



# REPRIEVE

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

## Site Newsletter 07/11/2016

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## Message from REPRIEVE Leadership

We wanted to take a moment to update you regarding the DSMB meeting that took place on June 24th, 2016. First and foremost, the DSMB gave approval for the study to continue and thanks to all your efforts, the DSMB was pleased with our progress. We expect to have the DSMB summary report for your IRB/EC shortly.

The DSMB also granted preliminary approval to increase the ASCVD eligibility for the trial. REPRIEVE Leadership is awaiting final approval from the DSMB and if granted, the ASCVD eligibility criteria would be expanded to allow participants with an ASCVD risk estimate of >10-15% and LDL < 130 mg/dL to enroll in REPRIEVE. This will be discussed on the next Monthly Site Call on Tuesday, July 19th. [Attached](#) is the presentation from the recent ACTG Network Meeting that provides more detail about this potential change, these slides will be posted on the REPRIEVE (A5332) PSWP shortly.

Until final approval is granted, please continue to enroll participants using the current approved ASCVD eligibility but make sure that you are able to follow up with any participants that would qualify using the proposed criteria.

### Current:

- ASCVD < 7.5 Eligible if LDL < 190 mg/dL
- ASCVD 7.5 -10 Eligible if LDL < 160 mg/dL
- ASCVD > 10 Not Eligible†

### Proposed:

- ASCVD < 7.5 Eligible if LDL < 190 mg/dL
- ASCVD 7.5 -10 Eligible if LDL < 160 mg/dL
- ASCVD >10 - 15 Eligible if LDL < 130 mg/dL\*

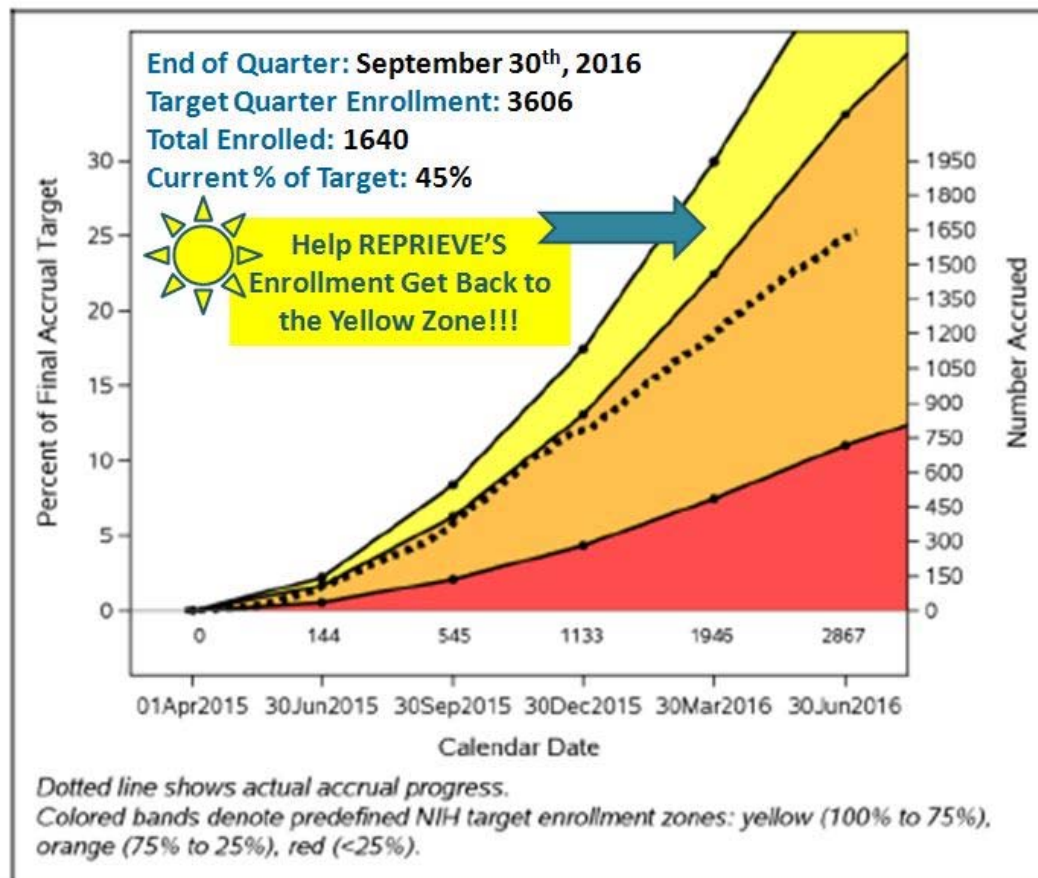
†Eligible if LDL < 70 mg/dL

\*For proposed eligibility, if ASCVD >15 eligible if LDL < 70 mg/dL

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## Enrollment Updates

Thank you to every site enrolling participants in REPRIEVE, with your help **we have enrolled 1640 participants, 21 participants were enrolled last week!!! 163 participants are in screening and we now have 89 sites open for enrollment.**



## FINAL RESULTS OF OUR SPRING ENROLLMENT CHALLENGE ARE IN!!!

**Thank you to everyone for joining our spring enrollment challenge, 413 participants were enrolled between April 1st and June 30th. With this same effort, we will reach 2,000 participants in September!**

The winners were the 14 sites that enrolled at least 3 participants per month between April 1-June 30th. Thai Red Cross AIDS Research Center took the #1 spot enrolling 36 participants while the Florida Department of Health enrolled 17 participants and took over the #2 spot in the last round.

Congratulations to all the winners!!! You will be contacted shortly by the REPRIEVE Clinical Coordinating Center.

# **MARCH Madness *REPRIEVE* Style**

Winners and # Participants Enrolled Between April 1 – June 30!	
1. Thai Red Cross AIDS Research Center	36
2. Florida Department of Health	17
3. 550 Clinic at U Louisville	16
4. Chiang Mai University HIV Treatment	15
5. UT Southwestern	12
5. UCSD Antiviral Research Center CRS	12
6. Penn Therapeutics CRS Denver Public Health	11
7. Cincinnati CRS	10
7. Case CRS	10
7. University of Illinois at Chicago	10
8. Chapel Hill CRS	9
8. Orlando Immunology Center CRS	9
8. Alabama CRS	9
8. Wake Forest University	9



## **TRAINING OPPORTUNITIES**

### **Tuesday, July 19th @ 1:00PM ET--Monthly Site Call**

REPRIEVE Site Calls take place on the 3rd Tuesday of each month at 1:00PM ET. Call details will be sent via email shortly. This month we will be discussing **REPRIEVE Adjudicated Events!**

### **Save the Date: ECG Training Dates Have Just Been Scheduled!**

***Invites were sent this morning***

Thursday, 21 July, 10:00 AM ET

Wednesday, 27 July, 10:00 AM ET

Thursday, 11 Aug, 10:00 AM ET

Thursday, 25 Aug, 10:00 AM ET

ECG training includes 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 already participated but would like a refresher, please feel free to attend.

This 30-minute training webinar includes information on the ECG machine and supplies, performing the ECG, and transmission of data to Quintiles. This training is specific to the REPRIEVE trial and at least one person from your site must attend one training to meet protocol activation requirements, although we encourage you to have all staff that will work with the Quintiles ECG machine to attend the training, eg, PI, study coordinator, CRA, backup personnel.

Your site does *not* need to be DAIDS site activated or protocol registered, nor do you need to have your Site Qualification Form (SQF) signed or the ECG machine onsite to participate in this training.

### Web LDMS Training Video

If you are a site using Web LDMS for REPRIEVE, check out the Web LDMS training video available on [FSTRF's YouTube Channel](#).

These training videos are the same training(s) that FSTRF staff have been providing REPRIEVE laboratories. We encourage lab staff to watch these videos as a means of refresher training. Please share these links with laboratory staff at your sites if they do not receive the REPRIEVE newsletter.

### Data Management Training Video

If you need a data management refresher, you can access the video in the [FSTRF portal](#) the video is located under the **Site Support Tab→REPRIEVE Training Videos**

### Protocol Training/ Start-Up Call Slides

Slides used for protocol training are kept in the Protocol Training Folder on the A5332 and A5333s protocol-specific pages (PSWPs). The PSWP is located in the Member portal of the [ACTG website](#).

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## MGH ACTG Site Team Shares Their Unique Follow YOUR Heart/REPRIEVE Promotion Event!



During the first two weeks of June, the **MGH ACTG Clinic**, along with the **MGH Infectious Disease Clinic**, held a special event, called **Follow YOUR Heart**, to raise awareness about heart disease, heart health, and the **REPRIEVE Trial**. The main component of the event was an educational table, filled with information about REPRIEVE, heart disease, and lifestyle interventions for maintaining



cardiac health, set up inside the ID clinic. Outside the clinic entrance, a colorful Follow YOUR Heart/REPRIEVE banner promoted the event. The table was staffed by ACTG and ID clinic volunteers during prime clinic hours, when patients and their family members could easily access the wealth of heart health resources and speak with enthusiastic heart health advocates.

### Highlights of the two-week event include:

- A “Wheel of Fortune” game where visitors could spin to win heart-adorned pens, pins, and beach balls. The team felt this was a good way to get the conversation started about heart health!
- A sign-up sheet for visitors to receive more info about REPRIEVE and to attend a special meeting of the MGH CAB
- Sara Looby, PhD, ANP-BC of the REPRIEVE team gave a lively talk on HIV and heart disease.
- Educational models of the heart, written information about REPRIEVE, HIV and heart disease, and general cardiac health populated the table

**Results:** The team feels that this event generated many questions about REPRIEVE and a number of referrals. In addition, the ACTG site team was able to educate the MGH ID clinical staff about REPRIEVE and enlist their help in recruiting participants.



### Resources used for the event

- Prizes given away for the “wheel of fortune” were found [at this website](#)
- Heart health information was found on the [AHA website](#)
- A [doodle poll](#) was used to staff the table
- A sample CAB presentation can be found on the [REPRIEVE trial/Follow YOUR Heart website](#)

If your site has a unique approach to recruiting, we would love to know so we can share this with other sites. Email [Katie Fitch](#), REPRIEVE CCC Project Manager.

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## Customizable Recruitment Materials Available

Did you know the REPRIEVE Clinical Coordinating Center has developed a portal for each site to login, customize, and order recruitment materials?\* The best part about this is you can order a "Sample Kit" of recruitment materials **all paid for by REPRIEVE!**

If you have not ordered already, [click here](#) to access the portal, then enter your site ID and the password "reprieve" to login. [Attached are instructions](#) that are helpful when ordering.

If you try to login and don't have access, please email [Katie Fitch](#), REPRIEVE CCC Project

Manager.

These materials are also available on the REPRIEVE Website, on our [Spread the Word](#) page.

\*Materials have been approved by the IRB for the REPRIEVE CCC, however please submit as per your local IRB requirements.



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## What's New on the REPRIEVE PSWP?

Presentations from the ACTG Annual Meeting have just been posted to the REPRIEVE (A5332) PSWP. They are located in the [REPRIEVE Presentations](#) folder and they are attached below.

- [REPRIEVE: Reprise and Reveal: Progress to Date and Future Directions](#)
  - [Survival Guide for Reporting Events](#)
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### REPRIEVE (A5332): Are you up to date?

**For A5332 please use**

**Protocol:**

Version 3.0 dated 01/28/2016

Clarification Memo #1 dated 04/04/2016

Clarification Memo #2 dated 04/12/2016 (corrects an error in CM #1)

**MOPS:**

Version 3.0, revision 1, dated 04/15/2016

**A5332 LPC for ACTG Sites:**

Version 3.0 dated 02/23/2016

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

Version 3.0 dated 05/05/2016

**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 05/05/2016

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

**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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