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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Don't Forget!

The 2nd REPRIEVE Team Sites Virtual Meeting will take place *tomorrow,* Wednesday, October 14th, 9:00 AM - 10:30 AM EDT

We have an amazing set of presentations for this meeting, take a look at the agenda below.

If you didn't receive the calendar invite, click on the link below to join the live stream.
http://healthcare.partners.org/streaming/Live/MGH/2020_REPRIEVE_Meeting.html

Time	Topic	Presenter
9:00–9: 15 AM	Welcome on Behalf of the REPRIEVE Team	Steven Grinspoon, MD REPRIEVE CCC Co-PI Massachusetts General Hospital
9:15–9:30 AM	***Keynote presentation:*** *Incidence and Severity of COVID-19 in People with HIV on ART: Findings from a Cohort Study in Spain*	Esteban Martinez, MD REPRIEVE (EU) PI Hospital Clinic of Barcelona
9:30–9:45 AM	*Correlates and Timing of Reproductive Aging Transitions Among Midlife Women with HIV in REPRIEVE*	Sara Looby PhD and Markella Zanni, MD Massachusetts General Hospital
9:45–10:00 AM	*Myocardial Steatosis Among ART-treated People with HIV in REPRIEVE*	Markella Zanni, MD and Tomas Neilan, MD Massachusetts General Hospital
10:00–10:15 AM	*Characteristics of REPRIEVE Participants Identifying Across the Transgender Spectrum*	Laura Smeaton, MS Harvard School of Public Health
10:15–10:30 AM	Questions	Team

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 REPRIEVE DSMB Meeting is December 1, 2020

The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE trial.

Please mark these important dates in your calendar and note that **October 23rd** is the data query resolution date.

Task		Deadline* (2020)	Weeks to DSMB Review
	Latest date for the occurrence of an evaluation for which complete data will be included in this DSMB review	Sep 22 (Tue)	10.0
Sites	All data for visits through Sep 22 entered	Oct 9 (Fri)	7.6
Sites	All adjudication packets for potential MACE events by Sep 22 with work-up complete submitted to DCC (MGH)**	Oct 9 (Fri)	7.6
Sites	All outstanding queries resolved	Oct 23 (Fri)	5.6
Sites	Respond to last minute outstanding queries	Nov 6 (Fri)	3.6
	DSMB Meeting	Dec 1 (Tue)	0

*Deadlines are Close of Business on the given date unless otherwise noted

**Please ensure that you have responded to all queries and clarifications from the DCC regarding source documents submitted for adjudicated events. This will ensure that the DCC is able to submit complete packets to TIMI for adjudication prior to the DSMB.

Common Shipment Issues Noted by BRI

Staff at BRI, the biospecimen repository, review all materials and specimens received, they then initiate a Shipment Evaluation so that laboratories are notified of any problems with a shipment. Each problem is identified with a code. Below are common codes noted with REPRIEVE shipments.

- **Code 601:** label/manifest mismatch
- **Code 606:** other labeling problems/missing codes
- **Code 207:** incomplete shipping notification or missing files
- **Code 302:** improper packaging
- **Code 502**: some vials out of order in box
- **Code 702:** sent first overnight, please send priority overnight (applies to FedEx shipments)

What are some things you can do to prevent shipment issues? Do a QA/QC of every single shipment by:

- Checking the Global Specimen ID. The global ID is specific to each aliquot and ends with -001, -002, etc.
- Checking the vial location. Each vial location in the physical box should perfectly match your Shipping Manifest and Shipping Container Report (box map). Ensure that there are no missing vials or extra vials.
- Checking that each label is clearly printed and legible.

A full list of BRI problem codes in the Shipment Evaluation SOP can be found at: https://www.hanc.info/labs/labresources/procedures/ACTGIMPAACT%20Lab%20Manual/073-ShipmentEvaluationProcedureSOP-LTC-SOP-073v7-2015-08-31.pdf

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.

Who's Who on the REPRIEVE Team?

Meet Carlos Malvestutto,MD, MPH

Dr. Malvestutto is an assistant professor in the Division of Infectious Diseases at the Ohio State University Wexner Medical Center. He is a clinical investigator at the OSU AIDS Clinical Trials Unit and is the principal investigator of various HIV and Hepatitis C treatment clinical trials. His areas of clinical research include cardiovascular complications of HIV, use of broadly neutralizing antibodies for HIV treatment and cure, and interventions to improve access to HIV and Hepatitis C treatment for underserved populations.

As part of the REPRIEVE team, Dr. Malvestutto has an essential role to answer clinical questions sent to the core team email. It is no surprise that he is able to do this in such a thoughtful manner, he has vast experience working in clinical trials not only as a

principal investigator but also as a Clinical Trials Specialist, he worked from 1998 to 2001 at the Community Program for Clinical Research on AIDS (CPCRA).

Dr. Malvestutto completed his Bachelor of Science in Biology at Yale University in 1996 and a Master of Public Health at Johns Hopkins University College of Hygiene and Public Health in 2000 and he earned his MD at the Ponce School of Medicine in Ponce, Puerto Rico in 2005.

Some fun facts about Dr. Malvestutto include that he was born in Buenos Aires, Argentina but moved to Ontario, Canada where he finished high school. He is married to Dr. Diana Osorio, who works as a pediatric neuro-oncologist at Nationwide Children's Hospital and they have a 13-month old daughter, Valentina. Dr. Malvestutto is an avid triathlete and runner and has completed multiple marathons and long-distance triathlons including four Ironman races.

Did you miss the September Site/Team Call?

Important topics included, presentations by Francoise Guigel and Heather Sprenger from the REPRIEVE Lab Committee! Francoise provided a specimen shipping refresher and Heather reviewed how to respond to lab queries. Click here to download the slides.

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*
Revised! 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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