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## **Randomized Trial to Prevent Vascular Events in HIV**

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### **Important Data and Specimen Collection Reminders and Tips!**

#### **Reminders: Data and Specimen Collection**

During the COVID-19 pandemic, we understand that specimen collection has been impacted and data entry delayed due to local restrictions. In order to maintain the scientific integrity and validity of REPRIEVE, the REPRIEVE CCC/DCC teams have been keeping a close eye on data entry and specimen collection across all REPRIEVE sites and **we would like to remind sites of these important points:**

1. Data related to a REPRIEVE study visit (in-person or remote) should be entered in OpenClinica within 3 weeks of the visit date.
2. The Adjudicated Events Tracking CRF (TRK0150) should be completed at every visit.
3. If a visit that includes specimen collection is missed or not conducted in person, complete the specimen collection at the next in-person visit. See section 4.3 of the REPRIEVE (A5332) MOPS for guidance on how to enter the specimens in OpenClinica and LDMS.

If you need more information on any of the points above or have any questions, don't hesitate to reach out to the core team at [actg.corea5332@fstrf.org](mailto:actg.corea5332@fstrf.org).

#### **Tips: REPRIEVE Site Teams Share Tips to Ensure Complete *and* Quality Data Entry**

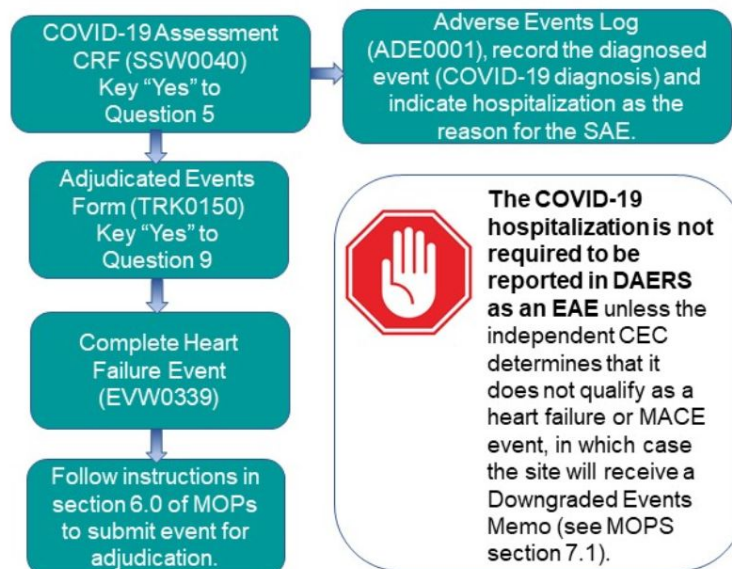
- Create a 'data entry checklist' of things that need to be done at each visit in order to consider the visit complete. Use this checklist at each visit and keep it with your source documents!
- Complete data entry immediately after the visit.
- Designate site personnel for data QA/QC.

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***In Case You Missed It: Guidance on Reporting COVID-19 Hospitalizations***

Use the workflow diagram below to assist you with reporting a COVID-19 hospitalization. A clarification on reporting of COVID-19 hospitalizations was made in subsection 4.2 of the revised MOPS (dated 020821). [Click here](#) to download the workflow.

## Reporting COVID-19 Hospitalizations



## COVID-19 and Influenza Vaccine Recording

- **COVID-19 vaccinations are required** to be recorded in OpenClinica on the Medications Log and categorized as COVID-19 treatment.
- **Influenza vaccines are not required** to be recorded on the Medications Log in OpenClinica. The COVID-19 Treatment List has been updated to reflect this, the updated version is now posted on the A5332 PWSP.

*REPRIEVE participants are not excluded from receiving a COVID-19 vaccination.*

## Learn More About Veeva SiteVault!

To support DAIDS in its effort to ensure remote source document verification (rSDV) is available at all sites where feasible and approved by the IRB/EC, the REPRIEVE CCC has been working with Veeva SiteVault Free in an effort to easily facilitate establishment of this platform for REPRIEVE sites that do not yet have an rSDV platform in place.

To learn more about how Veeva SiteVault can support your site, watch this informational session (that was recorded for REPRIEVE sites) [here](#). Full link: <https://veevasystems.wistia.com/medias/xshj9yttec>  
If you have any questions about rSDV at your site email Katie Fitch, [kfitch@partners.org](mailto:kfitch@partners.org).

## News from the REPRIEVE Data Coordinating Center (DCC)



### *Dr. Michael Lu is the new Co-PI of the DCC*

Dr. Michael T. Lu, MD, MPH, who has served as Co-Chair of the REPRIEVE Mechanistic Substudy since 2014, has now assumed the role of Co-Principal Investigator for the REPRIEVE DCC. Dr. Lu is replacing Dr. Udo Hoffmann as Co-PI of the DCC because Dr. Hoffmann has transitioned out of this role to pursue other interests.

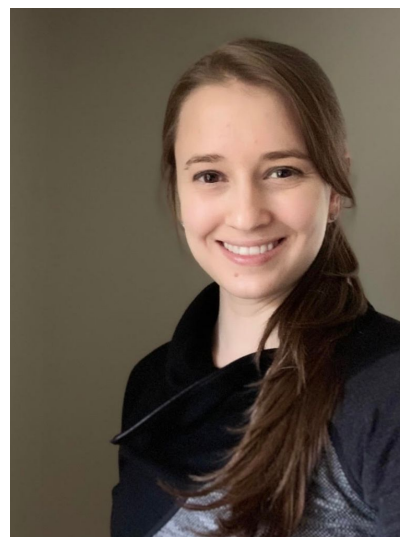
Dr. Lu is a cardiovascular radiologist and Co-Director of the Massachusetts General Hospital Cardiovascular Imaging Research Center (CIRC). He leads the REPRIEVE Cardiac CT core laboratory as well as several other studies involving cardiac CT and HIV. He completed his Bachelors, MD, and MPH degrees at Harvard University. His training included a residency in Diagnostic Radiology at the University of California, San Francisco, and fellowships in Thoracic and Cardiac Imaging at Massachusetts General Hospital.

Outside of work, Dr. Lu's twin kindergarten-age children keep his hands full.

### *Meet Kayla Paradis, new Project Manager of the DCC*

Kayla joined the REPRIEVE team in 2020 as the project manager for the REPRIEVE DCC. In her role, Kayla manages and oversees REPRIEVE adjudication, trial operations as related to the DCC, imaging and non-imaging data management, QA/QC, and clinical trials documentation.

Outside of work Kayla enjoys rock climbing and hiking with her dog.



## REPRIEVE Face Masks Available!

*Want to provide your participants with a token of appreciation for their participation in REPRIEVE?*



Provide them with a REPRIEVE branded face mask! The CCC has a limited number of these available, therefore we ask that you limit your request to 50 masks. If you would like to request face masks for your REPRIEVE participants email Emma Kileel at [ekileel@mgh.harvard.edu](mailto:ekileel@mgh.harvard.edu)!



## Have You Visited the DAIDS Score Manual Webpage?

<https://www.niaid.nih.gov/research/daids-score-manual>

The Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual describes operational requirements for Clinical Research Sites (CRSs) implementing DAIDS-sponsored clinical research within the DAIDS Clinical Trials Networks.

The DAIDS SCORE Manual serves as a resource for CRSs by consolidating operational requirements in a central location and providing tools to facilitate compliance with these requirements.

CRS staff should direct any questions related to these requirements to their Office of Clinical Site Oversight (OCSO) Program Officers (POs) and/or the Pharmaceutical Affairs Branch (PAB) Pharmacists as appropriate.

If you would like to see a recording of the training session about the SCORE Manual, go to the HANC website links below to access the recording and presentation slides.

**Presentation recording:**

<https://fredhutch.hosted.panopto.com/Panopto/Pages/Viewer.aspx?id=4f1e2c6a-4829-4163-baa8-accb010adb31>

**Presentation slides:**

[https://www.hanc.info/resources/Documents/DAIDS%20SCORE%20Manual%20Launch%20Webinar\\_Final%2009FEB2021.pptx](https://www.hanc.info/resources/Documents/DAIDS%20SCORE%20Manual%20Launch%20Webinar_Final%2009FEB2021.pptx)



**Save the Date Next Team/Site Call!**  
**April 20th, 2021 1PM EST**

Join us for the next Team/Site call on April 20th, 2021 at 1:00PM EST! The call will feature four presentations highlighting the latest findings from REPRIEVE baseline data:

- Cardiovascular Risk and Health Assessments among People with HIV Eligible for Primary Prevention: Insights from the REPRIEVE Trial, *presented by Pamela Douglas*
- Assessment of Obesity and Metabolic Profile by Integrase Inhibitor Use in REPRIEVE, *presented by Janet Lo.*
- Diet Quality by Global Burden of Disease Region in PWH in the REPRIEVE Trial, *presented by Katie Fitch.*
- Factors Associated with Systemic Immune Activation in a Global HIV Cohort, *presented by Markella Zanni.*
- Coronary Artery Disease, Traditional Risk and Inflammation Among PWH in REPRIEVE *presented by Steven Grinspoon.*

\*\*\*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.

1:00 PM HAITI (EST)  
 1:00 PM PERU (PET)  
 2:00 PM PUERTO RICO (AST)  
 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)\*\*\*

Remember that questions are always welcome at [actg\\_corea5332@fstf.org](mailto:actg_corea5332@fstf.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@fstf.org](mailto:reprieve.news@fstf.org)*



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