



National Institutes of Health  
National Institute of Allergy  
And Infectious Diseases  
Bethesda, MD 20892-6603  
6700B Rockledge Drive  
Phone: (301) 451-3696  
Fax: (301) 402-1506  
E-mail: [MP28S@NIH.GOV](mailto:MP28S@NIH.GOV)

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Subject: Retention of Investigational Brochures

It has come to the attention of the Division of AIDS (DAIDS) that there is an error in the table, "Essential Documents Recordkeeping Requirements," which is an appendix to the DAIDS Policy, "Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials." The Table incorrectly states that only the most recent version of the Investigator's Brochure (IB) should be retained by clinical sites, and that all older versions of the IB should be destroyed.

Effective immediately, all copies of the IB must be retained as essential documents in accordance with the ICH Guidance E-6, Federal Regulations, and the DAIDS Policy on Record Retention. The information contained in prior IBs is used by site monitors during their assessment of site performance. Please be aware that even obsolete IBs may contain proprietary information and should be stored in the same secure manner as the current IB.

DAIDS is in the process of updating this policy to correct the error. If you have already discarded previous versions of study IBs, there is no need to replace them and you should not request copies from DAIDS.

Please direct any questions you may have about this change to:  
[NIAIDOPCROPOLICYGROUP@mail.nih.gov](mailto:NIAIDOPCROPOLICYGROUP@mail.nih.gov)

Judith Brooks  
Chief, Participant Protections, Evaluation, and Policy Branch  
DAIDS/NIAID/NIH  
6700B Rockledge Dr. Room 2164  
Bethesda, MD 20892-7624  
301-594-6626  
[brooksju@niaid.nih.gov](mailto:brooksju@niaid.nih.gov)