



## Randomized Trial to Prevent Vascular Events in HIV

### Site Newsletter 01/09/2017

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### REPRIEVE Trial Status as of January 9th

**2564** participants are enrolled

**200** participants are in screening

**102** sites are open for enrollment

**18** sites have enrolled at least 1 participant in the past week

**21** sites have screened at least 1 participant in the past week



### Important Early 2017 Target

April 1st, 2017 marks the 2 year anniversary of the 1st enrollment in REPRIEVE. Let's make April 1st another important milestone, if ~50 participants are enrolled each week between now and April 1st, 2017 we will hit the target of 50% of participants enrolled (3,250 participants)!

## REPRIEVE Fall 50 Winners are Announced!

We would like to thank all sites for their efforts in the Fall 50 competition and congratulations to the sites that were able to meet the Fall 50 enrollment goals. The Clinical Coordinating Center will be contacting you soon to arrange for a gift certificate to be sent to your site.

### *And the winners are...*

#### 1st place prizes for the following sites that enrolled 4+ participants on average/month:

31802 Thai Red Cross AIDS Research Center  
 12101 Instituto de Pesquisa Clinica Evandro Chagas CRS  
 11101 University off the Witwatersrand Helen Joseph CRS  
 8950 Family Clinical Research Unit CRS  
 31470 Denver Public Health  
 31784 Chiang Mai University HIV Treatment CRS  
 2401 Cincinnati CRS  
 31864 UT Southwestern  
 1505 University of Nebraska Medical Center  
 31673 Orlando Immunology Center CRS

#### 2nd place prizes go for following sites that enrolled 3 participants on average/month:

31871 University of Kentucky  
 31791 Whitman-Walker Health CRS  
 2701 Northwestern University CRS  
 6201 Penn Therapeutics CRS  
 31845 Wake Forest University  
 3201 Chapel Hill CRS  
 6101 University of Colorado Hospital CRS  
 31834 AIDS Research Treatment Center of the Treasure Coast  
 31889 Toronto General Hospital

### Thank You to All Sites Enrolling Participants Week of 01/02/2017!

Univ. of Miami AIDS Clinical Research Unit(ACRU) CRS  
 University of Nebraska Medical Center  
 Duke University Medical Center  
 Northwestern University CRS  
 Greensboro CRS  
 Family Clinical Research Unit CRS  
 Orlando Immunology Center CRS  
 University of Cape Town Lung Institute CRS  
 Thai Red Cross AIDS Research Center  
 Medical University of South Carolina

UT Southwestern  
 Hamilton Health Sciences  
 Vancouver ID Research and Care Centre Society  
 University of Kentucky  
 Mt Sinai Comprehensive Health Program  
 Mount Sinai Clinical and Translational Research Center  
 Positive Health Clinic CRS  
 Abbott Northwestern Hospital CRS



## REPRIEVE Field Representative Named 2016 HIV/AIDS Nursing Certification Board's Certified Nurse of the Year!

In November 2016, [David Currin](#), RN, ACRN, CCRC and REPRIEVE Field Representative was honored as the HIV/AIDS Nursing Certification Board's 2016 Certified Nurse of the Year.

David has worked in HIV/AIDS nursing for the last 15 years and is currently working at the University of North Carolina, Chapel Hill ACTG site. David has served on multiple ACTG Network committees in member and leadership positions, most recently as chair of the Site Management and Clinical Care Committee. As a Field Rep on the REPRIEVE trial, David has done an excellent job guiding the team to always consider a site-level perspective. His guidance is essential to our team and we wish to congratulate David on being honored with this prestigious award.

## Important Reminders



- **A5332 Version 3.0, Clarification Memo #3**, dated 12/27/2016 was emailed on 12/27/2016 and can be downloaded from the A5332 PSWP: [Current Protocol Documents \(Version 3.0\)](#) folder
- An **updated version of the Spanish translation of the Heart-related Health Questionnaire** is now available. Go to the REPRIEVE (A5332) PSWP: [Protocol Specific Support Documents --> Spanish Translations](#)
- An **updated Package Insert for Pitavastatin (Livalo)**, dated November 2016 is now available on the DAIDS Regulatory Support (RSC) website, [click here](#). If you have any questions, please contact the DAIDS RSC Safety

Information Center (RIC) via email at [RIC@tech-res.com](mailto:RIC@tech-res.com) or call 1-301-897-1708.

## Reminder Regarding 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. **It is very important to note that when prompted to enter the Screening #, please ALWAYS enter the Patient ID (PID).**

Training slides are [attached here](#) and located on the A5332 PSWP: [Protocol Training](#) folder.

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>DO or U</b> ). Press ENTER or F2
<b>Study site ID</b>	Type your <b>Site ID</b> Press ENTER or F2



- **Updated LPCs for A5332 ACTG and non-ACTG sites** are posted on the A5332 PSWP, [Lab Resources](#) folder.
- **Updated LPC for A5333s** is posted on the A5333s PSWP, [Current Laboratory Documents and Memos](#) folder.
- **For non-ACTG sites only: An updated non-ACTG site shipping schedule** (dated 12/15/2016) has been posted on the A5332 PSWP, [Lab Resources](#) folder. No changes have been made for sites on the previous schedule, only new sites have been added.
- **Do not overfill cryovials for stored plasma and serum**, they should be filled with 1.8 mL. If cryovials are underfilled please remember to make a note of this in LDMS. See below for some helpful LDMS condition codes.

## LDMS Condition Codes 101

### If the Primary tube is underfilled

1. At the Primary tube level, change the LDMS code from SAT (Satisfactory) to SHV (Short Volume).
2. Replace the primary tube volume in the preload with the accurate volume of blood. (You may be asked to confirm that you intend to modify the preload)
3. Do not cascade the code to all aliquots as it may only apply to the Primary.
4. Add a short explanation in the Primary tube comment section. (i.e. difficult stick, vein collapsed, etc...)

### If the volume in the aliquot is less than expected

1. At the aliquot level, change the LDMS code from SAT to SHV.
2. Change the aliquot volume to reflect what was banked.
3. Save and reprint the label.
4. Repeat for all concerned aliquots.
5. If desired, add a short explanation in the Aliquot comment section.

### If an aliquot was frozen after specified time allowed

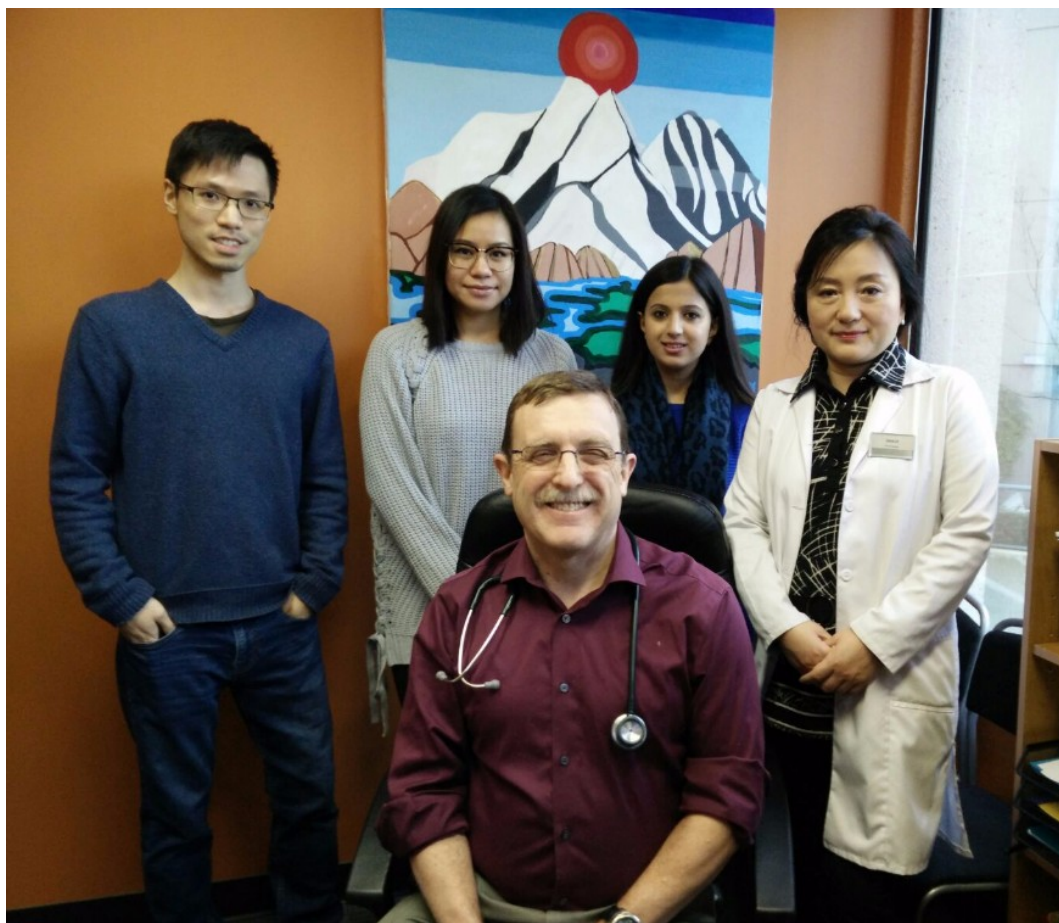
1. At the aliquot level, change the LDMS code from SAT (Satisfactory) to PST (Past Specified Time).
2. Cascade to all concerned aliquots
3. If desired, add a short explanation in the aliquot comment section.

**If the aliquot is already frozen:** Work fast and in dry ice, remove the incorrect label, and adhere the label with the correct volume. Secure the label with a rubber band if needed.

**If the blood arrived after specified time:** At the primary tube level, change the LDMS code from SAT (Satisfactory) to PST (Past Specified Time).

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## Meet the Team: Vancouver Infectious Diseases Centre (VIDC)



Back row: Victor Chiang (study coordinator), May Hang (research assistant), Yashna Bhutani (research nurse) and Grace Koo (pharmacist); Front row: Dr. Conway (PI).

**The Vancouver Infectious Diseases Centre (VIDC) is one of our top enrolling sites in Canada. A huge thank you to this team for their hard work, dedication, and enthusiasm!**

**When asked what helps their site successfully recruit participants for REPRIEVE, Brian Conway, Site PI, responded:**

"I think we are successful for 3 important reasons:

1. Our entire research group believes in the importance of this project and its promotion. Potential study subjects know and recognize this.
2. In recruiting subjects, it is all about them, not about us. If they are interested in participating in REPRIEVE, we will do everything we can to meet their needs to ensure maximal engagement from the time of consenting for the protocol through each and every follow-up visit.
3. We have successfully integrated the conduct of clinical research into the day-to-day function of our clinic. This makes it more flexible, more responsive and encourages long-term engagement of participants in studies such as REPRIEVE."

## REPRIEVE In the News

Below are some recent articles/papers mentioning REPRIEVE and/or CVD & HIV that can be great resources for yourself, your team, and your

patients.



- REPRIEVE was featured in a recent JAMA Cardiology editorial authored by Colleen Hadigan, MD, Catharine Paules, MD, Anthony Fauci, MD: "[Association Between Human Immunodeficiency Virus Infection and Cardiovascular Diseases: Finding a Solution to Double Jeopardy](#)"
- HIV Plus Magazine's new article "[If You Have HIV, You Are More Likely to Suffer a Heart Attack](#)" is a good resource for HIV patients.
- In its first issue of 2017, the Journal of the American College of Cardiology published two side-by-side reviews of HIV and heart disease: [one ischemic](#) and [one non-ischemic](#). REPRIEVE is mentioned in both.

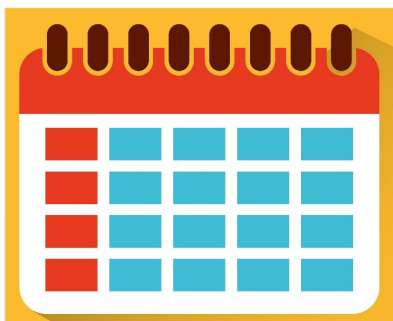
## Mark Your Calendars

### REPRIEVE Investigator's Meeting at CROI 2017

**Wednesday, February 15th 12:15 PM - 1:45 PM PT**

Grand Hyatt 721 Pine Street, adjacent to the Washington State Convention Center

**An invite will go out via email to Site PIs this week.  
Please RSVP as space is limited.**



## TRAINING OPPORTUNITIES

### Helpful Training Resources

#### 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 Videos

The REPRIEVE Data Managers have put together some excellent videos on the following topics:

- Changing Previously Saved Data
- Entering Logs
- Entering Missed Visits
- Answering Notes and Discrepancies
- Entering Out of Window Visits
- Entering Unkown or Missing Values

You can access these videos in the [FSTRF portal](#), go to -->**Site Support Tab** -->**REPRIEVE Training Videos**

## 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)

Clarification Memo #3 dated 12/27/2016 **(new!)**

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 01/04/2017 **(updated!)**

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

Version 3.0 dated 01/04/2017 **(updated!)**

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 01/04/2017 **(updated!)**

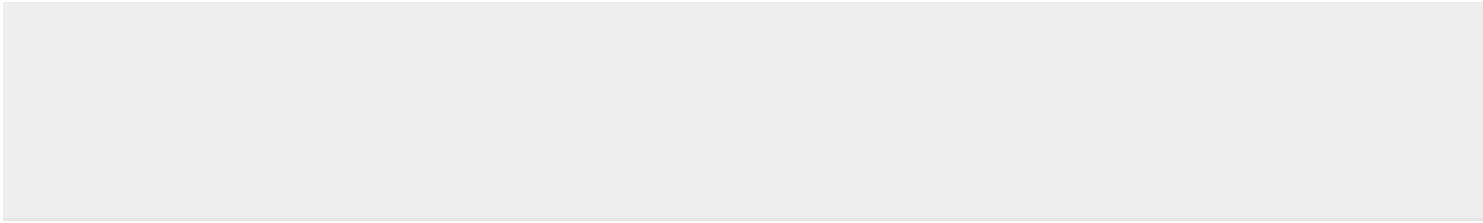
These documents are on the [A5333s PSWP](#)

**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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