

[View this email in your browser](#)



REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Please read this newsletter in its entirety as it contains important information relating to the conduct of REPRIEVE within the context of COVID-19.

A Message from REPRIEVE Leadership





Dear REPRIEVE Colleagues,

We hope you and your communities remain safe and well during this unprecedented time, we thank you for your continued commitment to REPRIEVE.

REPRIEVE, a cohort of over 7,770 PWH in over 5 continents remains a landmark trial to assess a novel cardiovascular prevention strategy in HIV. The trial is going well, in large part due to your efforts. At this critical juncture, as we face the COVID-19 pandemic, we are learning that COVID-19 may represent an important cardiovascular risk factor. REPRIEVE offers a unique opportunity to obtain important information about how SARS-CoV-2 infection and COVID-19 illness affects a diverse global population of PWH. In this context, it will be critical to assess symptomatology, as well as any potential protective effects of statin therapy against infection and complications of COVID-19 illness.

In order to collect this important information we are integrating a concise COVID-19 Assessment CRF to collect symptomatology, testing, and hospitalization history. Sites were notified of this via the Clarification Memo distributed on April 6th, the MOPS has been revised to provide further instruction about this new data collection, and we will be providing training during the April 21st site call.

By continuing to conduct REPRIEVE study visits either in person or remotely and ensuring participants remain on study drug, you are making important contributions not only to our knowledge of HIV and cardiovascular disease, but also HIV and COVID-19. Together, we will continue to make lasting contributions to the field of HIV research.

Thank you for being a critical part of the REPRIEVE Team.

Steve Grinspoon, MD CCC Co-Principal Investigator
Pamela Douglas, MD CCC Co-Principal Investigator
Udo Hoffmann, MD, MPH DCC Co-Principal Investigator
Heather Ribaldo, PhD, DCC Co-Principal Investigator

Report Potential Adjudicated Events

on the TRK0150



Identifying and recording potential adjudicated events on the Adjudicated Event Tracking CRF (TRK0150) per section 6.0 of the REPRIEVE (A5332) MOPS continues to be essential for the trial.

We do recognize that submission of source documents may present a challenge due to local restrictions during the pandemic. However, we ask that study teams continue to record any potential events on the TRK0150. Completion of source document collection and submission to the DCC can be done once local institutional restrictions are lifted.



Site Tools To Use

Due to site restrictions that may affect the routine conduct of study visits, the REPRIEVE CCC has developed a Tracking Log and Sample Remote Visit Encounter Form to help ensure the integrity of the trial and proper reconciliation of data so that we have an accounting of study visits and changes in study drug dispensation that may lead to missing information (e.g., for protocol-specified procedures) during the COVID-19 pandemic.

Tracking Log: A tracking log was developed to document how a participant's participation in REPRIEVE may have been altered due to restrictions related to COVID-19. **The REPRIEVE CCC will collect the A5332 COVID-19 Tracking Log* at the resolution of the Coronavirus Pandemic.**

- *This log will not replace or substitute for any existing requirement for data entry.
- [Click here](#) to download the A5332 COVID-19 Tracking Log.

Sample Remote Visit Encounter Form: The CCC is providing a sample tool on which data from a remote visit (i.e. phone visit or medical record review) can be documented for your records and referenced if you are keying data in OpenClinica at a later time.*

- *If you use this tool, please maintain it with your source documents.
- [Click here](#) to download the Sample Remote Visit Encounter Form.

Hold All REPRIEVE Specimens Until Further Notice!



All REPRIEVE specimens are to be held within your institution until further notice.

Specimens are not to be shipped to BRI due to concerns about the ability of carriers to maintain and / or deliver shipments.

Please continue your diligent efforts to maintain specimen integrity (i.e., temperature monitoring, chain of custody and tracking of specimens within LDMS). In addition, it will be important to document all circumstances surrounding these deviations from normal practices.

If you are at an ACTG site, please send emails concerning storage or shipment issues to COVID.labissues@fstrf.org, rather than ACTG.labcenter@fstrf.org so that they can be prioritized.

If you are at a non-ACTG site (REPRIEVE-only site) and have questions or concerns about specimen storage during this time, please reach out to the REPRIEVE Lab Committee at reprieve.labcom@fstrf.org, and ensure that REPRIEVE, Site ID and COVID-19 are in the subject line of your email.

We Need to Hear From You!



If you have not done so already, please complete a very brief 2 question survey to tell us whether or not your site has any restrictions in place regarding the conduct of research visits. It is very important that the REPRIEVE CCC has a record of which sites are under restrictions due to the COVID-19 pandemic.

To complete the survey [click here](#) or visit <https://bit.ly/3b2GNaq>.

If your site status changes, email kfitch@partners.org to notify us of the change.

Communications from DAIDS

DAIDS Memo (1): Due to the ongoing COVID-19 pandemic DAIDS is suspending all on-site

DAIDS Memo (2): DAIDS distributed guidance to research sites on March 13th regarding

monitoring visits globally. [Click here](#) to read the full memo distributed on March 19th.

research in the context of COVID-19. [Click here](#) to read the full memo.

Guidance from PAB:

On March 18th, PAB released a memo including guidelines for shipping study product from the site directly to participants. This method should only be used on a short-term, protocol-specific basis and only if permissible by the local institution and/or IRB/EC. If this method is to be implemented, each site pharmacist must develop appropriate procedures for the shipment or courier of study product to identified participants in accordance with these guidelines and must also include appropriately documented chain of custody. [Click here](#) to read the full memo.

Stay Up To Date With REPRIEVE Team Communications



Protocol 5332: Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE)

1 General

📄 Sites

🔗 Affiliations

📋 Site Protocol Activation Checklist

📁 PSWP

Current Protocol Status Announcements Folder

CMS Path » A5332 » Current Protocol Status Announcements

We understand that inboxes are inundated with emails right now. To ensure that you have received recent communications from the REPRIEVE Team, periodically check the **Current Protocol Status Announcements Folder** on the PSWP.



Next Team/Site Call Tuesday, April 21st, 2020 1:00 - 2:00 PM ET

During this site call, members of the REPRIEVE Team will provide instructions about where, when, and how to complete the *new* COVID-19 Assessment CRF.

Corresponding changes to the MOPS will also be reviewed. Call details are forthcoming via email, we hope you can join!

DATA MANAGEMENT CENTER NEWSLINE

The Data Management Center for ACTG & IMPAACT has released the April 2020 Newsline issue featuring important information on:

- COVID-19 Virtual Visits and Data Management Guidance for Sites
- Importance of LDMS Collection and Processing Fields

To view the full Newsline issue [click here!](#)

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 5.0 dated 04/01/2019

New! *Version 5.0, Clarification Memo 1* dated 04/03/2020

Revised! *MOPS Version 5.0* dated 04/08/2020

A5332 LPC for ACTG Sites Version 5.0 dated 04/11/2019

A5332 LPC for Non-ACTG Sites Version 5.0 dated 04/11/2019

These documents are on the [A5332 PSWP](#)

Mechanistic Substudy of REPRIEVE (A5333s): Are you up to date?

For A5333s please use

Protocol Version 5.0 dated 04/01/2019

MOPS Version 4.0 dated 04/10/2018

A5333s LPC Version 4.0 dated 03/23/2018

These documents are on the [A5333s 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



REPRIEVE Trial Clinical Coordinating Center

Massachusetts General Hospital
55 Fruit Street, 5LON 207
Boston, MA USA 02144

Our mailing address is:

reprieve.news@fstrf.org

Want to change how you receive these emails?

You can [update your preferences](#) or [unsubscribe from this list](#).

This email was sent to <<Email Address>>

[why did I get this?](#) [unsubscribe from this list](#) [update subscription preferences](#)

Massachusetts General Hospital · 5 Longfellow Place · Boston, MA 02214 · USA

