

MTN Financial Disclosure and Conflict of Interest Policy
(Excerpted from MTN 2015 Manual of Operational Procedures – Section 5.5)

To minimize the potential for bias in the design, conduct, reporting and analysis of research funded by any of the Awarding Components of the Public Health Service, U.S. Federal regulation, Title 42 CFR 50, states that each institution receiving or applying for such funding must obtain sufficient, accurate financial information that will allow the institution to identify and manage financial conflicts of interest (FCOI) and report them to NIH through the eRA Commons FCOI Module. The requirements of Title 42 CFR 50 (http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.4.23#se42.1.50_1604) apply to clinical and non-clinical research and focus broadly on senior/key personnel who are responsible for the design, conduct, analysis and reporting of the funded research. Failure to comply with these regulations, depending on the severity and duration of noncompliance, could result in suspension or termination of funding by the NIH.

Similarly, the FDA requires clinical investigators who are conducting research under an IND or Investigational Device Exemption (IDE) to disclose certain financial information to study sponsors. U.S. Federal regulations, Titles 21 CFR 312.53 and 21 CFR 812.43, state that before permitting an investigator to participate in a clinical study, the IND/IDE sponsor must obtain sufficient, accurate financial information, as required by Title 21 CFR 54, that will allow a marketing applicant to submit complete and accurate certification or financial disclosure statements to the FDA as part of the application (Titles 21 CFR 314.50 and 21 CFR 814.20). The requirements of Title 21 CFR 54 (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=54>) apply only to clinical research conducted under an IND/IDE and focus on the financial interests of the clinical investigators participating in the investigation at the various CTUs/CRSs. When the FDA reviews the data from a clinical study that supports an application for marketing approval, it may consider a study inadequate if appropriate steps have not been taken to minimize the potential for bias and ensure the objectivity of the research.

DAIDS, which is the financial sponsor and in some instances the regulatory sponsor for the research facilitated and managed by the MTN, has delegated to MTN the responsibility for collecting the financial disclosure information required by Federal regulations Titles 21 CFR 54 and 42 CFR 50. Two guidances are provided for the HIV/AIDS Networks to follow:

- Title 42 CFR 50 compliance: NIH HIV/AIDS Clinical Trials Networks Financial Disclosure and Conflict of Interest Guidelines Standard Operating Procedure (SOP) developed by the Office of HIV/AIDS Network Coordination (HANC), and which may be found on the MTN website (<http://www.mtnstopshiv.org/node/1639>).
- Title 21 CFR 54 compliance: DAIDS provided guidance, effective July 1, 2014, which can be found on the protocol registration web page: <http://rsc.tech-res.com/protocolregistration>.

Some investigators may be required to disclose significant financial interests according to both procedures, depending on their study and Network responsibilities.

Financial disclosures in compliance with Title 42 CFR 50 will be completed and maintained in the on-line HANC Financial Disclosure System (<https://fd.hanc.info>). To guide all investigators needing to complete their disclosures relative to Title 42 CFR 50, a list of the products and manufacturers that MTN has or is currently working with on microbicide research is located on the website (<http://www.mtnstopshiv.org/node/1639>) and updated, as needed.

Financial disclosures completed in compliance with Title 21 CFR 54 will be documented on a study-specific paper form that must be kept on file with other Essential Documents for each study (see section 12.1 of the MOP for further information on Essential Documents). The DAIDS Clinical Site Monitoring Group will routinely review site Essential Documents files to ensure that required documentation is maintained. The current MTN Financial Disclosure Policy and blank study-specific forms are available on the MTN website.

March 2016 addendum: Blank study-specific forms, along with FD training materials (PowerPoint slides), can be found with the “Study Implementation Materials” posted in each protocol folder on the MTN website.