



## Randomized Trial to Prevent Vascular Events in HIV

# Site Newsletter 03/09/2015

Welcome to the REPRIEVE trial! As we approach opening REPRIEVE for enrollment, we would like to thank you all for your efforts to move toward this important milestone. REPRIEVE will be among the largest randomized clinical trials conducted in HIV and the first study to investigate a large-scale cardiovascular disease prevention strategy in this population. While REPRIEVE is complex due to the large number of participants and clinical sites, we have designed the study to be simple and straightforward. The study will be a success due to the participation of ACTG and non-ACTG sites as well as the collaboration of our funders and supporters, the NHLBI, NIAID, and Kowa Pharmaceuticals America, Inc. We look forward to working with you over the duration of the trial and together we will make REPRIEVE a success!

*Sincerely,*

*Dr. Steven Grinspoon and Dr. Pamela Douglas, Co-Principal Investigators of the REPRIEVE Clinical Coordinating Center*

*Dr. Udo Hoffmann and Dr. Heather Ribaldo, Co-Principal Investigators of the REPRIEVE Data Coordinating Center*



### Did you know...

- The Quintiles contract for REPRIEVE is not yet final, although we expect that to happen soon. Until it is approved, we are waiving the requirement for ECG training on the Site Activation checklist. The REPRIEVE (A5332) MOPS will be updated soon to provide further information about REPRIEVE ECGs.
- Non-ACTG sites/labs will be using a new web based LDMS

program developed and provided by Frontier Science (FSTRF). Training dates will be announced soon, however, sites/labs must be registered for LDMS, meaning they must have a lab ID assigned, prior to attending training. Frontier Science will be contacting sites/labs directly regarding LDMS implementation & training. Questions concerning the implementation of LDMS at your site/lab should be directed to [ldmsinfo@fstrf.org](mailto:ldmsinfo@fstrf.org).

- A new Certificate of Confidentiality Agreement (CoCA), will be uploaded onto the PSWP shortly, please inquire with your local IRB regarding submitting the new CoCA. For sites using Chesapeake IRB, the CoCA will be submitted by the CCC.
- The Package Insert for Pitavastatin is located on the DAIDS RSC website: <http://rsc.tech-res.com/safetyandpharmacovigilance/PIList.aspx>

## We would like to introduce...



**Anthony Holguin and Ken Wood, REPRIEVE Data Managers** at Frontier Science (FSTRF) in Buffalo, NY. Data managers answer questions about case report forms, OpenClinica, eligibility checklists, data collection forms

schedules, transfers, delinquencies, and other data management issues.

## The DAIDS/OCSO Program Officer (PO) or Point of Contact (POC).

The OCSO PO provides oversight of site activities and facilitates the DAIDS/OCSO Site Approval process. Site Approval is one of 2 major prerequisites for active screening and enrollment on the REPRIEVE study. Using the Site Approval Checklist as the roadmap, OCSO POs help sites through all the requirements for site approval to ensure that sites meet all DAIDS and regulatory standards for conducting clinical research. OCSO POs also help facilitate training on some of the systems that will be used during the conduct of the protocol. Upon completion of the site approval process, the OCSO PO will issue a written site approval notification. After enrollment begins, sites will continue to work with their OCSO POs to address Site Monitoring findings. The OCSO PO is also a resource for issues



that may arise at the site during the course of implementing the protocol.

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### **When can we start enrolling participants into REPRIEVE?**

We anticipate opening the REPRIEVE trial to enrollment in the next few weeks – watch for an email message announcing this important event! After the trial opens to enrollment, each site's enrollment screens will be opened after 1) the site obtains approval by DAIDS and 2) the site successfully completes the Site Protocol Activation Checklist.

### **Is there a calendar with REPRIEVE training available online?**

All training for REPRIEVE is listed on the REPRIEVE website's calendar of events page at <http://reprivetrial.org/events/>

### **Who can answer my questions?**

Please send all questions to [reprivetrial@fstrf.org](mailto:reprivetrial@fstrf.org), which is a group of team members with the expertise to address various issues, such as budget, substudy, eligibility, and coenrollment. Other important resource include the Study Management section of the REPRIEVE protocol and the MOPS, both of these documents are located on the PSWP.

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## **Site Updates**

**Welcome to the following sites that have completed the DAIDS approval process!**

- CRS 1008 Georgetown University
- CRS 104 Boston Medical Center
- CRS 501 Stanford
- CRS 31475 Virginia Commonwealth University
- CRS 31476 Cooper University Hospital
- CRS 1601 Duke University

**Congratulations to the first 3 sites that have successfully completed protocol registration!**

- CRS 2101 Washington University Therapeutics (WT) CRS
- CRS 31673 Orlando Immunology Center CRS
- CRS 1008 Georgetown University CRS (GU CRS)

## Substudy Updates

**Clarifications:** Regarding phosphodiesterase inhibitors, sites should follow the substudy consent form and instruct participants to refrain from their use 5 days prior to the CCTA. Look out for this clarification in the upcoming version of the MOPS!

**7** sites have successfully transferred the required test data transfers! This is the last step before a site can be activated for the CT portion of the substudy. Please work with your imaging team to complete this important step!

The MGH CT Core Team is available to help with this process:

[MGHReprive@partners.org](mailto:MGHReprive@partners.org)

### Meet the MGH CT Core Lab Team!

**Principal Investigator:**

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**Co-chair:**

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**Project Lead:**

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For future reference, all newsletters will be available on the [REPRIEVE Website](#)

We welcome suggestions and ideas for upcoming newsletters. Please submit any comments or suggestions to [kfitch@partners.org](mailto:kfitch@partners.org).

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