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Randomized Trial to Prevent Vascular Events in HIV



Retention Tip of the Month!

Stay engaged with REPRIEVE participants by recognizing HIV/AIDS awareness days in your clinic and/or on your social media platforms! Below is a list of the remaining HIV/AIDS awareness days for the 2019 calendar year, mark them in your calendar and encourage your site staff to recognize them within your community!

Awareness Day	Hashtag	Date
National Youth HIV & AIDS Awareness Day	#NYHAAD	April 10
National Transgender HIV Testing Day	#TransHIV	April 18
HIV Vaccine Awareness Day	#HVAD	May 18
National Asian & Pacific Islander HIV/AIDS Awareness Day	#APIMay19	May 19
HIV Long-Term Survivors Day	#HLTSAD	June 5
National HIV Testing Day	#HIVTestingDay	June 27
National HIV/AIDS and Aging Awareness Day	#HIVandAging	September 18
National Gay Men's HIV/AIDS Awareness Day	#NGMHAAD	September 27
National Latinx AIDS Awareness Day	#NLAAD	October 15
World AIDS Day	#WAD	December 1



Read About REPRIEVE in the American Heart Journal!

REPRIEVE Leadership is excited to share with you that the manuscripts about the rationale and design of REPRIEVE (A5332) and the Mechanistic Substudy of REPRIEVE (A5333s) are each available online at the American Heart Journal. Click here to read more.

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 Monday, April 22nd is the next important deadline.

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 31st (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.



Return of the ECG Machines

THANK YOU to every site that has already returned their ECG machine to IQVIA!

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

- If you have received a "Retrieval of ECG Machine" request from IQVIA and you have not returned your ECG machine please do so as soon as possible.
- If you have not received an email retrieval request from the Machine Logistics group at IQVIA, email <u>csscdsupport@quintiles.com</u> to let them know your machine is ready to be returned.

Thank you so much for your attention to this matter.



DAIDS RSC Regulatory Support Center

The Office of Management and Budget's (OMB's) approval of Form FDA 1572 expired on February 28, 2019, however the form posted online is still valid for use by investigators and sponsors. The FDA is in the process of updating the Form FDA 1572. Even though it is expired, Investigators should continue to use the current form available. The most recent version of the Form FDA 1572 is the one available here. Once a Form FDA 1572 with an updated expiration date becomes available, sites do not need to send an updated Form just because the Form expiration date has been updated.

However, once the updated Form is available, sites should use the current version (updated Form) if/when sites change information on their current Form FDA 1572 submitted to the DAIDS PRO.



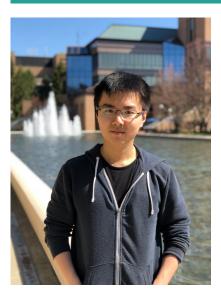






TRAINING OPPORTUNITIES

The DAIDS Protocol Registration Team will be hosting training sessions regarding revisions to the DAIDS Protocol Registration Manual and Policy. To view dates and times, and instructions on how to register please <u>click here</u>.



Meet Allen Jin! Clinical Research Coordinator at the REPRIEVE DCC

Allen just joined the Data Coordinating Center (DCC) and he is replacing Saeyun Lee. Allen is responsible for the collection, completeness, and transfer of source documentation information between the Clinical Research Site (CRS) and the Clinical Events Committee (CEC). Outside of work, Allen enjoys performance art and drawing. For any questions regarding a potential adjudicated event, please don't hesitate to contact Allen at:

ZJIN1@mgh.harvard.edu or MGHReprieve@partners.org



Before you ship, do a 100% QA/QC of your storage box

- Check the Global Specimen ID. The global ID is specific to each aliquot and ends with -001, -002 etc....
- Check 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
- Check that each label is clearly printed and legible.

The specimen repository, BRI, receives many shipments each day, doing a QA/QC prior to every single shipment ensures that samples move from the shipping container to freezers with ease and helps to prevent issues you will need to respond to in your Shipment Evaluation.



Specimen Collection Reminder

Specimen collection is important in both REPRIEVE (A5332) and the Mechanistic Substudy of REPRIEVE (A5333s) and you may have noticed that 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 the detailed instructions about processing, storing and shipping of specimens.

Save the Date!

Tuesday, April 16th, 2019 1:00 - 2:00 PM ET

For the April Monthly Site Call!



Please make every effort to join this call as we will be discussing the forthcoming full version protocol amendment

REPRIEVE (A5332): Are you up to date?

For A5332 please use:
Protocol Version 4.0 dated 03/28/2018
V4.0 LOA #1 dated 05/16/2018
MOPS Version 4.0 dated 10/16/18
A5332 LPC for ACTG Sites Version 4.0 dated 03/22/2018
A5332 LPC for Non-ACTG Sites Version 4.0 dated 07/23/2018
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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