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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Check Out the *New* Video to Raise Awareness About Our Effort to Better Understand COVID-19 in REPRIEVE!

Thank you to the NHLBI communications team for developing this video!

As you you know, REPRIEVE received a **supplemental funding award from the National Heart Lung and Blood Institute (NHLBI) to pursue critical COVID-19 research in REPRIEVE**. This is an exciting opportunity for all of us to contribute to important, ongoing COVID-19 research. The NHLBI communications team created this video to help us raise awareness of this important research in REPRIEVE.

The video is available on the REPRIEVE YouTube channel and also on the homepage of the REPRIEVE website, www.reprievetrial.org. Please share the video with your participants!

Don't forget that with the supplemental award we are able to offer each site additional funds to recognize efforts to collect data on COVID-19 among REPRIEVE participants.

Our finance group at MGH has started reaching out to sites to update contracts to provide additional funds for the COVID-19 assessments. Additional funds will be based on number of retained participants.

We want to thank each of you for your ongoing efforts, not only by playing an integral role in recruiting participants in the trial but also in maintaining trial integrity during the COVID-19 pandemic, including retention as well as assessments of study endpoints. All these activities are so critical to the success of REPRIEVE.

Key Prescribed Medications for COVID-19 in the Medications Log

For the list of specific COVID-19 treatments to be keyed, utilize the REPRIEVE (A5332) COVID-19 Medications list located on the A5332 Protocol Specific Web Page (PSWP) in the *Current Study-Specific Support Documents folder*.

Remember to Submit Protocol Version 5.0, LoA #1 to DAIDS Protocol Registration!

- Upon Version 5.0 LoA #1 IRB/EC approval, don't forget to submit to DAIDS Protocol Registration.
- Sites must submit the LoA to DAIDS PRO within 14 days of the CRS's receipt of all the required final written IRB/EC approval documentation for the LoA.
- Please refer to Section VI, B.2 of the Registration Manual (linked) for instructions and contact protocol@tech-res.com if you have any questions.
- Please email the REPRIEVE CCC if you require any additional documentation or have additional questions.

Reminder: BRI Holiday Closures

The BRI specimen repository will be closed on the following dates in observance of U.S. Veterans Day and Thanksgiving holidays:

Wednesday, November 11, 2020 for the Veterans Day holiday.

- All domestic site/labs are advised *not* to ship on the Monday (9 November 2020) or Tuesday (10 November 2020).
- BRI will reopen on Thursday, November 12, 2020.

Thursday, November 26, 2020 for the Thanksgiving holiday.

- All domestic sites/labs are advised not to ship on Tuesday (24 November 2020) or Wednesday (25 November 2020).
- If your site is scheduled to ship the 4th week of November, please only ship on Monday, November 23rd or contact brirepository@afbr-bri.com to make alternate shipping arrangements.
- BRI will reopen on Friday, November 27, 2020.

All international sites/labs are advised to confirm shipments are not due to arrive on the holiday.

Seeking REPRIEVE Community Advisory Board Members!

- The REPRIEVE Clinical Coordinating Center (CCC) is seeking REPRIEVE participants interested in serving on the REPRIEVE Community Advisory Board (CAB).
- The purpose of the CAB is to ensure that community concerns and suggestions are heard and carefully considered.
- The CAB also provides input on the development of participant resources such as the participant newsletter, the website, and many more.
- Meetings take place every 6 months.

Click here to learn more about our current REPRIEVE CAB members and if you might have interested participants, contact Katie Fitch at the REPRIEVE CCC via email kfitch@partners.org.

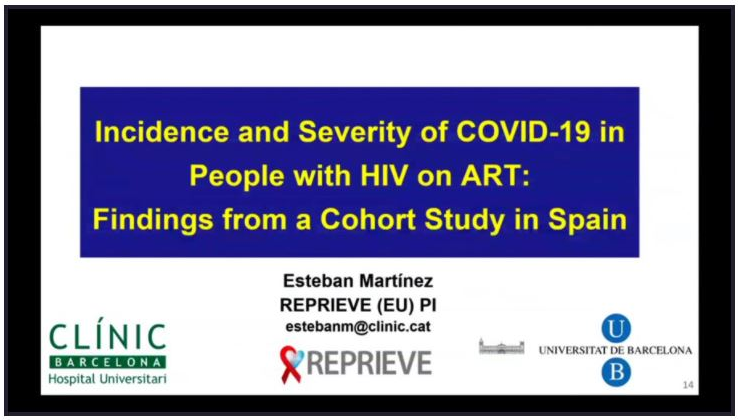
Collect Specimens as Per the Lab Processing Chart for Your Site Designation (ACTG or non-ACTG)

Collection of additional specimens for important COVID-19 biomarkers were introduced in Version 5.0, Clarification Memo #2, the LPC dated 05/04/2020 includes these additional specimens. Please make sure that you are using the revised LPC.

The A5332 MOPS has important guidance about collecting specimens if a participant misses a visit when stored specimens are to be collected, see Section 4.3 Timing of Data Collection. *We ask that you make every effort to collect specimens at the next in person visit in the event of a missed visit/specimen collection.*

In Case You Missed It: REPRIEVE Virtual Meeting!

If you were unable to join the REPRIEVE meeting on October 14th, click here to watch the recorded meeting.
We encourage you to share this link with your site team and participants.



Please remember to complete the Vital Status and Endpoint Assessment CRF (VSW0025)

The Vital Status and Endpoint Assessment CRF is intended to capture vital status and major adverse cardiovascular events (MACE) *for participants who are off study* for reasons other than withdrawal of consent or death.

This CRF is to be completed annually from the Date of Off-Study, as indicated on the Off-Study Form ***or*** at any time the site becomes aware of a potential MACE event or death.

Keying of the form is based on the attempt of contacting a participant who has discontinued study in an effort to obtain vital status or endpoint information. **Even if contact is not obtained, the attempt and date of attempt should be recorded in Section A of the log.**

Should contact be made, additional information about the participants vital status should be recorded in Section A of the log.

If it is discovered that a participant had a change in vital status or experienced a REPRIEVE MACE, additional information will be required in Section B of the log.

Please see **section 12.6 of the A5332 MOP** for more information, if you have any questions you can email the core team at actg.corea5332@fstrf.org.

Next Team/Site Site Call
January 19th, 2021 at 1PM ET

Details will be sent prior to the call via email.

If there are any topics you could like to be discussed please email Katie Fitch at kfitch@partners.org

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*
MOPS Version 5.0 *dated 09/15/2020*
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

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@fstrf.org

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