

## Randomized Trial to Prevent Vascular Events in HIV

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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 Thursday, September 29th. We will provide you with updates from the meeting as soon as we are able to.

# Tips/Reminders Regarding Events Submitted for Adjudication

If there are *any* updates to data related to a potential adjudicated event or additional information/source documents become available after the event has completed adjudication, the site should re-submit the event for adjudication. These updates also include changes to the event onset date entered on the AE log.



If you have updated information or have a question about how to re-submit the event for adjudication, reach out to the REPRIEVE Data Coordinating Center at <a href="mailto:mgh.harvard.edu">mgh.harvard.edu</a>

Re-submission for adjudication ensures that the most up-to-date and accurate data are used for the REPRIEVE primary analysis.



REPRODUCTIVE / HORMON	
7. Have you undergone testosterone replacement?	C Never
	C Former
	C Current
8. Have you used an oral estrogen- containing hormone replacement therapy?	C Never
	Former • If Current or Former, complete Question
	C Current
a. At what age did you start this therapy?	C <40 C 40-59 C >59
Questions 9 - 13 should be answ	vered only by subjects born female
9. Have you taken estrogen- containing oral contraceptive pills?	C Never
	C Former
	○ Current
10. Are you currently post-menopausal?	C Yes
	CNo
	○ Not Sure
a. Approximately how much time has elapsed since your last menstrual period?	(years) (months)
11. Have you had both of your ovaries removed?	<ul> <li>○ Yes           • If Yes, complete Question 11a</li> <li>○ No</li> </ul>
a. Approximately how many years ago:	(years) • NOTE: If less than 1 year, enter 0
12. Have you had a uterine ablation?	○ Yes • If <b>Yes</b> , complete Question 12a
a. Approximately how many years ago	(years) • NOTE: If less than 1 year, enter 0
13. Have you had a hysterectomy (uterus removed)?	○ Yes • If <b>Yes</b> , complete Question 13a ○ No
a. Approximately how many years ago:	(years) • NOTE: If less than 1 year, enter 0

FAQ

Q. What is meant by the "hormonal/reproductive health assessments relevant to CVD risk" that are indicated in the A5332 Protocol Version 6.0 Schedule of Evaluations?

A. The hormonal/reproductive health assessments are health questions at the study termination or premature discontinuation visits that correspond to questions 7 to 13 (section labeled "reproductive/hormone replacement") on the TRK0151, Cardiovascular Risk Assessment CRF, version 1.03, in OpenClinica.

These same questions were also posed to participants at screening. The other questions on the CRF (questions 1-6 and 14-15) should be omitted by the site at the study termination/discontinuation visit.

This point will be clarified in a future iteration of the A5332 MOPS.

Please be aware that we are updating the FAQs, and the following changes will be made:

- V5.0 was changed to V6.0 where necessary.
- FAQs from REPRIEVE newsletters are added.

Look for the updated FAQs on the A5332 PSWP in the FAQ folder.



#### **Change to REPRIEVE FedEx Account**

Does your site use the "A5332 nonnetwork Lab Processing Chart" (LPC)?

Is your site located in the US or Canada?

If you answered "yes" to both questions please read the important information below about a change to the REPRIEVE FedEx account.

Due to fraudulent activity on the current **REPRIEVE** FedEx account, we are in the process of altering our shipment processes.

The FedEx account information will be removed from the "A5332 non-network" (NON-ACTG) LPC and a revised version will be distributed shortly.

For all shipments going forward, a PDF of a shipping label will be sent to your site a week prior to your scheduled specimen shipment. Shipments sent with the old REPRIEVE FedEx account number will not be processed.

If you have ANY questions or need to ship outside of the NON-ACTG Shipping Schedule, please email <a href="mailto:mghreprieveshipping@mgh.harvard.edu">mghreprieveshipping@mgh.harvard.edu</a>

Please note this change does NOT apply to sites using the "A5332 ACTG Only" LPC or non-ACTG sites in Brazil.



### Join the REPRIEVE Lab Committee's Specimen Shipment and LDMS Query Response Refresher Call Tuesday, September 13th

The REPRIEVE Lab Committee is hosting a call to review shipping of specimens and tips on responding to lab queries. We will also be discussing the change to the REPRIEVE FedEx (relevant to sites using the A5332 non-network LPC in the US and Canada). Most importantly, Lab Committee members will be available to answer any questions you may have!

Join us today! Tuesday, September 13th, at:

1:00 PM EDT 12:00 NOON CDT 11:00 AM MDT 10:00 AM PDT 17:00:00 UTC

\*\*\*We do not expect site staff to join these calls during their off-work hours. Instead we will post slides from this call on the PSWP and a link to the recording of this call will be provided at a later date. Remember that questions are always welcome at <a href="mailto:reprieve.labcom@fstrf.org">reprieve.labcom@fstrf.org</a>

#### **Hot Off the Press!**

JOURNAL ARTICLE CORRECTED PROOF

## Cytomegalovirus Immunoglobulin G (IgG) Titer and Coronary Artery Disease in People With Human Immunodeficiency Virus (HIV)

Samuel R Schnittman, Michael T Lu, Thomas Mayrhofer, Tricia H Burdo, Kathleen V Fitch, Sara McCallum, Evelynne S Fulda, Markella V Zanni, Borek Foldyna, Carlos Malvestutto, Carl J Fichtenbaum, Judith A Aberg, Gerald S Bloomfield, Edgar T Overton, Judith Currier, Pablo Tebas, Beverly E Sha, Heather J Ribaudo, Jacqueline M Flynn, Pamela S Douglas, Kristine M Erlandson, Steven K Grinspoon X

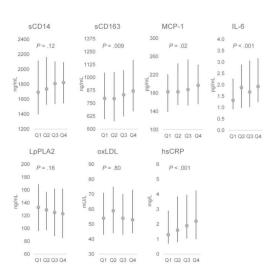
Author Notes

Clinical Infectious Diseases, ciac662, https://doi.org/10.1093/cid/ciac662

Published: 17 August 2022 Article history ▼

The REPRIEVE team recently published a report on cytomegalovirus (CMV) IgG titer and coronary artery disease in the REPRIEVE cohort. Key findings were:

- Higher CMV IgG titer was associated with older age, current CD4, and nadir CD4
- CMV IgG titer was associated with markers of inflammation
  - However, when considering other variables that may impact these inflammatory markers, the association between CMV IgG titer and markers of inflammation was reduced
- CMV IgG titer was not associated with the presence of plague



The figure shows the distribution of biomarkers across CMV IgG quartile groups. The figure represents the unadjusted biomarker medians by dots and range of first to third quartiles denoted by connecting lines, shown across increasing CMV IgG quartile groups.

Click here to read the article.

Don't forget to check our <u>publications page</u> on the REPRIEVE website for links to all publications and <u>plain language summaries</u> to share with participants.



#### **Special Site Recognition!**

As you may know, site performance evaluation in REPRIEVE is carried out by grouping sites into 4 teams. The Site Selection and Performance Committee (SSPC), the committee responsible for reviewing performance, just completed the review of sites in Team 2.

There were a few Team 2 sites that demonstrated great improvement in their efforts to contact and/or enter data for participants at risk of being lost to follow-up that we wanted to recognize:

Dallas VA Medical Center CRS (3752)
Baystate Infectious Diseases CRS (31841)
UT Southwestern HIV/ID CTU CRS (31864)

We are grateful for your outstanding work! Thank you for your incredible efforts!

### **Tokens of Appreciation Are Available**



### Birthday cards



Thank you cards



#### Face masks



We have REPRIEVE-branded tote bags, 'Happy Birthday' cards, 'Thank You' cards, and face masks. These tokens are a great way to show appreciation for our dedicated REPRIEVE participants.

#### Click Here to Order Swag for Your Site!



#### Next Team/Site Call October 18th

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 <a href="actg.corea5332@fstrf.org">actg.corea5332@fstrf.org</a> 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 6.0 dated 05/16/2022 MOPS Version 6.0 dated 06/10/2022 LPC for ACTG Sites Version 6.0 dated 06/03/2022 LPC for Non-ACTG Sites Version 6.0 dated 06/10/2022 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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#### REPRIEVE Trial Clinical Coordinating Center

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