



## Randomized Trial to Prevent Vascular Events in HIV

### Site Newsletter 03/14/2016

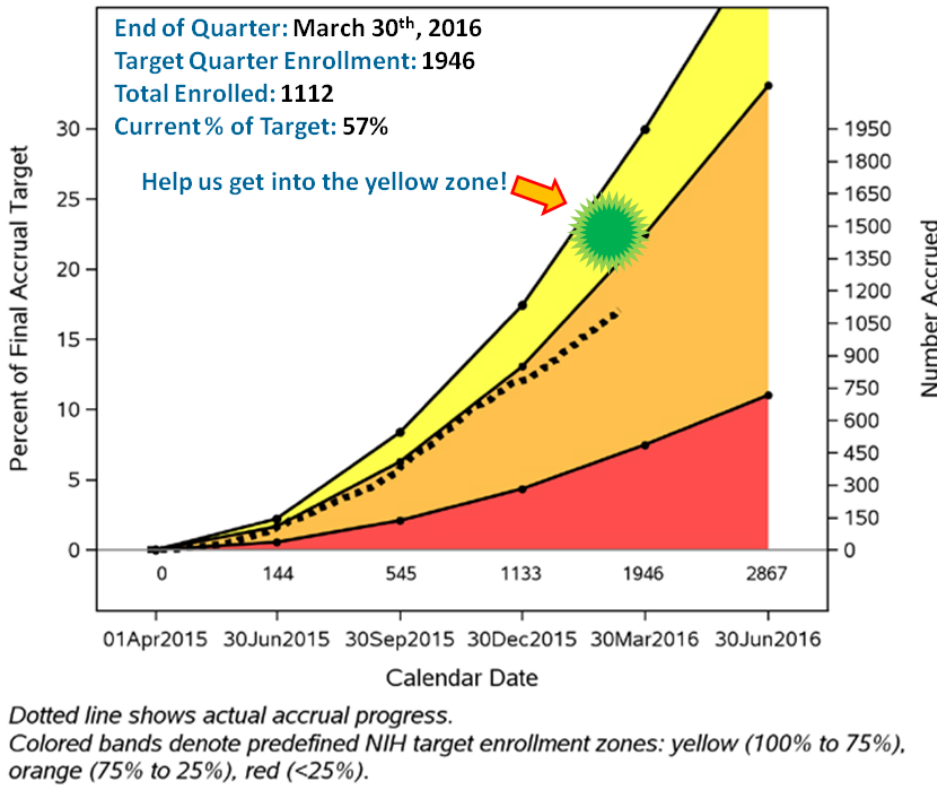
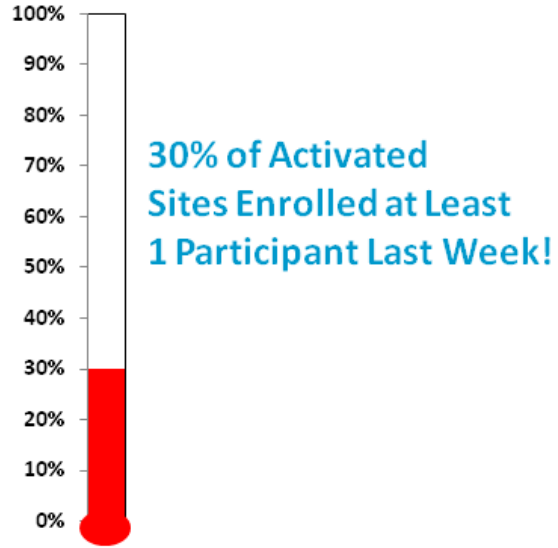
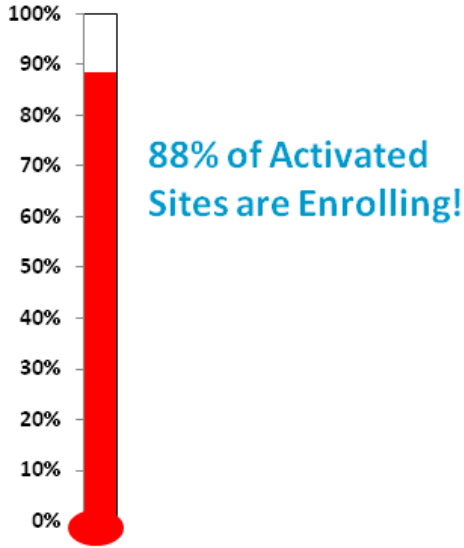
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With an amazing team effort, REPRIEVE has well over 1,000 participants enrolled, 1,644 screens completed, 161 participants in screening, and 80 sites now activated!

The end of quarter target enrollment date is March 30th, 2016. If all sites continue to work hard and convert pending screens to enrollments, we will come closer to the yellow zone!

# Trial Status: 03/7/2016-03/14/2016



**The University of Washington AIDS CRS  
 Enrolled the 1,000th Participant in REPRIEVE!  
 Congratulations UW!!!**

## **Congratulations to Sites Enrolling Participants**

### **Week of 03/07/2016**

University of Illinois at Chicago  
Florida Department of Health  
Baystate Infectious Diseases Clinical Research  
University of Kentucky  
Los Angeles LGBT Center  
Mt Sinai St Lukes Samuels Clinic  
Mt Sinai St Lukes Morningside Clinic  
Boston Medical Center  
Virginia Commonwealth University Medical Center CRS  
Yale University  
Thai Red Cross AIDS Research Center  
UCSD Antiviral Research Center CRS  
Alabama CRS  
Chapel Hill CRS  
Cincinnati CRS  
Chiang Mai University HIV Treatment CRS  
Columbia Physicians and Surgeons CRS  
Northwestern University CRS  
Harbor UCLA CRS  
Cornell Chelsea CRS  
University of Rochester Adult HIV Therapeutic Network CRS  
Vanderbilt Therapeutic CRS  
University of Pittsburgh CRS  
Whitman-Walker Health CRS

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**REPRIEVE will be successful if every  
activated site enrolls *at least 1* participant per  
week!**

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## **What's New on the REPRIEVE (A5332) PSWP?**

» [A5332](#) » [Current Protocol Documents \(Version 3.0\)](#)

The cover letter for the Spanish Sample Informed Consent was updated to reflect that The Mechanistic Substudy (A5333s) sample consent was also translated into Spanish. No changes were made to the translations!

» [A5332](#) » [Protocol Training](#) » [Site Calls](#)

The slides and call summary for the most recent monthly team-site call on February 16th are here.

» [A5332](#) » [Protocol Training](#) » [Site Calls](#) » [Site Initiation Call](#)

The most recent Site Initiation Call slides and call recording are available from the March 8th call. Please review if you need a refresher on the ACTG Member website, or the Site Approval / Protocol Activation procedures.

» [A5332](#) » [FAQs](#)

In addition to new questions, other questions have been revised to match changes made in protocol version 3.0, including questions about eligibility, missed visits, lost pills, rescreening, and the optimal time to report adverse events that become known between visits.

» [A5332](#) » [Coenrollment Guidelines](#)

The list of studies has been updated since November. See the list dated 3/14/16.

» [A5332](#) » [Lab Resources \(Protocol Version 3.0\)](#)

The lab processing charts have been updated:

- [ACTG Sites - A5332 V3 Revised Lab Processing Chart](#) *Dated: 02/23/2016*
- [Non-ACTG Sites - A5332 V3 Revised Lab Processing Chart](#)  
*Dated: 02/25/2016*

Looking for your site's assigned schedule to ship to the repository (BRI)? The list has been updated - no changes were made for sites on the previous shipping schedule, but sites that recently joined REPRIEVE were added: [Non-ACTG Site-Specific Shipping Schedule to BRI](#) *Dated: 02/18/2016*

Revisions were also made to the detailed lab processing and shipping portion of the WebLDMS training: [Lab Details from WebLDMS Training \(nonACTG sites only\)](#)



**Is Your Site Participating in the Mechanistic Substudy  
of REPRIEVE (A5333s)?**

**If So, Please Read These Important Reminders!**

**Remember to obtain the CBC with differential required at entry and year 2 on the same day as the PBMCs** are obtained, otherwise our lab will not be able to analyze the monocyte data.

**Confirm that the relevant laboratory personnel at your site and/or laboratory are following:**

- The [ACTG SOP 144 Shipment of Clinical Specimens to the ACTG Specimen Biorepository](#)
- The [Cross-Network PBMC Processing SOP](#)

This will ensure specimen integrity of stored specimens for future functional assays.

**Enrollment of women is very important in the Mechanistic Substudy!** Remember to ask all women screening for REPRIEVE (A5332) if they would also like to participate in the substudy.

Enrollment in the Mechanistic Substudy (A5333s) has been strong. There are 218 participants enrolled, however **please continue to enroll participants in the substudy**, as the data collected in the substudy is important for the main study REPRIEVE (A5332).

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## Site PIs Please Remember to Complete the ASCVD Risk Modification Query

So far we have received 37 responses to the ASCVD Risk Modification query emailed to Site PIs last week, thank you to those who have responded to far!

If you have not responded please [click here](#) to respond by March 18th and thank you for taking the time to complete this query.

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FAQ



**I have a participant who is pregnant and will be followed on study, off study drug. Do I continue to perform pregnancy tests and complete the Myalgia Symptom Assessment CRF as per the Schedule of Events?**

Yes, we ask in this scenario that all testing be completed as indicated in the Schedule of Events. If the participant refuses to have the pregnancy test performed or complete the Myalgia Symptom Assessment CRF please document as such on the appropriate CRF.

## We are an ACTG site and a non-ACTG site needs to transfer a participant to our site. What procedure should we follow?

REPRIEVE will follow [ACTG SOP 119](#), Study Participant Transfer for transfers between sites, including non-ACTG sites. The transfer SOP is on the [ACTG Member website](#). Please send an email to [reprieve.dmc@fstf.org](mailto:reprieve.dmc@fstf.org) to notify the REPRIEVE data manager of the participant transfer.

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# RECRUITMENT

## Sites can Unite at Local AIDS Walk/Run Event!

Many AIDS Service Organizations hold their annual AIDS Walk/Run during the spring and summer.

This is an excellent opportunity to get the word out about REPRIEVE. The NIAID Communications Team has helped us to compile a list of AIDS Walk/Runs near REPRIEVE sites, please see the [attached list](#) for more details.

If your site is in a city where there are multiple sites like New York, Los Angeles, Boston etc. please contact the [REPRIEVE Clinical Coordinating Center](#) so we can connect you with other REPRIEVE sites in your area that might want to participate.



## TRAINING OPPORTUNITIES

Training Opportunities

### Start Up Data Management Training for REPRIEVE

Wednesday, 16 Mar 2016, 2:00 PM ET

This training is a repeat of the data management training that has been given throughout the year, and is geared for sites that have not yet attended a data management training or new staff that will benefit from this training. This 2-hour training will include information on user accounts, the DMC portal, subject enrollment, case report forms and schedules, and OpenClinica (the clinical trials data management system used for this trial).

Please note: At least one person from your site must attend a data management training to meet protocol activation requirements. If someone from your site has already participated in a data management training, your site has met that requirement.

**Details for the training were emailed to the Protocol E-Mail Group on Monday, March 14th, 2016.**

## Next ECG Training Dates

**Wednesday, 30 Mar 2016, 1:00 PM ET**

ECG training will include information on the ECG machine, supplies, performance, and transmission of data. At least one person from your site must attend one training to meet protocol activation requirements. If you have participated already but would like a refresher, please feel free to attend.

You do not have to have an ECG machine onsite to participate in this training. We encourage you to have all staff that will work with the Quintiles ECG machine attend the training (eg, PI, study coordinator, CRA, backup personnel).

Calendar invites with call details have been sent out. Please email Katie Fitch, [kfitch@partners.org](mailto:kfitch@partners.org), if you did not receive the invites.



## We Would Like to Introduce our New CSS\* Representatives!

**Kate Borloglou** is an HIV advocate with an interest in clinical advances related to HIV treatment, as well as public policies related to treatment and support. She is excited to be a Community Scientific Subcommittee representative for the REPRIEVE study, which seeks to answer a crucial question within the HIV community concerning the increased risk of cardiovascular disease. Kate is also thrilled to be a part of the

REPRIEVE study which actively seeks to include underserved populations, such as women, within clinical studies.

Kate currently serves on the Community Scientific Subcommittee of the AIDS Clinical Trials Group (ACTG). She is also a member of the Women's Health Inter-Network Scientific Committee and Neurology Collaborative Science Group within the ACTG. Kate also serves on the community advisory board with the Ohio State University AIDS Clinical Trials Unit.

In addition, Kate is actively involved with The Well Project, serving as a Community Advisory Board member, as well as a blogger for The Well Project's, A Girl Like Me.

Kate graduated with a B.S. in Education from The Ohio State University and a post-baccalaureate Paralegal Certificate from Capital University Law School.

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**Karl Shaw** has been involved with HIV/AIDS clinical trials and has been a community



HIV/AIDS activist since 1993.

He was a member of the CCG (Community Constituency Group), now known as the GCAB, for several years. When the Henry Ford Health Systems site was de-funded by the ACTG he remained involved with the ACTG and the GCAB and is a member of the CSS as a non-ACTG member. He continued to share the information with his local community and the prior CAB members of Henry Ford Health Systems. Karl was also one of the founding community members of the Ryan White Planning Council of Detroit. As part of his CSS activities Karl has served as a past CSS Co-Chair of the Under Represented Populations Sub-Committee, Adherence Intervention Working Group, Policy and Procedures Sub-Committee and the Community Partners Sub-Committee.

Karl participates in many HIV/AIDS activities in his community of Detroit, Michigan and is a clinical trial participant with the NIH for the past several years, including the Long Term Non-Progressors study.

\*CSS = Community Scientific Subcommittee

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#HIVheartchat



## HIV Heart Chat was a Success!

Last month, REPRIEVE hosted its first ever Twitter chat in honor of Heart Health Month! The Twitter chat served as a method for HIV and cardiovascular experts to share the latest news and information regarding HIV and heart health, as well as to bring attention to the great work going on through REPRIEVE.

The event reached a large amount of clinicians, researchers, patients, and patient advocacy groups. The chat successfully engaged a great deal of HIV Advocacy and Public Health Organizations – in fact, 32 different organizations participated. You can read the full transcript of the chat [here](#).



Did you know you can follow the REPRIEVE Trial (@reprivetrial) on Twitter? @reprivetrial has close to 500 followers! Follow us for updates about REPRIEVE.

Did you know PDFs of REPRIEVE Site Newsletters are available on the REPRIEVE Website? [Check them out!](#)

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## REPRIEVE (A5332): Are you up to date?

### **For A5332 please use**

#### **Protocol:**

Version 3.0 dated 01/28/2016

#### **MOPS:**

Version 3.0 dated 02/10/2016

#### **A5332 LPC for ACTG Sites:**

Version 3.0 dated 02/23/2016

#### **A5332 LPC for Non-ACTG Sites:**

Version 3.0 02/25/2016

These documents are on the [A5332 PSWP](#)

## REPRIEVE Mechanistic Substudy (A5333s): Are you up to date?

### **For A5333s please use**

**Protocol:** Version 3.0 dated 01/28/2016

**MOPS:** dated 11/10/2015

**A5333s LPC :** Version 3.0 dated 02/22/2015

These documents are on the [A5333s PSWP](#)

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For future reference, all newsletters are available on the [REPRIEVE Website](#)

We welcome suggestions and ideas for upcoming newsletters. Please submit any comments or suggestions to the REPRIEVE News Team at [reprieve.news@fstrf.org](mailto:reprieve.news@fstrf.org).



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