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Randomized Trial to Prevent Vascular Events in HIV



Get involved with events happening in your area!

By participating in local events in your community, you create awareness of and

interest in cardiovascular health, HIV, and the REPRIEVE Trial. Below are just a few events we know about in the near future, there are many more!

- **AIDS Walk Los Angeles: Sunday, October 20**
- **Walk & 5K to End HIV (Organized by REPRIEVE Site Whitman-Walker Health): Saturday, October 26**
- **AIDS Walk Philly: Sunday, October 20**

We recognize participating in these events might take some planning, and the REPRIEVE CCC is here to help! We are happy to assist sites with planning for the events and provide some "REPRIEVE Swag". If you are planning on participating in an event in your area, please let Emma Kileel know (ekileel@mgh.harvard.edu) and send a photo of your team at the event!

Next REPRIEVE DSMB Meeting is December 16th, 2019

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 dates on your calendar and note that Monday, October 21st, is the data entry deadline.

Task		Deadline* (2019)
Sites	All data for visits through Oct 4 entered	Oct 21 (Monday)
Sites	All adjudication packets for potential MACE events by Oct 4 with work-up complete submitted to DCC (MGH)**	Oct 25 (Friday)
Sites	All outstanding queries resolved	Nov 8 (Friday)
Sites	Respond to last minute outstanding queries	Nov 22 (Friday)
All	DSMB Meeting	Dec 16 (Monday)

*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 potential adjudicated events. This will ensure that the DCC is able to submit complete packets to TIMI for adjudication prior to the DSMB.

Report Potential Adjudicated Events

One essential task we don't want sites to forget is to identify and report potential adjudicated events!



Adjudicated Events in REPRIEVE are:

- Atherosclerotic or other CVD death
- Nonfatal myocardial infarction
- Unstable angina hospitalization
- Coronary or peripheral arterial revascularization

- Peripheral arterial ischemia
- Nonfatal stroke or transient ischemic attack (TIA)
- Heart failure
- Death from any cause

Important steps in identifying and reporting adjudicated events include:

- Take a thorough history from the participant and review the medical record to identify any potential adjudicated events.
- Ensure that the Heart-Related Health Questionnaire has been completed and is kept with source documents
- Ensure that 100% of Adjudicated Event Tracking CRFs have been completed accurately and necessary steps have been taken to submit any potential events for adjudication as per section 6.0 of the REPRIEVE (A5332) MOPS.

If your site submits a packet for a potential adjudicated event, please make sure that the Site PI or their designee reviews the packet and agrees with the content before it is submitted to the REPRIEVE Data Coordinating Center.



Introducing Gerald (Jerry) Bloomfield, MD, MPH, and REPRIEVE Cardiologist!

Dr. Gerald (Jerry) S. Bloomfield is an Associate Professor of Medicine and Global Health at Duke University. Dr. Bloomfield's research interests are in the epidemiology, treatment and prevention of cardiovascular diseases domestically and in the global health context. He is particularly focused on heart failure and HIV-associated cardiovascular diseases, where he studies the application of ultrasound imaging to detect and predict myocardial dysfunction in people living with HIV.

Bloomfield has lived and worked in Kenya intermittently since 2003 where he has led studies of heart failure epidemiology, cardiovascular effects of indoor air pollution, genetic associations with cardiac arrhythmias and cardiovascular disease risk factors among people living with HIV.

To stay heart healthy: Jerry tries to get 7–8 hours of sleep every night and stays mindful of portion sizes!

Don't Forget!

OpenClinica Training Videos are Available in the FSTRF Portal

Under the 'Site Support' tab, you can find a ton of helpful videos to assist you with data entry in OpenClinica!

Unsure how to *change previously saved data* or *enter an out of window visit*? There are videos that address both of those questions and more!

All videos are located under Site Support on the REPRIEVE tab in the FSTRF portal, <http://www.fstrf.org>, and at <https://www.youtube.com/user/FSTRFfilms>.



Reminder About Timing of Vaccinations

With flu season approaching in the Northern Hemisphere, remember that sites may administer vaccinations on the same day as REPRIEVE study visits, but please do so after any blood to be banked has been drawn.

Participant moving? Transfer REPRIEVE participants to nearby sites!

Given the duration of REPRIEVE, it is likely one or more of your participants may move out of the area. REPRIEVE has sites in nearly every state in the US and in 11 countries around the world! So if one of your REPRIEVE participants is moving, chances are there is another site nearby! [Click here](#) to find a map of our clinical sites.

REPRIEVE follows [SOP ACTG-119, Study Participant Transfer](#) for participant transfers, however specific protocol guidance can be found in section 12.5 of the REPRIEVE (A5332) MOPs.



Save the Date!
Tuesday, November, 19th
2019
1:00 – 2:00 PM ET

For the next Monthly Site Call!

If you missed the September monthly site call, [click here](#) to download slides.

REPRIEVE (A5332): Are you up to date?*For A5332 please use:**Protocol Version 5.0 dated 04/01/2019**MOPS Version 5.0 dated 04/15/2019**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@fstrf.org



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