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Randomized Trial to Prevent Vascular Events in HIV



Recognize Your REPRIEVE Participants with our *new* REPRIEVE Tokens of Appreciation!

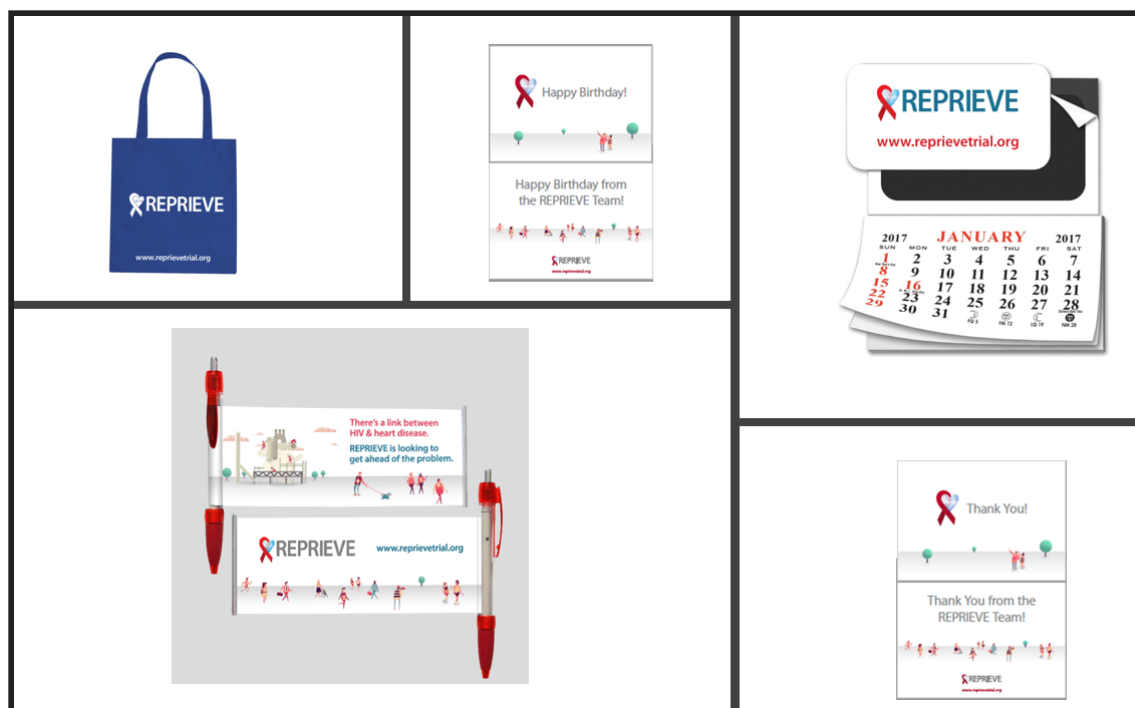
REPRIEVE Retention Champions shared with us that small tokens of appreciation are helpful tools to promote retention in REPRIEVE. The CCC has developed REPRIEVE-branded tools that are available to all sites (for free!)*.

The following items are available:

- New 2020 Magnet Calendars
- REPRIEVE Banner Pens (*new design!*)
- REPRIEVE Birthday Cards
- REPRIEVE Thank You Cards

If you would like to request tokens of appreciation for your participants, please email Emma Kileel at ekileel@mg.harvard.edu.

**These have been approved by the IRB for the REPRIEVE CCC, however please seek approval according to your local requirements.*



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 Friday, November 22nd, is the next important deadline.

Timeline for DSMB Meeting Dec 16th

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.



Q: What if a participant's PCP wants to prescribe a statin during study participation?

It is recommended that the site PI follow up with the clinician prescribing the statin in order to determine if there is a true clinical indication for this intervention. Participants initiating clinically prescribed statins must come off of study drug but should remain in study follow-up. If this occurs, please perform a premature treatment discontinuation evaluation for this participant as per the Schedule of Evaluations so that these participants are followed on-study, off-drug.

A template for a "participant card" with information about study participant is available on the A5332 PSWP and by [clicking here](#)*. This tool was developed so that participants can alert other clinicians of their participation in REPRIEVE and make them aware that they may already be on a statin therapy. Please consider using this helpful tool!

**Submit to your local IRB/Ethics as per your local requirements. If you require this tool in another language please email Emma Kileel at ekileel@mgh.harvard.edu*



Spotlight On: Durban International Clinical Research Team



Site 11201: Durban International Clinical Research Site

Located in Durban, South Africa, site 11201 has been a tremendous contributor to REPRIEVE, enrolling a total of 161 participants! Having successfully retained 98% of their participants, we asked the Durban Int'l team to share their retention tips:

- Ensure adequate staff time and effort to retention
- Host gatherings for study participants
- Perform random acts of kindness to participants.

Thank you, Durban Int'l team, for all your efforts in REPRIEVE!

Report Potential Adjudicated Events



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

If you would like to join a call with REPRIEVE Investigators to review REPRIEVE's Adjudicated Events and the workflow to report these events, the Clinical Coordinating Center would be happy to arrange this! Please email Katie Fitch at kfitch@partners.org

Adjudicated Events in REPRIEVE are:

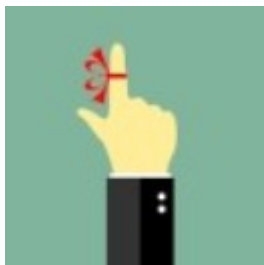
- Atherosclerotic or other CVD death
- Nonfatal myocardial infarction
- Unstable angina hospitalization
- Coronary or peripheral arterial revascularization
- Peripheral arterial ischemia
- Nonfatal stroke or transient ischemic attack (TIA)
- Heart failure

- 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 you have a question about reporting a potential adjudicated event do not hesitate to email the REPRIEVE (A5332) Core Team at actg.corea5332@fstrf.org, a designated team member is ALWAYS available to help.



Don't Forget!

The A5332 PSWP has protocol training refresher slides! These slides are located in the Protocol Training folder-->Optional Tools folder. Please remember to share these with new staff and review them periodically.

Have you sent us your REPRIEVE team photo?

We would like to feature sites on our website and on future newsletters! Please send a team photo and retention or heart healthy tip to reprieve.news@fstrf.org to be featured!



Reminder: BRI Holiday Closure

BRI will be closed on Thursday, November 28th in observance of the U.S. Thanksgiving Holiday. If your site is scheduled to ship the 4th week of November, please only ship on Monday, November 25th or contact brirepository@afbr-bri.com to make alternate shipping arrangements.



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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