



REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 06/13/2016

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Updates: REPRIEVE's March Madness Competition!!!

Updates from Week 10 of our March Madness-style competition are in! And never fear, there is still time to enter into the competition. **All enrollment through June 30th is counted and winners will be announced in the July 11th Site Newsletter!**

Current Site Standings!!!

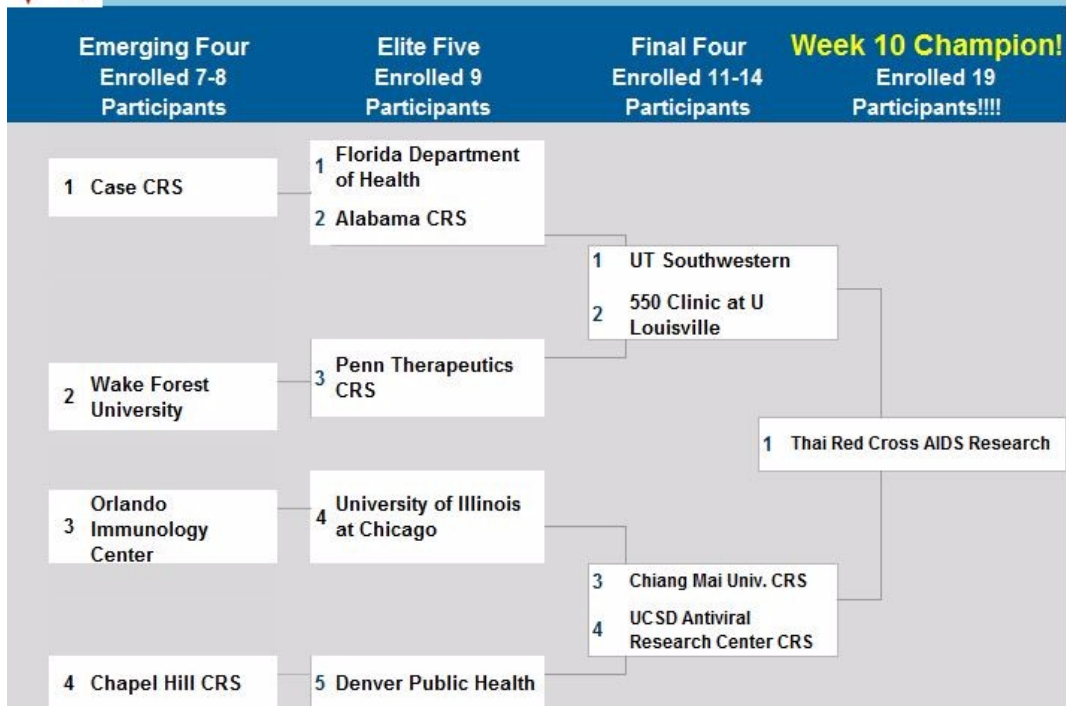
- **Thai Red Cross AIDS Research Center has taken the lead, enrolling 19 participants since April 1st!**
- **UT Southwestern is very close behind, enrolling 14 participants!**

We also have 5 new sites in the bracket since our last newsletter!

- Orlando Immunology Center
- Alabama CRS
- University of Illinois at Chicago
- Penn Therapeutics CRS
- Denver Public Health



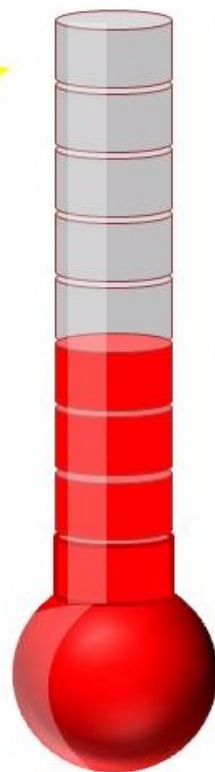
March Madness REPRIEVE Style!



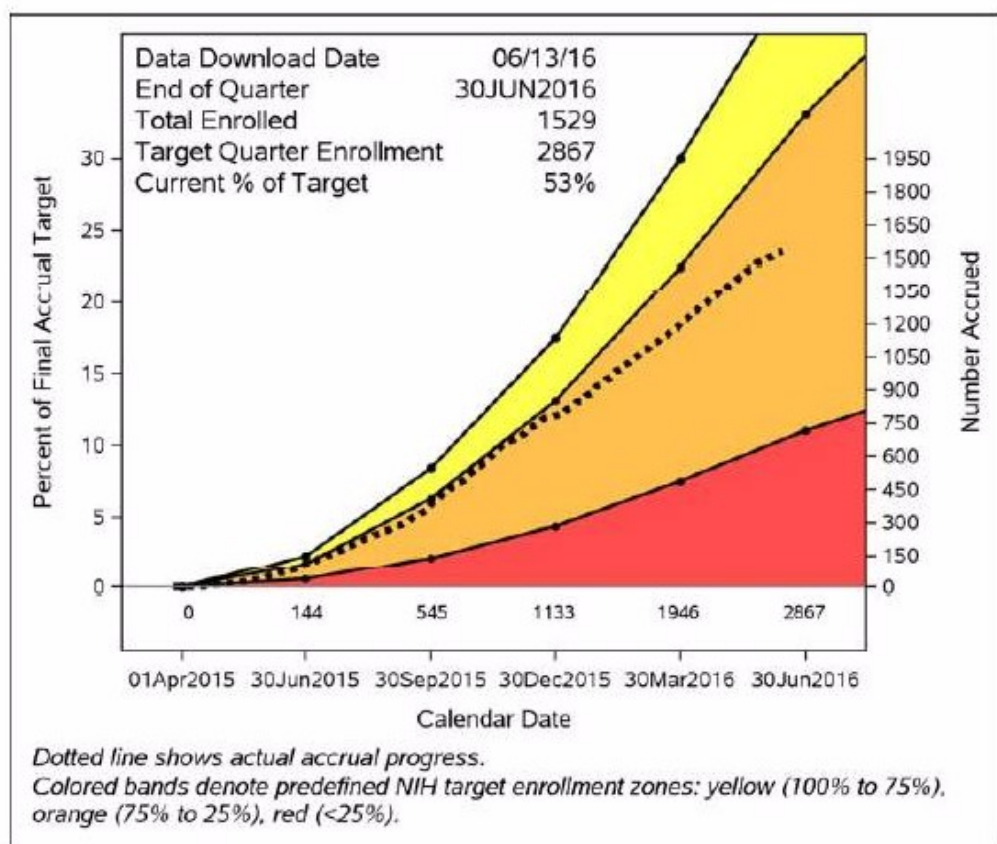
Thank you to every site enrolling participants in REPRIEVE, with your help we have enrolled over 1,500 participants, your support is key in helping us reach the REPRIEVE enrollment goals to help us present significant progress to our DSMB on June 24th as well as for our next enrollment target on June 30th.

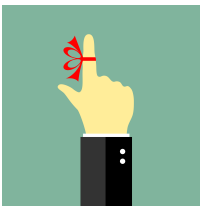


2867 Target Enrollment



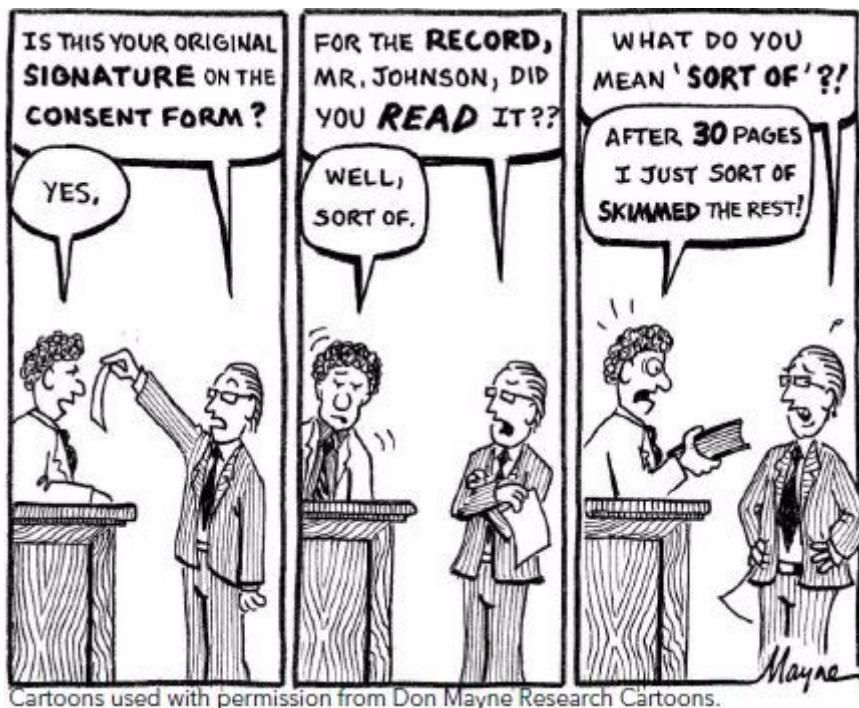
1529 Current Enrollment





Don't Forget!

For sites registered to protocol Version 2.0, the deadline for DAIDS Protocol Registration of protocol Version 3.0 is July 26th. The Version 2.0 enrollment screens will close shortly thereafter. If you have any questions about protocol registration, please contact the Protocol Registration Office via email at protocol@tech-res.com, or by phone at 301-897-1707.



Cartoons used with permission from Don Mayne Research Cartoons.

Informed Consent: Overview and Tips

[Click here](#) to read the April edition of the OCSO Monitoring Operations Branch (MOB) Newsletter. This edition features an article that we think will be helpful to site

staff on the informed consent process and the documentation of consent.

If you have any questions please contact the Monitoring Operations Branch (MOB) ocsomob@niaid.nih.gov



We have a participant in screening for REPRIEVE who is HCV co-infected and plans HCV treatment at some point in the next couple years. Can you provide recommendations for enrollment of participants who are likely to initiate HCV treatment while on study and management of potential drug interactions?

The REPRIEVE team agrees with treating REPRIEVE participants with any of the DAAs currently available. However, please be mindful of the complicated drug-drug interactions with Viekira. Otherwise, there are no specific concerns for pitavastatin.

Please delay treatment until after the participant has reached the month 1 safety visit to limit any concerns for overlapping toxicity.

Also, make sure that you document the HCV drug treatment on the medication log appropriately so we capture this data.

This information will be added to the Prohibited and Precautionary Medications list on the PSWP and we will address this on the next site call.

Additionally, REPRIEVE allows co-enrollment into ACTG hepatitis C studies. A coenrollment guide can be found on the A5332 PSWP.

Do I use a participant's actual weight or ideal body weight to calculate the creatinine clearance for eligibility in REPRIEVE?

Please use **actual weight** to calculate creatinine clearance to determine eligibility for REPRIEVE.



Helpful Tip Regarding the TRK0153 Form (Specimen Consent / Deconsent for Non-Protocol Defined Testing)

This form will help the team know whether or not to pull stored samples for testing that is not specified in the protocol but is approved in the future.

To complete the **TRK0153**, you need to know if the participant agrees or does not agree to the use of his/her samples in the future for tests that are not yet specified. The informed consent will reflect the participant's choices (see below). If the participant changes his/her mind, the form should be updated.

ACTG sites: participants at ACTG sites only are asked to provide a separate sample for future genetic testing, which is in addition to providing samples for A5128 or A5243. **If the participant consents for future genetic testing, the answer to Section A is YES. If they also agree to allow the team to use samples in the future for REPRIEVE-approved tests that are not yet specified, check off YES in Section B.**

Non-ACTG sites: The **answer to Section A is NO** because only ACTG sites are asked to provide a sample for future genetic testing. **If the participant agrees with the team pulling a stored sample in the future for a REPRIEVE-approved test that is not yet specified, check off YES in Section B.**

If your participant has refused to have samples drawn and stored for future unspecified testing (see text below), then the answer to both questions would be NO (because there would be no samples available for future unspecified testing).

Below is language from the A5332 consent that applies to Section B:

At entry, annual visits (as indicated in the Study Procedures table), and the end of study visit, some of your blood will be collected and stored for future REPRIEVE-approved research on conditions including cardiovascular disease, HIV, inflammation, cancer or statin medications. You do not need to agree to store this blood to join the study and you may change your mind about storing your blood at any time. Your blood may be stored (with the usual protectors of identity) for an indefinite length of time. You will not be told of the results of the research done on your blood.

Up to 14 teaspoons of blood will be collected at the entry, months 12, 24, 48, and end of study visit for these purposes.

Do you agree to let us store your samples for future research on conditions including cardiovascular disease, HIV, inflammation, cancer, and statin medications?

_____ YES _____ NO _____ Initials

Did you forget your user name or password for the ACTG Member website?

1. Go to <https://actgnetwork.org> and click on Member.
2. Your username is: firstname.lastname
3. To retrieve your password:
 - a. Click on **"Help! I don't remember my password"**
 - b. On the following page, to the right of User Account, click on "request new password"
 - c. Enter your email address and submit.

* If you have not registered to the ACTG Member website yet, click on [New User Registration](#) and follow the prompts.



When processing samples for storage please remember the following:

- Aliquot cryovials for storing samples should be **2mL screw cap micro tube, sterile, and external threaded tube.**
 - **Sarstedt 72.694.005** or equivalent should be used.
 - **Do not use** aliquot cryovials with internal threading, stoppers, or flip caps.
- When aliquotting, **do not overfill cryovials**, follow instructions on the Lab Processing Chart to guide you.

Please forward these important reminders to your lab team if they do not already receive the REPRIEVE Site Newsletter.

What's New on the REPRIEVE PSWP?

The "Non-ACTG Site Specific Schedule" for shipping specimens to the repository (BRI) has been updated. No changes were made for sites on the previous spreadsheet

- we only added new sites to the schedule. The updated schedule is dated June 2, 2016, and is found here » [A5332](#) » [Lab Resources \(Protocol Version 3.0\)](#).



TRAINING OPPORTUNITIES

Tuesday, June 21st @ 1PM ET--Monthly Site Call

REPRIEVE Site Calls take place on the 3rd Tuesday of each month at 1PM ET. Call details will be emailed to the 'prota5332' logon soon. This month, we will be discussing REPRIEVE Key Protocol Deviations, recent FAQs, and other REPRIEVE Hot Topics. This is a great forum to ask questions of the leadership team!

Friday, June 24th @ 1pm ET--Data Management Training

The Data Management Center is planning a start-up data management training for REPRIEVE sites!

This training is a repeat of the data management training that is given throughout the year, and is geared for sites that have not yet attended a data management training or new staff that will benefit from this training. This 2-hour training will include information on user accounts, the DMC portal, subject enrollment, case report forms and schedules, and OpenClinica (the clinical trials data management system used for this trial).

Conferencing information will be forwarded next week.

Please note: At least one person from your site must attend a data management training to meet protocol activation requirements. If someone from your site has already participated in a data management training, your site has met that requirement.

ACTG Network Meeting

The annual ACTG Network Meeting is coming up! The meeting will take place at the Omni Shoreham hotel in Washington, DC, between June 26-30th. Go to the [ACTG website](#) for more details. [Click here](#) to download the flyer.

If you are a non-ACTG site in the DC area please join us for the REPRIEVE sessions (note that the hotel block for the meeting is restricted to ACTG sites). For those outside the DC area, we will share the REPRIEVE presentations with you after the meeting, and discuss key topics on the July and August team-site calls.

- **REPRIEVE Meeting**
 - Monday, June 27th 9:00-10:00 AM EDT
- **Question and Answer Session with the REPRIEVE Team**
 - Monday, June 27th 10:30-11:30 AM EDT
- **DMC Forms Room**
 - Sunday, June 26th
 - 12:00 - 1:00 PM EDT: REPRIEVE DM Training
 - 4:00 - 5:00 PM EDT: Survival Guide to Reporting Events for REPRIEVE
 - Monday, June 27th
 - 11:00 AM - 12:00 PM EDT: REPRIEVE DM Training
- **LDMS Demo Room**
 - The demo room will be open on Monday, June 27, and Tuesday, June 28. LDMS trainers will be available to help REPRIEVE sites regarding the use of the LDMS, including web LDMS. Please stop by any time between 9:00 AM and 5:00 PM!

REPRIEVE Gets Out Into the Community



The Boston REPRIEVE team, including staff from the Massachusetts General Hospital CRS, Clinical Coordinating Center, and Data Coordinating Center, along with members

of the ACTG Leadership and Operations Center, participated in the Boston AIDS Walk on Sunday, June 5. Despite the rainy weather, the event had a great turnout!



The [REPRIEVE Participant Newsletter Spanish translation](#)* is now available. [Click here](#) to download the newsletter and [click here](#) to download the Certificate of Authenticity.

*This has been approved by the IRB for the REPRIEVE Clinical Coordinating Center however, please submit for approval as per your local IRB requirements.

REPRIEVE's *Follow YOUR Heart* Campaign was recently featured on the AIDS United blog post. [Click here](#) to read the article.

If you haven't been to the Follow YOUR Heart website, [click here](#) to learn more!

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.



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