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Randomized Trial to Prevent Vascular Events in HIV

From the Data Management Center: CRF Updates in OpenClinica



REPRIEVE (A5332) CRF updates include the following changes:

1. The team added a new instruction to the TXW0295 Medications Log v1.05 that clarifies how to correctly report COVID-19/SARS-CoV-2 vaccine dose(s).
2. The TRK0199 Consent/Deconsent for Genetic Information Sharing form v1.01 contains a configuration fix that stops the user from having to complete either 'Date of decision' field if s/he selects 'Not applicable' in the preceding data field(s).

The memo with more details was distributed via email on June 2nd and is attached [here](#). Please make sure you understand the changes and don't hesitate to reach out to the REPRIEVE Data Managers by email: reprieve.dmc@fstrf.org if you have any questions.



Next REPRIEVE DSMB Meeting: September 21, 2021 *See below for key dates!*

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, July 9** is the [data entry deadline](#). Please ensure that complete data have been entered for visits that have occurred by **Friday, June 25**, particularly data related to potential adjudicated events and COVID-19 diagnoses.

Please make an effort to reach out to participants who have not been seen in a while, including *other contact* or *chart review*, if 3 consecutive visits have been missed (see Appendix V in the MOPS).

Please also review that vital status and endpoint follow-up of participants who have discontinued study is current (see protocol section 6.3.10).

	Task	Deadline* (2021)	Weeks to DSMB
	Latest date for the occurrence of an evaluation for which complete data will be included in this DSMB review	June 25 (Fri)	12.6
	US Independence Day holiday (observed)	Jul 5 (Mon)	
Sites	All data for visits through June 25 entered into OpenClinica	Jul 9 (Fri)	10.6
Sites	All adjudication packets for potential MACE events by June 25 with work-up complete submitted to MGH DCC**	Jul 9 (Fri)	10.6
Sites	All queries resolved	Aug 6 (Fri)	6.6
Sites	Respond to last minute outstanding queries	Aug 13 (Fri)	5.6
	US Labor Day holiday	Sep 6 (Mon)	
	DSMB Meeting	Sep 21 (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.

Did you know that prescribed medications for the treatment of COVID-19 should be entered on the Medications Log (TXW0295)?



The list of medications to be entered is located on the A5332 Protocol Specific Webpage in the Current Study Specific Support Documents (Version 5.0) folder and it is attached [here](#) for your reference. Please make sure you use this list when entering medications prescribed for COVID-19.

Share this exciting event with your REPRIEVE Community!

Ask your participants to *save the date* for the first **REPRIEVE Trial Virtual Community Forum on Thursday, June 17th at 11AM EDT!**

The forum is intended for REPRIEVE participants and community members but is open to anyone interested in joining. The forum is being held as part of the ACTG Annual Network Meeting but is open to members outside of the ACTG Network. Visit the [Community Forum webpage](#) on the REPRIEVE website for more information

THE REPRIEVE TRIAL

COMMUNITY FORUM

Join us for a virtual gathering to discuss trial progress!

**JUNE 17TH
11AM EDT**

This forum is open to all, including REPRIEVE participants and community members. The forum is being held as part of the ACTG Annual Network Meeting.

Registration information will follow.



APRIL 2021



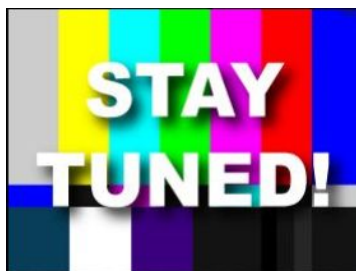
REPRIEVE PARTICIPANT NEWSLETTER

Don't Forget to Request the 2021 Participant Newsletter!

Sites may now request hard copies of the 6th Annual Participant Newsletter! The participant newsletter is an excellent way to update your participants about REPRIEVE and keep them engaged in the trial! [Click here](#) to request hard copies of the newsletter for your site! Please indicate which language(s) your site would like and the quantity of each. To download the English version, [click here](#).

The newsletter has been approved by the IRB for the CCC, please submit to your local IRB/EC as per your local requirements.

During the month of September we will have a virtual meeting dedicated to shipping and other lab topics. Any team members who are responsible for shipping and LDMS entries should join. Stay tuned for more details to be sent closer to the date!



Thank you to REPRIEVE site teams! In case you missed the email, [click here](#) to see the thank you graphic from REPRIEVE leadership!



Save the Date Next Team/Site Call!
July 20th 1PM EDT

Join us for important trial updates!

- 1:00 PM HAITI (EDT)
- 1:00 PM PERU (PET)
- 2:00 PM PUERTO RICO (ADT)
- 3:00 PM BRAZIL (BRT)
- 8:00 PM BOTSWANA (CAT)***
- 8:00 PM SOUTH AFRICA (SAST)***
- 8:00 PM ZIMBABWE (CAT)***
- 9:00 PM UGANDA (EAT)***
- 11:30 PM INDIA (IST)***
- 1:00 AM 01/20/2021 THAILAND (ICT)***

***We do not expect site staff to join these calls during their off-work hours. Instead we will update you on other scheduled calls, e.g., your calls with the ACTG NCC.

Remember that questions are always welcome at actg_corea5332@fstrf.org and if there are slides used for a call, they are available on the PSWP in the Protocol Training >> Site Calls folder.

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
Version 5.0, Letter of Amendment 2 dated 12/14/2020
MOPS Version 5.0 dated 02/08/2021
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](#)

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@fstfrf.org



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