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Read Below About the Next Enrollment Challenge: March Madness REPRIEVE Style. Help Enroll the First 50%!



Randomized Trial to Prevent Vascular Events in HIV

Site Newsletter 03/28/2016

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ALERT: March Madness Extended for REPRIEVE!

By June 30th we hope to be close to 50% enrolled. To help get us to this target, March Madness has been extended for REPRIEVE!

Between April 1st and June 30th, 2016, the top 29 enrolling sites will be recognized in March Madness fashion. Team prizes will be awarded to sites depending on the site's enrollment numbers between April 1st and June 30th, 2016. Prizes will include a team lunch, REPRIEVE t-shirts, and swag bags.

If you are a site that is close to opening for enrollment/activation, now is the time to complete those last few tasks, submit your activation checklist, and join the competition!

Will you be in the Sweet Sixteen? Final Four? Or the ultimate winner, the REPRIEVE Champion site?

Who will be our Cinderella Sites and Bracket Busters?

Time to get your uniforms on and play ball!

The bracket is blank, let's fill it up!





36 Participants Were Enrolled Last Week! Congratulations to Sites

Congratulations to Sites Enrolling Participants Week of 03/21/2016

UT Southwestern

Denver Public Health

University of Kentucky

Duke University Medical Center

Mount Sinai Clinical and Translational Research Center

Mt Sinai St Lukes Samuels Clinic

Virginia Commonwealth University Medical Center CRS

Indiana University School of Medicine

University of Mississippi

550 Clinic at University of Louisville

Michael D. DeBakey VAMC
Thai Red Cross AIDS Research Center
UCSD Antiviral Research Center CRS
Chapel Hill CRS
University of Colorado Hospital CRS

Houston AIDS Research Team CRS
Chiang Mai University HIV Treatment CRS
Case CRS

Northwestern University CRS Harbor UCLA CRS

Ohio State University CRS

New Jersey Medical School Clinical Research Center CRS
Johns Hopkins University CRS
Trinity Health and Wellness Center
University of Southern California CRS

REPRIEVE will be successful if every activated site enrolls at least 1 participant per week!



FAC

My local IRB/RE has approved Version 3.0 of the protocol. Can I begin to implement the amendment immediately, or do I need to submit to DAIDS PRO and wait for approval to implement?

If you are already registered to Version 2.0, you can implement the Version 3.0 amendment immediately upon approval from your IRB/RE. See the workflow diagram that is located in the A5332 MOPS, Section 1.0, which applies to your situation. (New sites: if you are submitting Version 3.0 as your initial protocol submission, you DO have to wait for DAIDS PRO approval of your submission, and wait for your site to be activated for REPRIEVE before implementing the trial at your site. Also, DAIDS PRO WILL review your local consent.)

ites

- Receive IRB/RE approval for an amendment
- Implement amendment immediately
- Submit amendment registration packet to DAIDS PRO

DAIDS PRO

- · Review submitted protocol registration packet
- Site-specific informed consents will not be reviewed and approved
- Distribute Amendment Registration Notification to sites

Sites

- Obtain copy of Amendment Registration Notification from DAIDS PRO
- Place in regulatory files

Are the enrollment screens closed for Version 2.0 now that Version 3.0 is final?

No, if you are enrolling under Version 2.0 please continue to screen and enroll participants until you have IRB/RE approval for Version 3.0.

What's New on the REPRIEVE (A5332) PSWP?

- » <u>A5332</u> » <u>Protocol-Specific Support Documents (Versions 3.0 and 2.0)</u> » <u>Spanish Translations</u>
 - The Spanish translation of the Cardiovascular Risk Assessment v1.03, and the Certificate
 of Translation have arrived. Remember that this assessment is to be done via interview.



Recruitment



The University of Washington Site Team has Shared a Cool Recruitment Tool!

Staff from the UW have developed a really cool tool to get the word out about REPRIEVE in their area. Attached is a template we have modified for your site to use.*

Thank you University of Washington for sharing this!

*Please submit to your IRB as per your local IRB requirements

Does your site have a unique recruitment tool to share? We would love to showcase it in a future newsletter. Please email Katie Fitch, REPRIEVE CCC Project Manager.

Customizable Recruitment Materials are Now Available

Did you know the REPRIEVE Clinical Coordinating Center has developed a portal for each site to login, customize, and order

recruitment materials?* The best part about this is you can order a "Sample Kit" of brochures, posters, postcards, infographics, and flyers, 100 of each, all paid for by REPRIEVE! Click here to access the portal, then enter your site ID and the password "reprieve" to login. Attached are instructions that are helpful when ordering.

If you try to login and don't have access, please email Katie Fitch, REPRIEVE CCC Project Manager.



These materials are also available on the REPRIEVE Website, on our new **Spread the Word** page.

*These materials have been approved by the IRB for the REPRIEVE CCC, however please submit as per your local IRB requirements.

Sites Unite at Local AIDS Walk/Run Event!

AIDS # MALK

Many AIDS Service Organizations hold their annual AIDS Walk/Run during the spring and summer.

This is an excellent opportunity to get the word out about REPRIEVE. The NIAID Communications Team has helped us to compile a list of AIDS Walk/Runs near REPRIEVE sites. Please see the attached list for more details.

If your site is in a city where there are multiple sites like New York, Los Angeles, or Boston, please contact the REPRIEVE Clinical Coordinating Center so we can connect you with other REPRIEVE sites in your area that might want to participate.









TRAINING OPPORTUNITIES

Training Opportunities

Next ECG Training Date

Wednesday, 30 Mar 2016, 1:00 PM ET*

ECG training will include information on the ECG machine, supplies, performance, and transmission of data. At least one person from your site must attend one training to meet protocol activation requirements. If you have participated already but would like a refresher, please feel free to attend.

You do not have to have an ECG machine onsite to participate in this training. We encourage you to have all staff that will work with the Quintiles ECG machine attend the training (eg, PI, study coordinator, CRA, backup personnel).

Calendar invites with call details have been sent out. Please email Katie Fitch, kfitch@partners.org, if you did not receive the invite.

*This is the last ECG training scheduled at this time, therefore please make every effort to attend if your site has not completed this yet.

Sites New to REPRIEVE: Please Save the Date

Tuesday, 26 April 2016, 1:00 PM ET

A site startup training call/protocol training for brand new sites (in the US and Canada) and any site that needs a refresher will be held on Tuesday, April 26th. Please note that participation in this training is required for site activation. The announcement will be sent shortly.

REPRIEVE (A5332): Are you up to date?

For A5332 please use

Protocol:

Version 3.0 dated 01/28/2016

MOPS:

Version 3.0 dated 02/10/2016

A5332 LPC for ACTG Sites:

Version 3.0 dated 02/23/2016

A5332 LPC for Non-ACTG Sites: Version 3.0 dated 02/25/2016

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 02/22/2015

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.

