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REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

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From the Data Management Center: Message About FSTRF Forms Management Utility

Historically, re-formatted versions of OpenClinica-produced CRF prints have been posted to the FSTRF Forms Management Utility (FMU). Going forward this will not be done as this manual editing and creation is not a "validated" process.

The DMC does not plan to replace or remove any of the old-style forms that are posted to the FMU, however study teams are **now** required to use only OpenClinica-produced hardcopy prints. As such, the forms on the FMU may look different than expected.



FAQ

Q: The COVID-19 Symptom Duration CRF (SSW0090) form asks about symptoms (i.e., heart palpitations, concentration difficulty, difficulty sleeping, memory difficulty, fatigue) that are not included on the COVID-19 Assessment CRF (SSW0040), is this intentional?

A: The SSW0090 is distinct from the SSW0040 as the SSW0090 relates to long-COVID symptoms. There is not exact overlap between the two forms as some symptoms are more common during acute COVID and some symptoms are more common during long-COVID. We do not anticipate sites using the SSW0040 to complete the SSW0090, the SSW0090 should be completed via an interview with the participant.

Q: The SSW0090 inquires about how long after the first positive COVID-19 test or confirmed COVID-19 diagnosis did new or worsening symptoms begin. How should this question be answered if a participant had symptoms prior to testing?

A: If a participant had symptoms prior to testing, it is best to choose the “1 month or less” option.

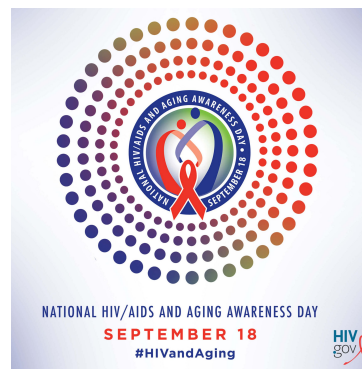
Note: The team is aware that some of participants may have been diagnosed with COVID-19 more than a year ago and may have trouble remembering the symptoms. We do not expect participants to remember the exact details, rather an estimation of symptoms experienced is anticipated.

2021 National HIV/AIDS and Aging Awareness Day!

The 14th National HIV/AIDS and Aging Awareness Day (NHAAAD) is September 18th!

According to the AIDS Institute, which launched NHAAAD in 2008, the goals of this awareness day are “to emphasize the need for prevention, research, and data focused on the aging community and increase medical understanding of the impact of HIV on the natural aging process”. REPRIEVE is very important in this context as we are evaluating a prevention strategy for cardiovascular disease among people living and aging with HIV. Please remember to remind REPRIEVE participants at your site of the importance of their continued participation in REPRIEVE around NHAAAD!

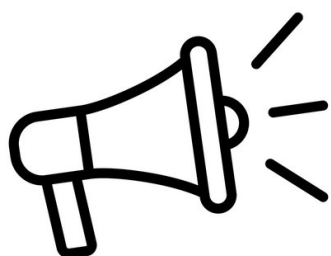
[Click here](#) to go to a webpage developed by the New England AETC focusing on HIV and aging. The webpage has a downloadable education packet, as well as curated



and annotated resources, including fact sheets, guidelines, recommendations, and compiled resources from a variety of sources.

And check out the #NHAAAD posts on the official REPRIEVE social media platforms, please like and retweet!

Memos from DAIDS: Expansion of Remote Pharmacy Monitoring and Minor Updates to DoD Log Template



In case you missed the email distributed August 30th on behalf of the DAIDS Office of Clinical Site Oversight (OCSO)!

Two memos were included:

1. Expansion of Remote Pharmacy Monitoring
2. Minor Updates to DAIDS SCORE Manual: DAIDS Delegation of Duties (DoD) Log template.

Both memos are posted on the HIV/AIDS Network Coordination (HANC) website under the [DAIDS Resources](#) page.

General questions related to either memo should be directed to your OCSO Program Officer.

Pharmacy-related monitoring questions or concerns can be sent to the DAIDS Pharmaceutical Affairs Branch (PAB) at NIAIDDAIDSPABMonitoring@mail.nih.gov.

Updated COVID-19 Medications List

An email summarizing revisions to the COVID-19 Medications List was distributed last week to sites by Laura Moran.

In this document, there are two tables with categories of medications/treatment/vaccines related to COVID-19 to be aware of:

1. COVID-19 Medications/Treatment/Vaccines that *should be* entered into the Medications Log
2. Supportive Medications that *should not be* entered into the Medications Log

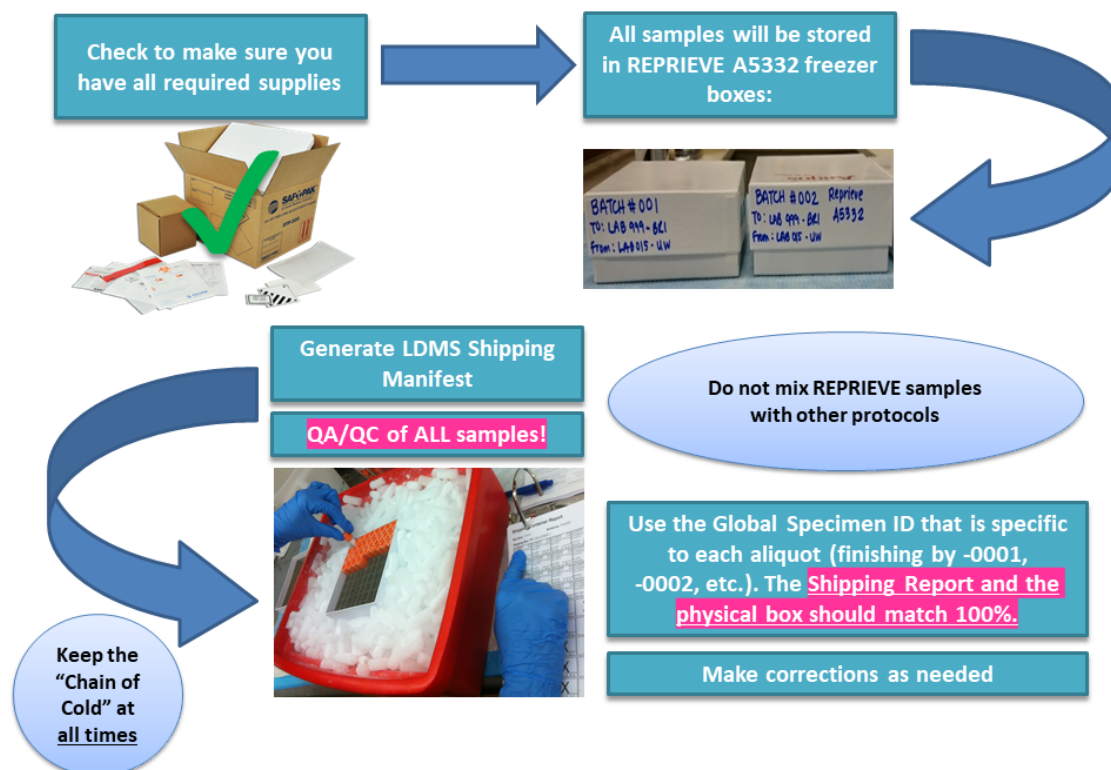
The updated COVID-19 Medication List is posted on the REPRIEVE PSWP or [click here](#) to download. Please make sure that you are using this updated version.

If you have a question about whether or not to enter a COVID-19 Medication into the Medications Log, email the Core Team at actg.corea5332@fstrf.org.

REPRIEVE (A5332): COVID-19 Medications and Supportive Medications 07 September 2021	
Below are 2 tables with categories of medications related to COVID-19:	
1. COVID-19 Medications/Treatment/Vaccines that <i>should be</i> entered into the Medications Log	
2. Supportive Medications that <i>should not be</i> entered into the Medications Log	
These tables will be updated frequently; notification of updates will be sent via email.	
COVID-19 Medications/Treatments/Vaccines that should be entered into the Medications Log	
Class	Medication/Treatment/Vaccine
Immunotherapies	IL-6 inhibitors (tocilizumab, sarilumab, or others) IL-1 beta inhibitors (anakinra, canakinumab, or others) JAK-STAT inhibitors (ruxolitinib, tofacitinib, baricitinib, or others) Other targeted immunotherapy
Monoclonal antibodies	LY3819253, REGN10989, REGN10933+REGN10987 combination therapy, or others
Antimalarials	chloroquine hydroxychloroquine (Plaquenil)
Antibiotics	azithromycin nitazoxanide
Antivirals	Remdesivir, favipiravir, EIDD-2801/MK-4482, or others
Antiparasitics	ivermectin
Corticosteroids	Betamethasone, prednisone, prednisolone, dexamethasone, or others
Angiotensin Converting Enzyme (ACE) Inhibitors	lisinopril, ramipril, enalapril, or others
Angiotensin II Receptor Blocker (ARB)	azilsartan, valsartan, losartan, or others
HIV Protease Inhibitors	lopinavir/ritonavir (LPV/r or Kaletra) darunavir/cobicistat (DRV/c or Prezcoibik)
Interferons	interferon alfa-2b, interferon beta-1a, interferon lambda
Blood products	Intravenous immunoglobulin (IVIg) Convalescent plasma
SARS-CoV-2 (COVID-19) Vaccines*	Inactivated virus, protein-based, viral vector, genetic/nucleic acid vaccines (mRNA vaccines)

*When recording these vaccines on the Medications Log, key multiple doses as separate log lines with respective dates. For COVID-19 vaccines, key vaccine manufacturer, COVID-19 vaccine, and dose number. Example: Moderna, COVID-19 vaccine, dose 1.

In Case You Missed the Lab Refresher Call on September 9th!



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Slides will be available with a link to the recording on the REPRIEVE (A5332) PSWP, in the Lab Resources folder.

Please reach out to the REPRIEVE Lab team by emailing reprieve.labcom@fstrf.org with any

lab questions!

Thank you to everyone who was able to join!



Save the Date Next Team/Site Call! October 19th 1PM EDT

Join us for important REPRIEVE 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 09/13/2021 (**revised version!**)
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@fstrf.org



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