



Date: September 22, 2011
To: Investigators, Site Staff and Operations Offices
From: Mary Anne Luzar, Ph.D., Chief, Regulatory Affairs Branch, Division of AIDS
Subject: Proper handling of confidential documents

Dear Investigators, Site Staff and Operations Offices,

The Division of AIDS, as the sponsor of many clinical protocols conducted under Investigational New Drug (IND) applications, is issuing this message to remind all investigators, site staff and networks about the importance of proper handling of confidential documents such as the investigator's brochure (IB).

The IB is a proprietary document that contains confidential information regarding study products. The IB may only be disclosed to those individuals directly involved in the conduct of the study. This includes site investigators, nurses, pharmacists, IRBS/ECs and, for certain trials, contractors and/or consultants for whom it is necessary to disclose the IB for the purpose of conducting the trial. Any person who is given access to the IB by the DAIDS site or operations center should be informed of the requirement to maintain its confidentiality. In addition, sites and operations centers should protect confidentiality by storing the IB in a secure location. The requirement to maintain the confidentiality of the IB applies regardless of the format used to send it to the site (e.g., as a written document, CD-ROM, or other electronic transmission). **While we recognize the value of the network websites to manage clinical trial information, the Division of AIDS has determined that IBs should not be posted on network websites.**

The Division of AIDS would also like to take this opportunity to remind you of the importance of proper handling of other sensitive documents, such as protocols under development, IND safety reports, and Data and Safety Monitoring Board reports. Please take time to review your network and site procedures regarding these documents to ensure that confidentiality is not breached during the development and conduct of DAIDS clinical trials.

If you have any questions about this message, please do not hesitate to contact Dr. Scott Proestel, Acting Director, Office for Policy in Clinical Research Operations (OPCRO), Division of AIDS at (301) 402-6709 or Dr. Mary Anne Luzar at (301) 435-3737.

Sincerely,

Mary Anne Luzar, Ph.D.
Chief, Regulatory Affairs Branch
Division of AIDS, NIAID, NIH

Scott Proestel, M.D.
Acting Director, OPCRO
Division of AIDS, NIAID, NIH