REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

THANK YOU REPRIEVE Site Teams for all your continued efforts during this time. We recognize that many of you are being pulled in a number of new and different directions right now, which can be challenging. However, we are able to see that site visits are taking place (remote or in person), a large number of people joined the site call in April, and the volume of site questions remains steady. We do appreciate your continued efforts on REPRIEVE!

This newsletter highlights important REPRIEVE news, FAQs about the new COVID-19 Assessment CRF, and some important activities to remember during the pandemic. For the Clinical Coordinating Center, maintaining consistency is essential and we will continue to send out the newsletter monthly. If you would like to share a story about an experience you've had during the pandemic, a unique activity that you have taken on, or ideas for future newsletters please email reprieve.news@fstrf.org, we would love to hear from you.

The Team from the REPRIEVE Clinical Coordinating Center

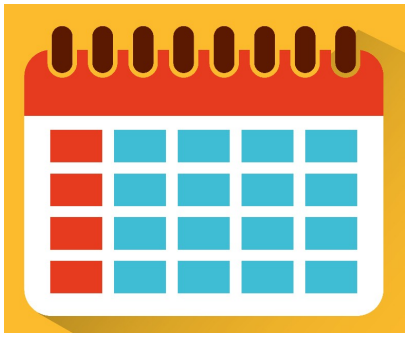
A5332 Clarification Memo #2, dated 05/04/20 which contains a clarification on blood collection due to COVID-19 was distributed on Monday, May 4th. If you did not receive the email, please download the memo from the A5332 PSWP, Current Protocol Documents (Version 5.0) folder.

REPRIEVE Manuscripts to be Published in the *Journal*

of Infectious Diseases!

A collection of 6 manuscripts, plus an introduction piece, have been accepted for publication in the Journal of Infectious Diseases! Highlighting key baseline characteristics of the REPRIEVE population, the manuscripts - which will be published as a supplement in JID this summer - include:

- Patterns of Antiretroviral Therapy Use and Immunologic Profiles at Enrollment in the REPRIEVE Trial, *Fichtenbaum et al.*
- Characteristics of REPRIEVE Trial Participants Identifying Across the Transgender Spectrum, *Smeaton et al.*
- An Evaluation of Baseline Kidney Function in the REPRIEVE Trial, *Overton et al.*
- Myocardial Steatosis among Antiretroviral Therapy-Treated People with HIV Participating in the REPRIEVE Trial, *Neilan et al.*
- Physical Function Impairment and Frailty in Middle-Aged People Living with HIV in the REPRIEVE Trial Ancillary Study PREPARE, *Umbleja et al.*
- Correlates and Timing of Reproductive Aging Transitions in a Global Cohort of Midlife Women with HIV: Insights from the REPRIEVE Trial, *Looby et al.*



Save the Date: Friday, July 24th REPRIEVE Virtual Meeting!

On Friday, July 24th, at 10:30AM EST, ALL REPRIEVE Investigators and site staff are invited to join the REPRIEVE Virtual Meeting!

During this meeting we will share important trial updates, hear a keynote presentation from Dr. Sandra Wagner Cardoso from Brazil, as well as three presentations from REPRIEVE Co-Investigators, Dr. Turner Overton, Dr. Carl Fichtenbaum, and Dr. Kristine Erlandson on key baseline REPRIEVE data being shared widely for the first time!

You should have received a calendar invite distributed on April 28th, if not email Katie Fitch, kfitch@partners.org, and she can forward the invite to you.

2 Very Important Activities to Remember During the COVID-19 Pandemic

(1) Report Potential Adjudicated Events on the TRK0150

Identifying and recording potential adjudicated events on the Adjudicated Event Tracking CRF (TRK0150) per section 6.0 of the REPRIEVE (A5332) MOPS continues to be essential for the trial.

We do recognize that submission of source documents may present a challenge due to local restrictions during the pandemic. However, we ask that study teams continue to record any potential events on the TRK0150 and completion of source document collection and submission to the DCC can be done once local institutional restrictions are lifted.

Going forward we are asking that the COVID-19 Assessment CRF (SSW0040) be submitted with all future source document packets for adjudication. If the CRF is not available please mention this in the event summary signed by the PI.

(2) Annual Specimen Collection

Please remember the annual specimen collection! If a participant misses an annual visit when specimens are collected, you can collect them at the next in person visit. Use the revised Lab Processing Chart depending on your site designation (ACTG or non-network/non-ACTG) located on the PSWP.

Below is some guidance about missed visits when specimens are to be collected from section 4.3 of the A5332 MOPS

NOTE: If a participant misses a visit when stored specimens are to be collected, eg, the month 12 visit, but returns for the next visit, eg, the month 16

visit, obtain specimens as per the Lab Processing Chart (LPC) for the missed visit (month 12) and complete the following:

- In OpenClinica: Key the SPW0492 - Specimen Tracking form in the Supplemental Forms visit, key all other month 16 forms in the month 16 visit.
- In LDMS: Use the month 12 Preloads or Quick Add and note in the comments field that month samples were collected at month 16. See the LPC for instruction on how to enter these specimens in the LDMS.

2020 Participant Newsletter Now Available!

The 5th annual Participant Newsletter is now available for sites to distribute to their participants and is available in over 8 languages! Click here to download the electronic version of the English newsletter. If your site would like to receive hard copies, please click here to tell us how many copies you would like and in which languages.

**These have been approved by the IRB for the CCC, please submit to your local IRB/EC as per your local requirements.*

New LDMS Preloads Available!

FSTRF is pleased to announce that the version 5 update of preloads/templates for protocol REPRIEVE A5332 are now available. To receive these new preloads please perform an LDMS Export. Preloads for the following REPRIEVE A5332 visits are included with this release;

A5332 Month 36- All Sites
A5332 Month 60- All Sites
A5332 Month 72- All Sites
A5332 Month 84- All Sites
A5332 MONTH 24 - NON-NETWORK SITES
A5332 MONTH 48 - NON-NETWORK SITES

Please be sure your CRS affiliated LDMS processing laboratory staff are made aware of this announcement.
If you are unsure what a preload/template is or how to use them in LDMS, please contact ldmshelp@fstrf.org for assistance.

These preloads were developed by the A5332 Laboratory Data Managers (LDM). Editing and customization of FSTRF defined preloads is not permitted. Please inform the A5332 LDMs if any issues are found with a FSTRF defined preload.

Who's Who on the REPRIEVE Team?

Meet Heather Sprenger, Rebecca LeBlanc, and Frederic Bone, REPRIEVE Lab Data Managers!

Heather Sprenger is the Laboratory Data Division Chief at Frontier Science, where she has worked on HIV laboratory data management for almost 18 years. She provides instruction and oversight to the laboratory data managers, and collaborates with other departments at Frontier Science to make sure the REPRIEVE laboratory data management needs are met. She participates in the REPRIEVE Laboratory Committee and contributes to laboratory monitoring efforts. Heather's hobbies include birding, camping, crochet, knitting, and gardening.

Rebecca LeBlanc has been a Laboratory Data Manager at Frontier Science since 2016. She currently works as an LDM for the REPRIEVE, ACTG, IMPAACT, and PHACS projects. She is also part of the LDMS Training team and teaches laboratories how to use the LDMS software.

Rebecca's primary role as a Laboratory Data Manager on the REPRIEVE project is to coordinate shipment of samples

to testing labs, receive the data, and upload to the database once testing is complete. She looks forward to continue working with the team and watching the project progress.

Many of you have also probably communicated with our longstanding Lab Data Manager, Frederic Bone. Frederic is a Laboratory Data Manager at FSTRF, he is responsible for the day-to-day laboratory data monitoring duties for the REPRIEVE trial; mostly managing the specimen inventory monitoring aspect of it. Frederic worked as a laboratory technician for 20 years before joining FSTRF.

Helpful FAQs about the new COVID-19 Assessment CRF (SSW0040)

Q: When completing the SSW0040, the participant reported nasal congestion due to allergies, not COVID-19, do I key "yes" for nasal congestion on the SSW0040?

A: Key "yes" for nasal congestion. The intent of collecting these symptoms is to collect general information on the prevalence of symptoms in the REPRIEVE population.

Q: I just want to confirm that "assessing for COVID-19" is asking the participant if they have tested positive for COVID-19 or asking the screening questions to identify potential symptoms of COVID-19?

A: The SSW0040 prompts study staff to ask if a participant has had a test for CVOID-19 and to key the result of the test (positive, negative or unknown). The SSW0040 then prompts study staff to ask if the participant has experienced potential symptoms of COVID-19 since the last study evaluation.

Q: On the SSW0040 there is a question "Has the participant been evaluated by a Health Care Professional for COVID-19?" Does this include the current evaluation? That is, if nobody else has evaluated the participant for COVID and I am now asking him these COVID related questions, how should I answer this question?

A: This question is intended to be interpreted as follows: "Has the participant been evaluated by a Health Care Professional for COVID-19 [other than the current evaluation]? If nobody else has evaluated the participant for COVID and you are now asking him these COVID related questions, the CRF response should be "No". Sites are not clinically screening participants for COVID-19 but rather tracking their history of symptomatology and diagnosis.

Reminder: Continue to Hold All REPRIEVE Specimens Until Further Notice!

New NIAID HIV Language Guide!

The NIAID Office of Communications developed the NIAID HIV Language Guide to encourage the use of non-stigmatizing language. The guide has received input from and been reviewed by members of the Underrepresented Populations Committee and the Women's Health Inter-Network Scientific Committee. We encourage REPRIEVE sites to review the guide and share it with members of your community!
Click here to download the NIAID HIV Language Guide

Next Team/Site Call
Tuesday, July 21st, 2020
1:00 - 2:00 PM ET

If you missed the April 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*
Version 5.0, Clarification Memo 1 *dated 04/03/2020*
New! Version 5.0, Clarification Memo 2 *dated 05/04/2020*
MOPS Version 5.0 *dated 04/08/2020*
Revised! A5332 LPC for ACTG Sites *Version 5.0 dated 05/04/2020*
Revised! A5332 LPC for Non-ACTG Sites *Version 5.0 dated 05/04/2020*
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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