Process for collection of financial disclosure by clinical investigators per 21 CFR 54.4

Background:

U.S. regulations, 21 CFR 321.53 and 21 CFR 812.43, state that before an investigator is allowed to begin an investigation, the Investigational New Drug (IND)/Investigational Device Exemption (IDE) sponsor shall obtain sufficient, accurate financial information that will allow an applicant of a marketing application to submit complete and accurate certification or disclosure statements as required under 21 CFR 54. Per the FDA Guidance regarding Financial Disclosure by Clinical Investigators, the IND/IDE holder, even if not the applicant filing the marketing application, is required to collect financial information before permitting an investigator to participate in a clinical study. Each clinical investigator who is participating in a study that could be used to support a marketing application must submit either a completed financial disclosure statement attesting to the absence of financial interests/arrangement or disclosing any financial interests/arrangements and steps taken to minimize the potential for bias. Based on the requirements outlined in the Code of Federal Regulations for IND sponsors, DAIDS has developed a process to ensure that financial disclosure forms/statements are completed by all investigators listed on all Form FDA 1572s for any DAIDS sponsored and/or supported study where DAIDS is the IND holder. This process does not pertain to non-IND/IDE studies.

Procedures:

1. Each clinical trials network (i.e., ACTG, IMPAACT, HPTN, HVTN, MTN) will develop a generic financial disclosure form/statement for all network studies that are conducted under an IND. Each network must have their financial disclosure form/statement approved by DAIDS prior to implementation. DAIDS will develop a financial disclosure form/statement for all non-network studies that are conducted under a DAIDS held IND. This form will be available on the Regulatory Support Center (RSC) website.

2. At the time a clinical research site (CRS) completes a Form FDA 1572 for a study being conducted under an IND/IDE, all investigators listed on the Form FDA 1572, including all sub-investigators, must complete the DAIDS approved network financial disclosure form/statement or the drug company-specific financial disclosure form/statement.

3. Any time a CRS adds or changes an Investigator of Record (IoR) or sub-investigator listed on their Form FDA 1572 for any study, the new investigator must complete the DAIDS approved network financial disclosure form/statement or the drug company-specific financial disclosure form/statement

4. Any time there is a change in an investigator's financial interest during the course of a clinical trial, the investigator should complete an updated DAIDS approved network financial disclosure form/statement or the drug company-specific financial disclosure form/statement.

5. At a minimum, the DAIDS approved network financial disclosure form/statement or the drug company-specific financial disclosure form/statement must be completed prior to the initiation of and at the completion of the clinical trial at a CRS. If the collection of financial disclosure forms/statements is required at additional times (i.e., when a cohort closes, during the course of a trial, etc.), the IND sponsor will inform the study team of this requirement.

6. All original, completed and signed DAIDS approved network financial disclosure forms/statements or the drug company-specific financial disclosure forms/statements must be filed and retained in a CRS's regulatory binder along with the original and/or updated, signed Form FDA 1572 for that study. These forms need not be submitted to DAIDS or the Network Operations Centers unless requested.

7. Monitors will verify during a review of a CRS's regulatory binder that every investigator listed on all Form FDA 1572s has accurately completed and signed either the DAIDS approved network financial disclosure form/statement or the drug company-specific financial disclosure form/statement for that clinical trial. The effective date for this process is July 1, 2014.

8. If an applicant of a marketing application requests financial disclosure forms/statements from DAIDS, the DAIDS Regulatory Affairs Branch (RAB) will work with the appropriate Network Operations Center and/or DAIDS Network/Grant Program Officer to collect the required forms/statements from the CRSs. In the event financial disclosure forms/statements are collected, CRSs will be required to provide the original signed documents and to keep a copy of all forms/statements in the regulatory binders at the site.

9. If an applicant of a marketing application requires that CRSs complete a company specific-financial disclosure form/statement, the appropriate Network Operations Center and/or DAIDS Network/Grant Program Officer will distribute and collect the required forms/statements from the CRSs participating in the clinical research protocol. In the case where a company specific-financial disclosure form/statement is provided for a study, CRSs do not need to complete the standard DAIDS approved network financial disclosure form/statement.

Document History

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DAIDS Approvals

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