

Policy
**Collection of Financial Disclosure by Clinical Investigators Conducting DAIDS-Sponsored
IND Trials**

Effective Date: 03/23/21

Document No.: **POL-A15-OPC-016.00**

1.0 PURPOSE

- 1.1 The purpose of this policy is to describe the DAIDS' process to ensure that financial disclosure forms/statements are completed by all investigators listed on all Form FDA 1572s in accordance with the FDA regulation 21 CFR, Code of Federal Regulations Title 21 and DAIDS Policies and Procedures for any DAIDS sponsored and/or supported study where DAIDS is the IND holder.

2.0 SCOPE

- 2.1 This scope applies to all investigators, sub-investigators (individuals listed on Section 6 of Form FDA 1572) participating in any DAIDS sponsored and/or supported study where DAIDS is the IND holder.

3.0 DEFINITIONS

For additional definitions, see [DAIDS glossary](#).

4.0 RESPONSIBILITIES

- 4.1 Each clinical investigator /sub-Investigator must submit either a completed financial disclosure statement attesting to the absence of financial interests/arrangement or disclose any financial interests/arrangements and steps taken to minimize the potential for bias.
- 4.2 Each Clinical Trials Network (e.g. ACTG, IMPAACT, others) is responsible for developing a generic financial disclosure form/statement for all network studies that are conducted under an IND/IDE.
- 4.3 DAIDS approval of the generic financial disclosure form/statement is required before implementation. DAIDS approval is also required for changes/revisions to existing financial disclosure forms/statements.
- 4.4 All DAIDS developed and approved financial disclosure forms are available on the Regulatory Support Center (RSC) website (see section 7, Appendices).
- 4.5 The determination regarding which financial disclosure form will be used for a clinical trial (DAIDS approved vs drug-company specific) must occur prior to the initiation of the study at any Clinical Research Site (CRS). The DAIDS

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Sponsor's Authorized Representative (SAR), in consultation with the drug company and protocol team, will make the final decision regarding which financial disclosure form will be used.

- 4.6 During a review of a CRS's regulatory binder, monitors will verify 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.
- 4.7 If an applicant of a marketing application requests financial disclosure forms/statements from DAIDS, the SAR in 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 keep a copy of all forms/statements in the regulatory binders at the site.

5.0 POLICY

- 5.1 This policy has been created in accordance with U.S. regulations, 21 CFR 321.53 and 21 CFR 812.43. Per U.S. regulations, 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. 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.
- 5.2 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 (individuals listed on Section 6 of the Form FDA 1572), must complete the DAIDS approved network financial disclosure form/statement or the drug company-specific financial disclosure form/statement.

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- 5.3 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.
- 5.4 Any time there is a change in an investigator's financial interest during a clinical trial, the investigator must complete an updated DAIDS approved network financial disclosure form/statement or the drug company-specific financial disclosure form/statement.
- 5.5 The DAIDS approved network financial disclosure form/statement or a drug company-specific financial disclosure form/statement must be completed prior to the initiation 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 a trial, etc.), the IND/IDE sponsor will inform the study team of this requirement.
- 5.6 Applicant of a marketing application requiring CRSs to complete a company specific-financial disclosure form/statement, must provide this document to the IND/IDE sponsor prior to study initiation. The appropriate Network Operations Center and/or DAIDS Network/Grant Program Officer is responsible for distribution and collection of completed forms/statements from the CRSs, If CRSs complete the company specific forms, they do not need to complete the standard DAIDS approved network financial disclosure form/statement.
- 5.7 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 clinical research site's regulatory binder along with the original and/or updated, signed Form FDA 1572 for that study in compliance with the FDA regulations and guidelines. DAIDS, through the Network Operations Center, will collect the completed forms.

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6.0 REFERENCES

- 6.1 DAIDS Protocol Registration Manual
- 6.2 21 CFR 312.53(a), Code of Federal Regulations Title 21
- 6.3 21 CFR 312.3(b), Code of Federal Regulations Title 21
- 6.4 21 CFR 812.43, Code of Federal Regulations Title 21
- 6.5 21 CFR 54.2(d), Code of Federal Regulations Title 21

7.0 APPENDICIES

- 7.1 [DAIDS approved financial disclosure forms](#)

8.0 REVISION HISTORY

- 8.1 POL-A15-OPC-016.00 is the original version of this policy. The policy had been in effect since July 2014 (updated in February 2017, Version 2.0) in the form of a guidance document.