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# REPRIEVE

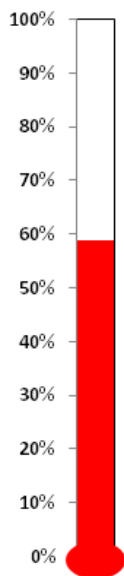
## Randomized Trial to Prevent Vascular Events in HIV

### Site Newsletter 8/10/2015

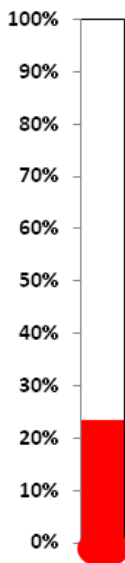
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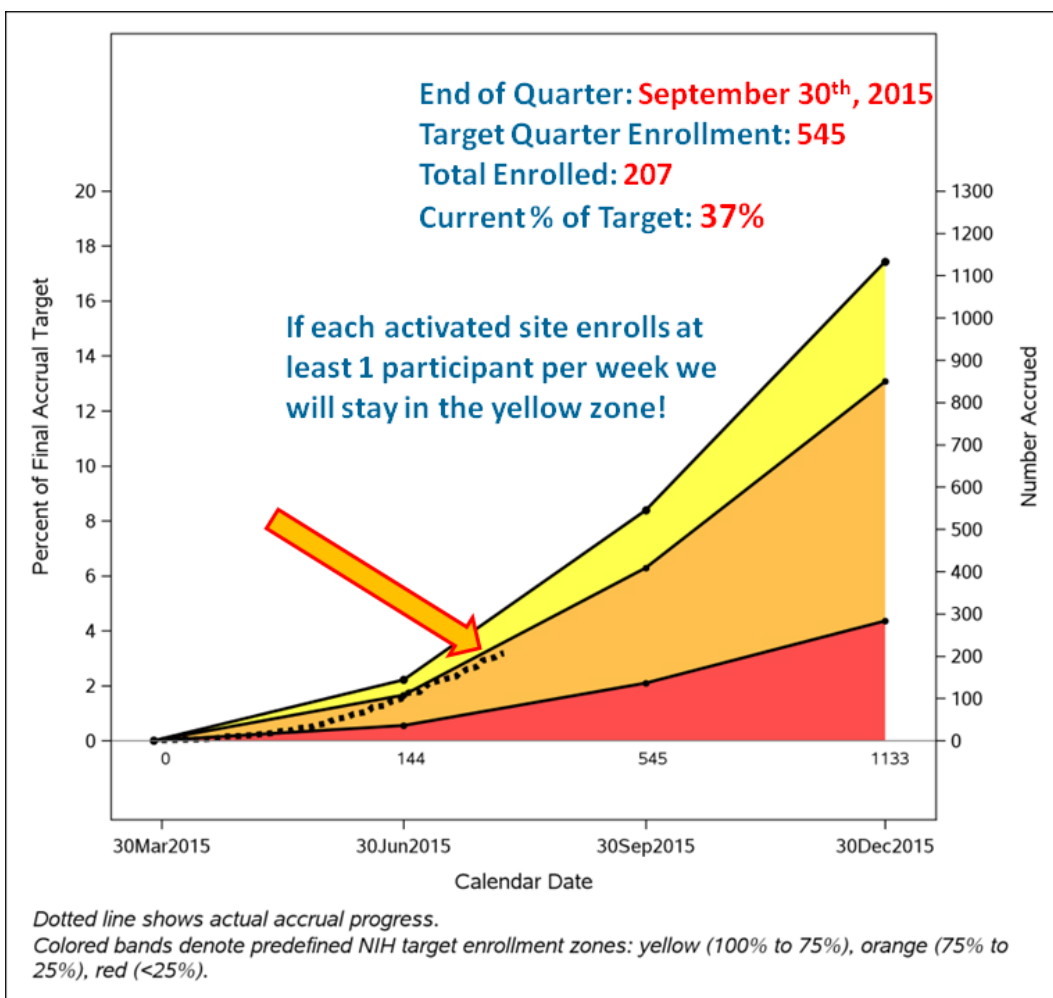
### Trial Status: 8/3/2015-8/10/2015



**59% of Activated Sites are Enrolling!**



**24% of Activated Sites Enrolled at Least 1 Participant Last Week!**



**Congratulations to Sites Enrolling Participants Week of 8/3/15**

Houston AIDS Research Team CRS

Chapel Hill CRS  
UCSD Antiviral Research Center CRS  
Cincinnati CRS  
Puerto Rico AIDS Clinical Trials Unit CRS  
Massachusetts General Hospital (MGH) CRS  
Vanderbilt Therapeutics (VT) CRS  
Penn Therapeutics CRS  
Cornell Chelsea CRS  
Rush University CRS

**Help Make REPRIEVE a Success:  
Enroll at Least 1 Participant per Week!**

### Important note regarding the FIB-4 Calculator

The website to calculate FIB-4, that we refer you to in the REPRIEVE (A5332) MOPS, has been updated and we have noted that when age, AST, ALT and platelets are entered and the score is calculated, the original data entered to calculate the score disappears and therefore it is not possible to print a screen shot with data used for the calculation.

Alternatively, you can use the following website that provides the same score and you can print the screen with the data entered for the calculation visible:

<http://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4>

Of note, for both calculators, you should only enter the platelet count to 3 digits. For example, 150,000 should be entered as 150.



## Who can I contact if I have a lab related question, including lab processing charts, acquisition of supplies etc.?

For any lab questions please email [reprieve.labcom@fstf.org](mailto:reprieve.labcom@fstf.org)

## Are non-statin lipid lowering agents allowed before or after entry in REPRIEVE?

**Prior to study entry**, "use of any lipid lowering agents *including* fibrates, ezetimibe, red yeast rice, niacin or omega-3 fatty acids (> 3 grams) in the 90 days prior to study entry" is exclusionary. This enables us to maintain the low-to-moderate risk study population that we are trying to recruit.

**After entry**, the protocol instructs sites to refer to the PSWP for the Prohibited and Precautionary Medication List. In the current version of the Prohibited and Precautionary Medication List (dated 7/15/2015), bile acid sequestrants are prohibited while other non-statin lipid lowering medications are permitted at this time. Please note that non-statin lipid lowering medications are not recommended by the ACC/AHA guidelines.

### ***We would also like to remind you that prior to starting any concomitant medication to follow the instructions in Section 5.4 of the REPRIEVE (A5332) protocol:***

"Whenever a concomitant medication or study agent is initiated or a dose changed, investigators must review the concomitant medication's and study agent's most recent package insert, Investigator's Brochure, or updated information from DAIDS to obtain the most current information on drug interactions, contraindications, and precautions."



## Helpful Tips!

### Regarding Creatinine Clearance Calculation for the Mechanistic Substudy of REPRIEVE (A5333s)

If your site is also participating in the Mechanistic Substudy for REPRIEVE (A5333s), please use the screening CrCl for the main study (A5332) to determine eligibility for the substudy. However, please note that to perform the CCTA in the substudy, you must have an estimate for CrCl based on a serum creatinine that was collected within 14 days of the CCTA.

There are 2 approaches you should consider to assure you have this assessment:

1. If you are scheduling the CCTA for the day of enrollment into the substudy, consider ordering the serum creatinine either on another day within the 14 day window or order the serum creatinine STAT on the day of entry.
2. If you are scheduling the CCTA on a subsequent day within the 14 day window, you can use the entry creatinine collected as part of the substudy entry visit.

### Regarding Pregnancy Testing

All women of reproductive productive potential must have a pregnancy test unless they have had surgical sterilization (defined as either hysterectomy or bilateral oophorectomy) or are post-menopausal. Please note that women who have had a tubal ligation or have tubal micro-inserts still require pregnancy testing to confirm that they are not pregnant for enrollment criterion 4.1.6.

### Regarding Abstinence

Please counsel all women who report they are abstinent to use some form of barrier method of birth control if they engage in sexual activity.

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## Training Opportunities



## TRAINING OPPORTUNITIES

All training call dates and call details are listed on the public [REPRIEVE website calendar](#).

### Monthly Site Calls

Monthly Site Calls are held the 3rd Tuesday of each month at 1PM ET. Barbara Bastow sends out the email announcement regarding these calls. During these calls, the team tries to address questions raised by sites during the previous month and we are available to answer any questions during these calls.

### Stay Tuned. . .A Site Start up Call will be scheduled soon!

For sites new to REPRIEVE or those who have not yet participated in a Site Start Up call, please watch for an email announcement in the next few weeks, we plan to schedule our next call in September. Please note, participation by your site is mandatory for site activation.

### Future ECG Training

ECG training, which is provided by Quintiles, will be offered again in the near future. An

announcement will be sent via email and will be included in the REPRIEVE newsletter. Please note, participation by your site is mandatory for site activation.

### **Need a Data Management or A5332 or A5333s Site Training Refresher?**

Another Data Management training session will be offered in September, please watch for the email from Laura Smith at FSTRF. Please note, this training is a requirement for site activation.

- REPRIEVE training videos from the Data Management training sessions are located in the [Frontier Science portal](#)
- Slides from the A5332 training calls are available in the Protocol Training folder of the [A5332 PSWP](#), there is also an audio recording available.
- Slides from the A5333s training calls are available in the Protocol Training folder of the [A5333s PSWP](#).

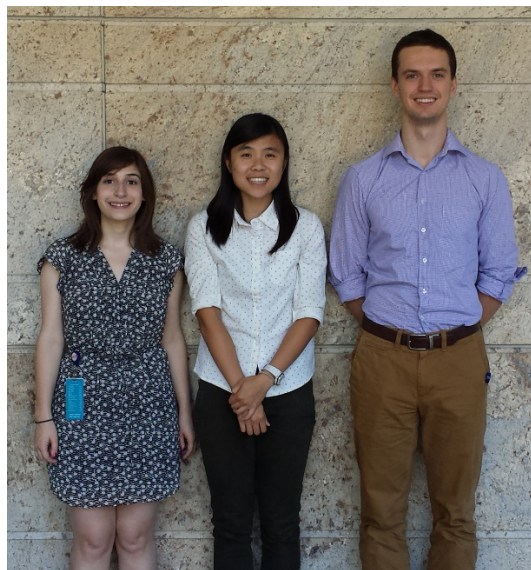
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## **We would like to introduce...**

### **Research Assistants at the Clinical and Data Coordinating Centers for the REPRIEVE Trial**

Kimberly Wong and Jenny Gilbert are Research Assistants in the Clinical Coordinating Center.

Jenny Gilbert, is our newest team member, she previously worked on large-scale public health projects at Harvard School of Public Health and John Snow, Inc, and received her BA at Boston University. Jenny will be helping with the team's marketing campaign, including social media, as well as the site specific performance monitoring, site score cards, and IRB compliance.



Kimberly Wong, who graduated with a BA from Boston University, joined the REPRIEVE team in March, 2015. Kimberly helps with managing the [REPRIEVE Trial](#) website, developing the REPRIEVE Newsletters and Weekly Updates, and she coordinates shipment of the PaxGene Tubes for the Mechanistic Substudy.

Alex Ivanov is the lead Research Assistant for the Mechanistic Substudy of REPRIEVE. He joined the REPRIEVE team in September 2014 and works on activating sites for the substudy. Currently, he reviews the CT scans and communicates with sites to ensure excellent imaging

quality. Please feel to reach out to [Alex](#) with any substudy related questions!

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### Check out the latest articles about REPRIEVE!

These could be helpful tools to get the word out about REPRIEVE in your area



Dr. Turner Overton's article: "[REPRIEVE Trial Likely to Clarify Value of Statins in HIV Population](#)" in [Infectious Disease News](#).

REPRIEVE featured in [JAMA](#)! "[Exploring Statins to Decrease HIV-related Heart Disease Risk](#)".

Dr. Steven Grinspoon and Aaron Laxton (one of our CAB members), co-wrote the article, "[REPRIEVE for Heart Disease in HIV](#)," in [POZ magazine](#).

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## What's In the Folders on the REPRIEVE (A5332) PSWP?

What's in the "Current Protocol Status Announcements" folder?

- Look here for the official notice of the status of the REPRIEVE Trial (for example, open to accrual, closed to accrual, closed to study follow-up, concluded). Of course, REPRIEVE is Open to Accrual now, and the memo to that effect is in this folder. The memo also includes some important information to sites about preparing for participating in the trial.

What's in the "Current Protocol Documents" folder?

- This folder contains the protocol and related documents, including:
  - Version 2.0 of the protocol document
  - The cover letter distributed with the protocol, which contains important instructions to sites.
  - The Sample Informed Consent translated into Spanish.
  - A Clarification Memo issued in February 2015 that allows pregnancy testing at clinics as well as labs, measures waist circumference at the month 72 visit, corrects a typo in the sample informed consent, and clarifies the timing of study drug initiation for substudy participants.

**JUST POSTED on the A5332 PSWP  
Revised LPCs**

## **REPRIEVE presentations from the ACTG Network meeting DSMB Summary Report for IRBs/ECs!!!**

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

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

#### **For A5332 please use**

**Protocol:** Version 2.0 dated 12/19/14

**MOPS:** dated 6/15/2015

**A5332 LPC for ACTG Sites:**

dated 7/30/15 (just posted)

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

dated 7/30/15 (just posted)

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

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### **What's New on the A5333s PSWP?**

#### **JUST POSTED!**

**A5333s IMAGING TIPS V 1.0:** dated 07/16/2015

These Imaging Tips from the MGH CT Core Lab review important CT reconstructions and will promote successful CT scanning for the Mechanistic Substudy of REPRIEVE.

Please distribute to your imaging teams!

*This document is in the Protocol Training section of 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@fstf.org](mailto:reprieve.news@fstf.org).

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