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Randomized Trial to Prevent Vascular Events in HIV



Hold regular REPRIEVE team meetings! Many sites have shared that regular meetings are a great opportunity to discuss participants who are missing visits and to brainstorm ways to reengage the participant(s).

And don't forget! There is new guidance in Version 5.0 of the A5332 protocol and MOPS about participants who are missing visits. Please discuss this as a team and ask any questions you may have about this on the next site call (May 21st).

Retention Tools are Available!





REPRIEVE Retention Champions shared with us that *pens, participant newsletters, thank you cards, and birthday cards (above)* are helpful tools to promote retention. The REPRIEVE CCC has developed these REPRIEVE-branded tools which are *available to all sites (for free!)*. Some sites have begun handing these out to participants and they have been very well received!

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



Dr. Judith Currier, professor of medicine and chief of the Division of Infectious Diseases at UCLA Health.

Congratulations to Judy Currier: "Game Changer in HIV Care"

ACTG Chair and Investigator of Record for REPRIEVE at UCLA Care Center, Judy Currier, was selected by the prominent HIV platform, TheBody.com, as a "Game Changer in HIV Care" for 2019. Judy was selected for her longstanding commitment to the HIV community. As always, we are honored to have such dedicated physicians and researchers as part of our REPRIEVE Team! Congratulations Judy!





The 4th REPRIEVE Participant Newsletter is now available!*

<u>Click here</u> to download. If you would like hard copies, please email Emma Kileel at <u>ekileel@mgh.harvard.edu</u> and let her know how many copies you need.

Participant newsletters are an excellent way to remind your participants of the importance of REPRIEVE and keep them engaged in the trial!

Newsletters will also be translated to Spanish, Portuguese, French, Xhosa and Africaans. If you require another language please let us know.

^{*}This has been approved by the IRB for the REPRIEVE CCC however, seek approval according to your local requirements.

Reminder: Next DSMB Meeting is June 24th, 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 important dates in your calendar and note that Friday, May 31st is the deadline to respond to last minute outstanding queries.

Task		Deadline* (2019)
Sites	Last date for the occurrence of an evaluation for which complete data will be included in this DSMB review	April 22 nd (Monday)
Sites	All data for visits through April 22nd entered	Apr 29 th (Monday)
Sites	All adjudication packets for potential MACE events with a work-up complete by April 22nd submitted to DCC (MGH)**	May 3 rd (Friday)
Sites	All outstanding queries resolved	May 13 th (Monday)
Sites	Respond to last minute outstanding queries	May 31 st (Friday)
	DSMB Meeting	June 24 th (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.



Important Reminder About ECG Machines

THANK YOU to every site that has already returned their ECG machine to IQVIA! Over 70 machines have been returned so far.

For sites that have not yet returned their REPRIEVE (A5332) ECG machine:

- All sites should have received an email from IQVIA Machine Logistics with an airway bill (AWB) and instructions to return the machine. If you have not received this email please email <u>kfitch@partners.org</u> as soon as possible.
- Sites have 60 days from the receipt of the 1st retrieval email to return the machine, the CCC will be charged for any ECG machines not returned within this time.

Thank you so much for your attention to this matter.

Updated A5332 Documents are Available on the PSWP!



What's new?

- Version 5.0 Spanish Sample Informed Consent
- Version 5.0 of the A5332 protocol, Manual of Operations (MOPs) and Lab Processing Charts (LPCs).*
- Key messages and talking points about REPRIEVE and the increased follow up to share with your participants.**

If you have not downloaded these updated documents please do so as soon as possible.

In case you missed the email. During the team/site call on Tuesday, April 16th, there was a question about whether a protocol-specific signature page is required for the A5333s substudy for Version 5.0 of the protocol.

Since there are no changes to A5333s, DAIDS has confirmed that a protocol-specific signature page is <u>not</u> required for A5333s for Version 5.0.









TRAINING OPPORTUNITIES

The DAIDS Protocol Registration Team will be hosting training sessions about revisions to the DAIDS Protocol Registration Manual and Policy.

To view dates and times, and instructions on how to register please <u>click</u> here.

The next training date is Thursday, May 16th at 10:00 PM ET

^{*}The updated MOPs and LPCs will be reviewed on the next monthly site call.

^{**}This has been approved by the IRB for the REPRIEVE CCC however, please follow your local IRB requirements.



Specimen Collection Reminder

Specimen collection is important in both REPRIEVE (A5332) and the Mechanistic Substudy of REPRIEVE (A5333s) and the specimen collection schedule is very straightforward.

Please make every effort to collect specimens as per section 6.0 of the protocol and ALWAYS refer to the appropriate Lab Processing Chart for detailed instructions about processing, storing and shipping of specimens.



Save the Date! Tuesday, May 21st, 2019 1:00 - 2:00 PM ET

For the May Monthly Site Call!

Please make every effort to join this call as we will be discussing the updated MOPS and LPC.

REPRIEVE (A5332): Are you up to date?

For A5332 please use:

Protocol Version 5.0 dated 04/01/2019 (new version!)

MOPS Version 5.0 dated 04/15/2019 (new version!)

A5332 LPC for ACTG Sites Version 5.0 dated 04/11/2019 (new version!)

A5332 LPC for Non-ACTG Sites Version 5.0 dated 04/11/2019 (new version!)

These documents are on the A5332 PSWP

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

For A5333s please use

Protocol Version 4.0 dated 03/28/2018 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







REPRIEVE Trial Clinical Coordinating Center

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Our mailing address is: reprieve.news@fstrf.org

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