



CIRB Operations Office  
c/o: The EMMES Corporation  
401 N. Washington St. Suite 700  
Rockville, MD 20850  
Tel: 1-888-657-3711 (Toll Free)  
Fax: 301-560-6538  
E-mail: [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com)

### **Process Change Involving Adverse Event Review and Posting to CIRB Website**

The review and CIRB website posting processes for SAE reports related to pediatric or adult trials has been revised. SAEs will now be posted as soon as they are received from the reporting Cooperative Group and prior to review by the CIRB. The pre-review SAEs will have a Recommended Board Action Code of 99 – which means ‘Review Pending’.

This change was made in response to requests by local sites to provide additional documentation for use at time of audit to confirm CIRB receipt of SAEs reported by a Cooperative Group. The additional documentation should confirm for auditors that the SAE has been submitted to the CIRB within the audit requirement of 90 days. Please note: the audit requirement is for submission to the CIRB within 90 days, not CIRB review within 90 days.

If you have any questions or comments about this change, please contact the CIRB Helpdesk at [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com) or by telephone at 1-888-657-3711.

Sincerely,

NCI CIRB Operations Office  
[ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com)  
1-888-657-3711 (toll-free)