



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

30 January 2008

Subject: DAERS System for Submission of EAE Information

Dear Site Leader,

Thank you for volunteering to participate in the DAIDS Adverse Experience Reporting System (DAERS) initial rollout!

As part of the rollout, your site will be using the DAERS system instead of sending the paper EAE Form to submit reports of new events that must be reported to DAIDS on an expedited basis as specified by the DAIDS EAE Reporting Manual. This memorandum is to notify you that your site will be in compliance with DAIDS requirements for expedited adverse event reporting when using the DAERS system for submission of EAE information. Serious Adverse Events (SAEs) that are reported as specified by one of the DAIDS SAE Reporting Manuals will continue to be reported to RCC using the associated paper form.

Please file this memorandum in your regulatory files. You are not required to submit this memorandum to your IRB for review and approval. However, if you would like to submit it to your IRB, please feel free to do so.

Please share this information with appropriate clinical research staff. If you have any questions on the DAIDS EAE manual or EAE reporting requirements, contact RCC at:

- Phone: 1 (800) 537-9979 (U.S. only) or 1 (301) 897-1709
- E-mail: RCCSafetyOffice@tech-res.com
- Fax: 1 (800) 275-7619 (U.S. only) or 1 (301) 897-1710
- Mail: DAIDS Safety Office, 6500 Rock Spring Drive, Suite 650, Bethesda, MD 20817

For questions about the DAERS system, contact DAIDS-ES Support at:

- Phone: 1 (866) 337-1605 (US Only) or 1 (240) 499-2239
- Fax: 1 (866) 337-1606 (US Only) or 1 (301) 948-2242
- E-mail: DAIDS-ESSupport@niaid.nih.gov (You may also use this e-mail address to submit comments or suggestions about DAERS.)

Thank you for your cooperation,

A handwritten signature in cursive script that reads "Richard Hafner".

Richard Hafner, MD
Director, Office for Policy for Clinical Research Operations
National Institute of Allergy and Infectious Diseases