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Randomized Trial to Prevent Vascular Events in HIV

Dear REPRIEVE Team,

These challenging times give us the opportunity to pause, reflect, and think of the ways in which we can help those in need. REPRIEVE is comprised of a global network of health professionals, located in 5 continents, representing diverse regions of disease burden. Our team is dedicated to the care of people living with HIV. Members of the HIV community are often marginalized, affected by prejudice and violence, and suffer from interrelated medical comorbidities. The REPRIEVE team is working every day to engage our participants in health care, ensuring that scientific advancements are extended to the broader HIV community. Our work is not without challenge, but we can be secure in the knowledge that our efforts to study heart disease and related comorbidities in HIV will help to increase the health of the whole community. Moreover, this work will address underlying inequities in the access and provision of care for the global HIV community that is so important at this time.

Thank you for all that you do for the REPRIEVE Team!



On Friday, July 24th, at 10:30AM ET, 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.



REPRIEVE CAB Member, Alicia Diggs, appointed to the Presidential Advisory Council on HIV/AIDS (PACHA)!

Alicia Diggs is a native of Philadelphia, PA, USA but currently resides in North Carolina. Alicia has served on REPRIEVE's Community Advisory Board (CAB) since it's inception in 2017. Outside of her work on REPRIEVE, Alicia is a Medical Case Manager working with persons living with HIV and is the CEO and Founder of "I Will Live", whose goal is to help the community understand the importance of STD and STI prevention, advocating against stigma and discrimination, knowing your HIV status by getting tested as well as living healthy and productive lives through empowerment and education. In addition to earning multiple degrees: Bachelor's Degree in Social Work, Master's Degree in Public Health, and currently earning a PhD in Public Health with a focus in Advocacy and Leadership, Alicia has been an HIV/AIDS Activist, Educator, and Speaker since 2004.

Alicia has spoken for various organizations who provide services for persons living with HIV in North Carolina such as Piedmont Health Services and Sickle Cell Agency, Guilford County Health Department, and Triad Health Project. She has served on many boards including the UNC Center for AIDS Research's Community Advisory Board, the HIV Prevention Community Advisory Council (HPCAP), the National Community Advisory Board (NCAB) for the Women's Interagency HIV Study (WIHS), and most recently her advocacy has earned her a position on the Presidential Advisory Council on HIV/AIDS (PACHA).

Alicia is an integral member of the REPRIEVE Team, along with all of our CAB members! <u>Click here</u> to read her full bio on the REPRIEVE website, and bios of our other CAB members! You can also learn more about Alicia by reading her published autobiography 'Standing On My Healing: From Tainted To Chosen'.

Thank you, Alicia, for all your do for REPRIEVE and the HIV Community!



Don't Forget to Complete the EVW0344 Pill Count and Adherence CRF!

If your site is performing remote visits due to local restrictions preventing in person study visits, the **EVW0344 - Pill Count and Adherence** form questions can still be obtained over the phone with the participant, including the participant's recollection of the number of pills taken in the last 7 days.



Thank you Dr. Karin Klingman, we wish you the best!

Karin Klingman, MD, the DAIDS Medical Officer for REPRIEVE, will be retiring the end of June! Karin has been a crucial member of the REPRIEVE teamshe has been dedicated to REPRIEVE, has shown level headed judgement and has always been available for any question, big or small. She has been essential to help move REPRIEVE forward in a safe and successful manner. While we are sad that she is leaving the team, we are so happy that she is starting this new chapter in her life, as she describes it "sailing off into the sunset."

The new DAIDS Medical Officer for REPRIEVE will be Dr. Christine Chiou, email: cchiou@niaid.nih.gov.

We will introduce her at a later date!

A few words about Karin from the team...

From Turner Overton, MD, University of Alabama: "I have had the good fortune to work closely with Dr. Klingman on a number of NIH-funded trials over the past decade (or so). I will miss her greatly. She was always ready to help answer my queries, study-related or otherwise. She will be missed not only for her comprehensive knowledge of all aspects of her job, but more importantly for her thoughtful approach to each issue. She never reacted to a question, but turned it over in her mind and provided a thoughtful response. I will miss hearing her voice."

From Markella Zanni, MD, Massachusetts General Hospital: "Karin has made enormous contributions to REPRIEVE, bringing her knowledge and insight to bear on every question and challenge encountered through the study. On a more personal note, Karin has been a consistently kind, caring, and thoughtful colleague – we will miss her!"

From Carl Fichtenbaum, MD, University of Cincinnati College of Medicine: "I have

known and worked with Karin for more than a decade. She has been a tireless advocate for good science. She always finds a way to solve a problem. She has been a tremendous partner and medical officer making significant scientific contributions to end suffering and help those affected by HIV. She will truly be missed!"

From Steve Grinspoon, MD, Massachusetts General Hospital: "Karin has made enormous contributions to the success of REPRIEVE and many other HIV trials. Her decisions are informed by a significant medical knowledge, and a true compassion and dedication to the health care of the trial participants. She will be missed not only by us, but by the many whose lives and medical care were entrusted to her over the past two decades."



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.

If you have already completed this from to request hard copies of the newsletter, no need to complete it again, we will be shipping hard copies soon!

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

Who's Who on the REPRIEVE Team?

Meet Anthony Holguin and Ken Wood, REPRIEVE Data

Managers!

Anthony Holguin is a Lead Data Manager at Frontier Science in Amherst NY, where he has worked in the Special Projects department for over 6 years. Anthony provides the day-to-day clinical data management duties for the

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REPRIEVE trial, which he has worked on since the beginning. His responsibilities for REPRIEVE include the building and maintenance of the study and it's forms in OpenClinica along with QA/QC of data entry.

Ken Wood is the REPRIEVE Project Manager at Frontier Science in Amherst NY. Ken provides data management oversight of the REPRIEVE project and coordinates the various clinical facets of the project.



If you have a data management question, feel free to reach out to this stellar team by emailing reprieve.dmc@fstrf.org

Domestic REPRIEVE Sites can resume shipments to BRI!



The BRI repository is now open to receive shipments. At this time, only domestic (US) ACTG and non-ACTG sites may resume shipping specimens to BRI effective June 8, 2020. Information regarding international shipments will be forthcoming in the near future.

Please adhere to your normal shipping schedule. You may want to confirm that Fed-Ex is available to ship from your location prior to preparing a shipment.

If you have any questions about specimen shipments please direct them to the BRI repository, brirogon afbr-bri.org or 301-881-7636 or email the REPRIEVE Lab Committee at reprieve.labcom@fstrf.org.

DAIDS OCSO Guidance on Resuming

Site Operations

DAIDS OCSO circulated a memo to sites on May 21, 2020 to provide guidance and important considerations as local restrictions start to be lifted and sites begin to resume in-person visits. We would also like to remind our REPRIEVE site teams that if a participant missed a visit where stored specimens were to be collected due to the pandemic, these specimens can be collected at the next in-person visit. Please see section 4.3 of the MOPS for instructions on how to key the Specimen Tracking form (SPW0492) and enter these specimens into the LDMS system.

Click here to read the full memo from DAIDS.



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

If you missed the April call, <u>click here</u> 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
Version 5.0, Clarification Memo 2 dated 05/04/2020
MOPS Version 5.0 dated 04/08/2020
A5332 LPC for ACTG Sites Version 5.0 dated 05/04/2020
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







REPRIEVE Trial Clinical Coordinating Center

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