



## Randomized Trial to Prevent Vascular Events in HIV

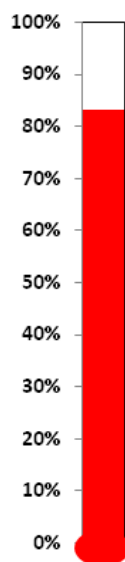
### Site Newsletter 11/09/2015

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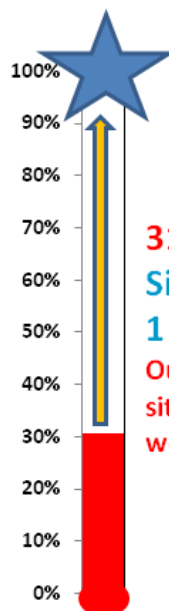
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### Trial Status: 11/2/2015-11/9/2015

There are 566 participants enrolled in REPRIEVE! We had our best week so far, with 46 new enrollments the week of October 26th. Thank you for all your efforts to recruit for REPRIEVE. If every activated site enrolls at least 1 participant this week, we will exceed 600 participants in REPRIEVE!!!



**83% of Activated  
Sites have Enrolled!**  
This is increasing each  
week!



**31% of Activated  
Sites enrolled at least  
1 Participant last week.**  
Our target is 100% of activated  
sites to enroll 1 participant each  
week.

## **Congratulations to Sites Enrolling Participants**

### **Week of 11/2/15**

UCSD Antiviral Research Center CRS

Alabama CRS

Greensboro CRS

Cincinnati CRS

Thai Red Cross AIDS Research Center

Weill Cornell Uptown CRS

Chiang Mai University HIV Treatment Center CRS

Rush University CRS

Whitman-Walker Health CRS

University of Rochester Adult HIV Therapeutic Network CRS

Georgetown University CRS

University of Illinois at Chicago

Denver Public Health

University of Nebraska Medical Center

Mt Sinai Kreuger Clinic

Medical College of Wisconsin

Florida Department of Health

Orlando Immunology Center CRS

Virginia Commonwealth University medical center CRS

Drexel University

## Race to November 15th! Help Us Meet Our Internal Deadline!!!

The NIH has set an internal deadline of November 15<sup>th</sup> for REPRIEVE to enroll at least 629 participants. **We want to urge you to move any screens forward into randomized participants as quickly as possible.** By doing so we may meet this internal recruitment goal!



### FAQ



#### Who can perform the screening physical exam for REPRIEVE?

In most care settings, Registered Nurses are responsible for collection of vital signs and often physical examination information. The screening physical exam for REPRIEVE is within the scope of a Registered Nurse's practice and qualifies as ancillary care. Registered Nurses performing screening and targeted exams should be delegated these responsibilities on the delegation of authority/duties logs, but they do not need to be recorded on the FDA 1572. In this capacity, the Registered Nurse is collecting physical information, he/she is not making decisions on the standard of treatment for an individual participant.

#### Who should be listed in Section 6 (sub-investigator) on the FDA 1572 form?

FDA's regulation at 21 CFR 312.3 (b) states 'In the event an investigation is conducted by a team of individuals, the investigator is defined as the responsible leader of the team'. Sub-investigator includes any other individual member of the team who will be assisting the investigator in the conduct of the investigation(s). The purpose of Section 6 of the FDA 1572 is to capture information about individuals who as part of this investigative team will provide a direct and significant contribution to the data. The decision to list an individual in Section 6 of the FDA 1572 depends on whether they are performing significant clinical investigations. In general if an individual is directly involved in the performance of procedures required by the protocol and the collection of data that person should be listed on the 1572. The Guidance goes on further to clarify the position on nurses, residents, fellows, office staff or other hospital staff who provide ancillary or intermittent care. The

discriminator is whether they make a direct and significant contribution to the clinical data. If they do not – they do not need to be listed.

## Reminder regarding data entry deadline for this week!

Please note that Friday, November 13th is the [data entry deadline for the upcoming DSMB review](#).

The timeline below lists important tasks and deadlines for the upcoming Data and Safety Monitoring Board (DSMB) review of the REPRIEVE trial. This timeline will be posted under the Study Monitoring tab on REPRIEVE (A5332) PSWP for future reference.

Task		Deadline	Weeks to DSMB
Sites	Latest date for the occurrence of a clinic visit for which complete data must be included in this DSMB review	Oct 30 (Fri)	6.9
Sites	<b>All data for visits through October 30 entered [note: expedited - within 2 weeks of visit]</b>	<b>Nov 13 (Fri)</b>	<b>5</b>
Sites	All queries resolved by this date	Nov 27 (Fri)	2.9
All	DSMB Meeting	Dec 17 (Thur)	0

Please mark these important dates in your calendars, and thank you for your attention to this timeline in the weeks ahead.



Lab Tips

## Helpful Tips for Non-ACTG Sites

### What supplies do we need for REPRIEVE?

On page 1 of the non-ACTG A5332 LPC you will find ordering information for cryovials, freezer boxes, and labels.

### How should we ship specimens to the repository?

Over the course of the trial your processing lab will make about 15 shipments to the repository (BRI). You may be able to use only one or two shippers back and forth, if you protect them by completely covering the outside with clear tape before using them for the first time. One example of a great shipper is the [Saf-T-Pak STP320](#). You will need to include a completed air bill (FedEx number to use is in the non-Network LPC, Section 5) and a sheet of paper with "EMPTY" written on it in your shipment for the return of your shipper. When BRI returns the shipper to you, they will cover all hazard labels with the sheet of paper indicating the box is "EMPTY."



## Recruitment Tip for Sites Not Yet Activated

For sites not yet activated to begin enrolling in REPRIEVE, you can begin to compile a list of potential participants in order to begin screening and enrolling immediately upon activation.



## Check out the recent article about REPRIEVE in [HIV Plus Magazine!](#)

We have recently begun outreach to many media outlets, so stay tuned for more press about REPRIEVE in the next few months.

## JUST POSTED on the A5332 PSWP

- [REPRIEVE, ACTG, and Canadiana HIV Trials Network Site Designation](#)
- [CAB Slides from ACTG Network Meeting \(Useful for recruitment!\)](#)
- [Provider summary sheet/infographics](#)

- **Participant postcards and participant summary sheet**
- **Revised Entry Verification Checklist and Screening Checklist provided by UNC**

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



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

### **What's in the "Study Monitoring" folder?**

A Data and Safety Monitoring Board (DSMB) was established by the NHLBI to monitor data and oversee patient safety in the REPRIEVE trial. You will find Summary Reports of DSMB meetings in this folder.

Sites are required to forward these reports to their IRBs/ECs and file them in the regulatory files. The monitors will look for documentation of the submission to the IRB during the regulatory file review.

Currently, these memos and reports are in the **Study Monitoring** folder:

- **Summary Report of the June 2015 DSMB Meeting and a memo** from the REPRIEVE team about the findings of that review.
- **Summary Report of the September 2014 DSMB Meeting.** This was the first meeting of the REPRIEVE (A5332) DSMB when the Board reviewed the Study Protocol, Monitoring Plan, Consent Form, and DSMB Charter.

### **What's in the "Lab Resources" folder?**

This folder contains the Lab Processing Charts (LPCs) for the current version of the protocol and other useful resource material related to lab tests and the LDMS. Remember that there are different LPCs for ACTG sites and sites not in the ACTG (non-ACTG sites). Because ACTG sites are collecting additional lab specimens, we felt it would be easier and less confusing to create separate LPCs.

Here is a list of what is currently in the Lab Resources folder:

#### **ACTG Sites:**

- **The current LPC** (in Word and in PDF file formats)

#### **Non-ACTG Sites:**

- **LPC** (in Word and in PDF file formats)
- **Lab Details from WebLDMS Training**
- **Lab Processing Worksheet**
- **Shipping Schedule** – **very important! Check your site's schedule of when to ship samples to the specimen repository (BRI).**
- **Specimen Worksheets** - this folder contains worksheets for each visit.
- **Step-by-Step Guide for LDMS Entries using the REPRIEVE Processing Worksheets** – this is a guide that sites can use if their processing lab does NOT

have LDMS access.

- **WebLDMS Reference Guides**
  - Shipping
  - Specimen Management
  - Storage
- **FDA 1572 Template**

## **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 9/17/15

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

dated 9/17/15

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

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

### **For A5333s please use**

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

**MOPS:** dated 3/16/2015

**A5333s LPC :** dated 9/21/15

*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@fstfrf.org](mailto:reprieve.news@fstfrf.org).

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