April 21, 2014

Dear ACTSI Investigator,

The ACTSI Safety Advisory Subcommittee (SAS) of the Atlanta Clinical and Translational Science Institute (ACTSI) is charged with ensuring the safety of subjects participating in research studies supported by the ACTSI, in collaboration with the ACTSI partner institution's IRBs and research compliance programs. This activity is an outgrowth of the Clinical and Translational Science Awards (CTSA) Research Subject Advocate (RSA) program. The two ACTSI RSAs are Carlton Dampier MD, Assistant Dean for Clinical Research, Emory School of Medicine, and Winifred Smith, MPH, Morehouse School of Medicine.

The ACTSI Safety Advisory Subcommittee will focus its specific safety oversight on ACTSI-funded/supported studies conducted by new investigators, and ACTSI-funded/supported clinical trials (i.e. those with treatment and comparison groups) who are not already reporting subject safety information to a local or sponsor-supported Medical Monitor, Data Safety Monitoring Committee, or Data Safety Monitoring Board. Currently funded ACTSI investigators with studies in these categories will be contacted by the Subcommittee to set up a review schedule, and new studies for review will be identified during the ACTSI scientific review process. This safety reporting to the SAS will be tailored to the individual study, and will supplement but not replace required safety reporting by the investigator to the study's institutional IRB.

The SAS is also available to the ACTSI research community (investigators, regulatory, compliance staff, and sponsors) for consultation concerning initial preparation of data safety monitoring plans, to assist with investigator review of any specific study adverse event, or review of any new study information that might change study risks or benefits. The committee can assist investigators and research staff with any questions or concerns regarding specific consent or study conduct issues.

In collaboration with the research compliance activities of the various ACTSI institutions, the SAS will also help oversee any internal auditing of ACTSI research studies to help ensure subject safety and research staff compliance with federal, state and local research regulations as well as institutional policies.

The SAS will also identify areas of concern for setting priorities for research safety education, infrastructure or policy changes within the ACTSI. It will make recommendations to the appropriate institutional leadership concerning

research safety and ethical concerns based on observations or reports related to individual projects or system–wide areas.

Other Activities of the ACTSI SAS:

The SAS is currently working with the Emory IT group to develop a new web-based SAS Safety Tracking and Reporting System, which will replace and expand the old Adverse Event database previously used by the General Clinical Research Center. All ACTSI investigations reporting to the SAS will be required to utilize this SAS reporting system when it becomes available. The system will also be made available to all Emory investigators and affiliates of the ACTSI who desire to take advantage of this newly developed support system.

Information generated through the SAS Safety Tracking system will facilitate investigators ability to analyze adverse events and other subject safety information. The SAS Reporting system will generate safety reports that will be customizable and appropriate for submission to the SAS, the various ACTSI institutional IRBs, and clinicaltrial.gov. However, reporting to these agencies will still be the responsibility of the investigators as electronic links to these external systems may not be possible. We anticipate this new application will be ready in approximately six months. ACTSI investigators should continue to use existing resources for recording and analyzing study safety data until the new system is available.

Please contact me if you have questions

Sincerely,

Carlton D. Dampier, MD
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Chair, ACTSI Safety Advisory Subcommittee
ACTSI Program Director, Ethics, Regulatory Knowledge and Support
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cc: David S. Stephens, MD; Elizabeth Ofili, MD

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CTSA Clinical & Translational Science Awards

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