



## Randomized Trial to Prevent Vascular Events in HIV

### Site Newsletter 10/10/2016

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### REPRIEVE Announcements!



Have you heard that there are over 2,000 participants enrolled in REPRIEVE?! Thank you to all sites for helping REPRIEVE reach this major milestone and a special thank you to Site 2701 Northwestern University CRS for enrolling the 2,000th participant!

The week of September 26th was a record week for REPRIEVE, as 47 participants were enrolled and 52% of activated sites enrolled at least 1 participant.

There are now 2061 participants enrolled, with 35 participants were enrolled this past week. With 91 sites activated, our goal of 50

participants enrolled per week is achievable!

## REPRIEVE's Fall 50 Updates

Between October 1st and December 30th, all sites enrolling 3 participants per month will receive a \$50 gift card and all sites enrolling 4 or more participants per month will receive a \$100 gift card.

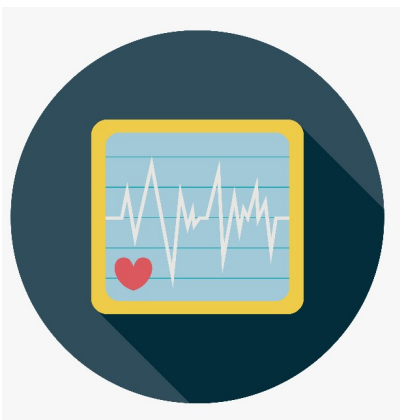
**Check out the sites below that are on their way to enrolling 3+ participants this month!**

#	Site Name	Participants Enrolled This Month
12101	Instituto de Pesquisa Clinica Evandro Chagas CRS	8
31802	Thai Red Cross AIDS Research Center	6
30347	University of Illinois at Chicago	3
201	Johns Hopkins University CRS	2
31784	Chiang Mai University HIV Treatment CRS	2

**Thank You to All Sites Enrolling Participants  
Week of 10/03/2016!**

- Instituto de Pesquisa Clinica Evandro Chagas CRS
- Thai Red Cross AIDS Research Center
- University of Illinois at Chicago
- Johns Hopkins University CRS
- Chiang Mai University HIV Treatment CRS
- Duke University Medical Center
- Rush University CRS
- Chapel Hill CRS
- Greensboro CRS
- Puerto Rico AIDS Clinical Trials Unit CRS
- University of Colorado Hospital CRS
- Weill Cornell Uptown CRS
- Cornell Chelsea CRS
- Columbia Physicians and Surgeons CRS
- Denver Public Health
- Orlando Immunology Center CRS
- Alabama CRS
- Whitman-Walker Health CRS
- Drexel University
- 550 Clinic at U Louisville
- University of Kentucky
- Mt Sinai St Lukes Morningside Clinic
- Mt Sinai St Lukes West 17th Clinic
- Abbott Northwestern Hospital CRS

## A Reminder About ECGs!



Please make sure you are entering participant demographic information when you perform an ECG.

The required information to be entered is outlined in the ECG Training Slides and in the image below. **For example, when prompted to enter the Screening #, please *ALWAYS* enter the Patient ID (PID).**

Training slides are [attached here](#) and located in the Protocol Training folder on the REPRIEVE (A5332)

PSWP.

Screen Prompt	Data Entry Instructions for Site Staff
<b>REPRIEVE-A5332</b> <i>*Note: this will be hard-coded into the ECG unit</i>	Skip this field. Press ENTER or F2.
<b>Subject Initials</b>	Subject initials are <u>not</u> being collected, skip this field. Press ENTER or F2.
<b>Subject Gender</b>	Type <b>Female</b> or <b>Male</b> . Press ENTER or F2.
<b>Age</b>	Skip this field. Press ENTER or F2
<b>Screening #</b>	Type in the <b>Patient ID</b> . Press ENTER or F2. <i>(*Note: the PID should not <b>BEGIN</b> with any alpha values. Do not enter the Screening number of the Subject)</i>
<b>Visit Code**</b>	Enter the appropriate visit identifier from the visit schedule ( <b>D0 or U</b> ). Press ENTER or F2
<b>Study site ID</b>	Type your <b>Site ID</b> Press ENTER or F2



### What should I do regarding specimen collection if a participant misses their Month 12 visit but returns for their Month 16 visit?

If a participant misses the Month 12 visit, but does come in for a Month 16 visit, perform the specimen collection as part of the Month 16 visit and contact the REPRIEVE Data Manager for instructions on entering the data into OpenClinica. The REPRIEVE Data Manager can be contacted by emailing [reprieve.dmc@fstrf.org](mailto:reprieve.dmc@fstrf.org)

## Timeline for the Next REPRIEVE DSMB Meeting

The next REPRIEVE DSMB meeting will take place on Friday, December 16th.

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 the REPRIEVE (A5332) PSWP for future reference.

Task		Deadline (2016)	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 28 (Fri)	7
Sites	All data for visits through October 30 entered [note: expedited - within 2 weeks of visit]	Nov 11 (Fri)	5
Sites	All queries resolved by this date	Nov 23 (Wed)	3
All	DSMB Meeting	Dec 16 (Fri)	0

## A Reminder About Training Calls

If you receive an email reminder inviting you to attend a specific training, for example ECG training or protocol training, this means that we have reviewed our records and your site still needs to complete the specific training you are being invited to in order to open for enrollment. Please make every effort to attend, otherwise this may delay protocol activation at your site.

## Don't Forget! Actively Assessing for Adjudicated Events is Essential!



It is important in REPRIEVE that all adjudicated events (AKA REPRIEVE MACE\*) are captured. **It is absolutely essential for the REPRIEVE adjudication team to evaluate all possible MACE events to determine if they are actual MACE events. We ask that sites have a LOW THRESHOLD for submitting ANY POSSIBLE MACE event for adjudication.** Don't forget to complete the Adjudicated Events Tracking CRF (TRK0150) at every visit post screen.

**The next Monthly Site Call, Tuesday, October 18th at 1:00 PM ET will be focused on REPRIEVE Adjudicated Events/REPRIEVE MACE, please join the call and be ready with any questions you may have.**

The team has developed [this tool](#), located in the Protocol Training folder on the REPRIEVE (A5332) PSWP. The tool contains descriptive terms for adjudicated events and may be helpful when completing the Adjudicated Events Tracking CRF. Please review this tool so that you can carefully capture any possible REPRIEVE MACE at every visit post screen.



\*MACE= major adverse cardiovascular event

## Thank You from the Division of AIDS Program and Office of Clinical Site Oversight team!!!



Top row left to right: Jess Landis, Dapo Ali, Brain Weingartner

Middle Row: Ron Barnett, Karin Klingman, Isabel Guerra, Jenese Tucker, Blanca Castillo

Front Row: Cindy Coates, Keisha Easley, MJ Humphries, Daniella Livent

### In Case You Missed It!

Dr. Carl Dieffenbach, Director of the Division of AIDS, National Institute of Allergy and Infectious Diseases has a special message regarding the 2,000+ participant milestone. Click the image below to open the message.



## Mechanistic Substudy of REPRIEVE (A5333s) Updates

**The Mechanistic Substudy has enrolled 369 participants, 6 new participants were enrolled last week!**

During the recent call with sites participating in the Mechanistic Substudy, several sites requested a video or other informational material to describe the Coronary CT Angiography (CCTA) procedure to participants. We found [this video](#),\* that may help participants to be more familiar with the procedure prior to their first

CCTA.

Please remember to ask every participant screening for REPRIEVE (A5332) if they would also like to participate in the Mechanistic Substudy.

\*Please submit to your local IRB depending on their requirements.



## Woman-Centric Research and Why it's Time to Listen to the Ladies

JEANNE BARON  
THURSDAY, SEPTEMBER 29, 2016

**AVAC**

Global Advocacy for HIV Prevention

Check out the latest [blog post](#) mentioning the  
importance of REPRIEVE!

### 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)

Letter of Amendment, Version 3.0 #1 dated 08/17/16

**MOPS:**

Version 3.0, revision 1, dated 09/09/16

**A5332 LPC for ACTG Sites:**

Version 3.0 dated **09/28/2016 (new!)**

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

Version 3.0 dated **09/27/2016 (new!)**

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:** Version 3.0 dated 09/02/2016

**A5333s LPC :** Version 3.0 dated **09/29/2016 (new!)**

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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