)*



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