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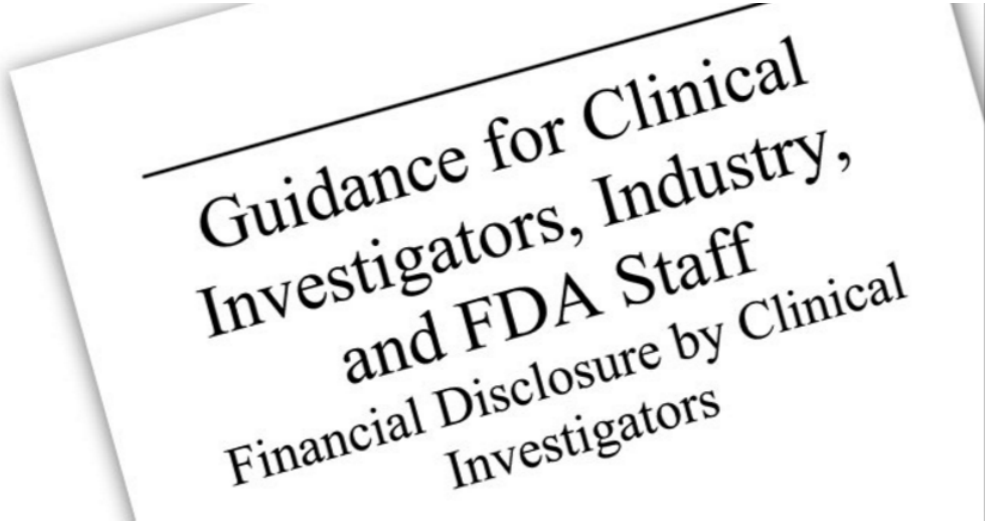
Requirement for Investigators and Sub-Investigators to File Financial Disclosure Forms



Investigator of Record – Definition

"The individual at the CRS responsible for ensuring that a clinical trial is conducted in accordance with the protocol, applicable U.S. federal regulations, in-country regulations and any provisions imposed by the reviewing IRB/EC/other regulatory entity. This person is the signatory for the Form FDA 1572 for studies conducted under an IND or the DAIDS Investigator of Record Form for non-IND studies." (from DAIDS Protocol Registration Manual, p.8)

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Reporting Financial Interests

- Goal: Preserve objectivity of clinical research and the protection of human subjects
- Regulations: 21 CFR 54 and 21 CFR 312.53
- Requirement: Each clinical investigator must disclose any financial interests that may be affected by the outcome of the research or attest to the absence of relevant significant financial interests

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Specific Requirement

- Per 21 CFR 54, each clinical research Investigator and Sub-Investigator (anyone listed on the FDA Form 1572 for the study) is required to disclose the aggregated financial interests of themselves, their spouse and dependent children, as they relate to the study sponsor and/or study product(s).
- Per 21 CFR 312.53, financial disclosures must be completed prior to study involvement

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When to Report: 5 Time Points

1. Prior to or on the date an Investigator or Sub-Investigator begins study activities (i.e., before final sign off by the IoR of the 1572).

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When to Report: 5 Time Points

2. Within thirty (30) days of discovering that relevant changes to their significant financial interests have occurred (during their study involvement and for one year following the end of their study involvement).

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When to Report: 5 Time Points

3. When an Investigator or Sub-Investigator is removed from the FDA Form 1572 prior to study completion

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When to Report: 5 Time Points

4. At the completion of all study-specific activities, that is, the date of the last participant follow-up visit at the study site. Investigators and Sub-Investigators listed on the *current* FDA Form 1572 must disclose.

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When to Report: 5 Time Points

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5. One year after the completion of study follow-up at each site all staff ever listed on FDA Form 1572 must complete an FD form.

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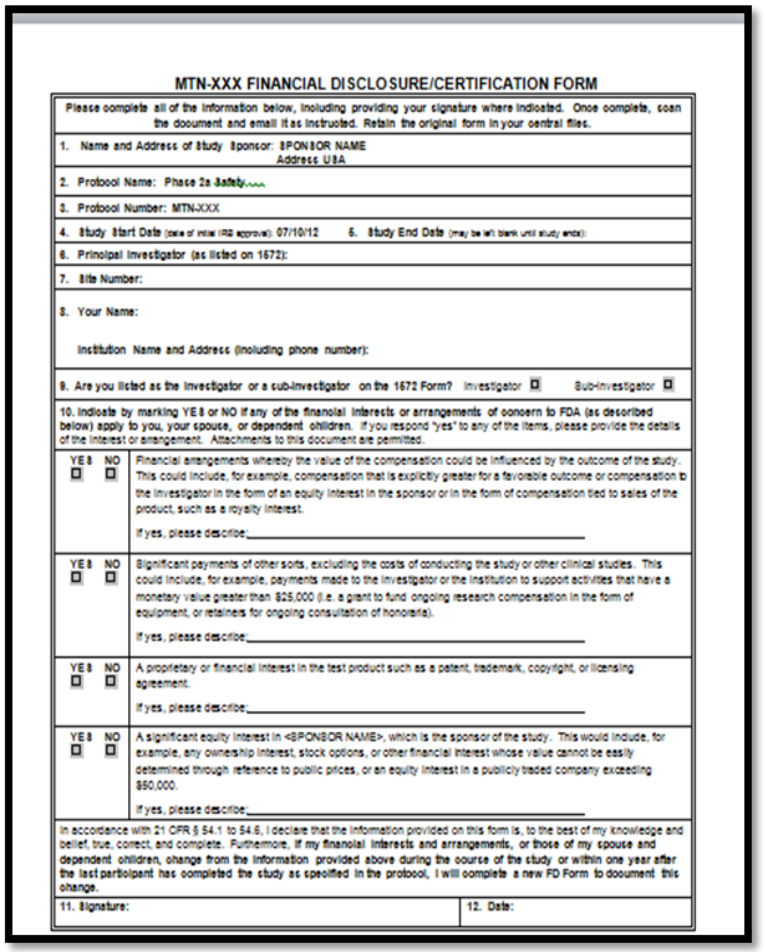
How to Report Financial Disclosure

- Blank study-specific Financial Disclosure Forms and instruction page available on MTN website (www.mtnstopshiv.org)
  - Under "Studies", click on relevant study number, then click on "Study Implementation Materials", and look under "Financial Disclosure".
  - All items can be entered electronically except signature and date
- Definition of reportable financial interests (as per 21 CFR 54) and instructions for completion of the form will be provided with the form



MTN-XXX FINANCIAL DISCLOSURE/CERTIFICATION FORM

Please complete all of the information below, including providing your signature where indicated. Once complete, scan the document and email it as instructed. Retain the original form in your central files.

1. Name and Address of Study Sponsor: SPONSOR NAME
   Address USA
2. Protocol Name: Phase 2a Safety
3. Protocol Number: MTN-XXX
4. Study Start Date (date of initial IRB approval): 07/10/12
5. Study End Date (may be left blank until study ends):
6. Principal Investigator (as listed on 1572):
7. Site Number:
8. Your Name:

   Institution Name and Address (including phone number):
9. Are you listed as the Investigator or a sub-investigator on the 1572 Form? Investigator ☐ Sub-Investigator ☐
10. Indicate by marking YES or NO if any of the financial interests or arrangements of concern to FDA (as described below) apply to you, your spouse, or dependent children. If you respond "yes" to any of the items, please provide the details of the interest or arrangement. Attachments to this document are permitted.

YES ☐ NO ☐	Financial arrangements whereby the value of the compensation could be influenced by the outcome of the study. This could include, for example, compensation that is explicitly greater for a favorable outcome or compensation to the investigator in the form of an equity interest in the sponsor or in the form of compensation tied to sales of the product, such as a royalty interest. If yes, please describe:_____
YES ☐ NO ☐	Significant payments of other sorts, excluding the costs of conducting the study or other clinical studies. This could include, for example, payments made to the investigator or the institution to support activities that have a monetary value greater than $25,000 (i.e. a grant to fund ongoing research compensation in the form of equipment, or retainers for ongoing consultation of honoraria). If yes, please describe:_____
YES ☐ NO ☐	A proprietary or financial interest in the test product such as a patent, trademark, copyright, or licensing agreement. If yes, please describe:_____
YES ☐ NO ☐	A significant equity interest in <SPONSOR NAME>, which is the sponsor of the study. This would include, for example, any ownership interest, stock options, or other financial interest whose value cannot be easily determined through reference to public prices, or an equity interest in a publicly traded company exceeding $50,000. If yes, please describe:_____

In accordance with 21 CFR § 54.1 to 54.6, I declare that the information provided on this form is, to the best of my knowledge and belief, true, correct, and complete. Furthermore, if my financial interests and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study or within one year after the last participant has completed the study as specified in the protocol, I will complete a new FD Form to document this change.

11. Signature:	12. Date:

Steps to Report Financial Disclosure

- Print the study-specific, Financial Disclosure Form.

- Complete the form in its entirety (Items #1-12).
  - Remember to check all boxes, sign and (hand) date the form.
  - 'Study start date' = date on the cover of Version 1.0 of the protocol
  - 'Study end date' = last follow-up date at site.

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Steps to Report Financial Disclosure (continued)

- Upload a scanned copy of the completed, signed and dated Financial Disclosure Forms to the DAIDS Protocol Registration System.
  - Submit ALL scanned FD forms under "Other" submission category.
  - Identify the submitted FD forms as "Financial Disclosure Forms".

  Note: *Updates to personnel listed on the FDA Form 1572 (additions and deletions) should always prompt the completion of FD form(s) and a subsequent DPRS upload. Ideally updated FDA Form 1572s and FD Forms are uploaded to DPRS simultaneously.*

- File the original, completed, signed and dated FD forms in the study binder along with the associated FDA Form 1572.

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What To Do if an FD Form was Not Obtained When Leaving?

- In the event an Investigator/Sub-Investigator leaves the site before you are able to obtain a completed FD Form, documentation of due diligence to obtain the form is required.

- MTN provides the following guidelines for documenting the due diligence (see next slide)

MTN Guidance Regarding Missed FD Forms

- In the event an FD form has not been obtained:
  - Over a minimum of two-weeks, at least three (3) attempts should be made by 2 different contact methods (e.g., phone, text, mail, email) to obtain the completed FD form. Documentation of contact attempts is required (copies of emails, phone log, etc.)
  - If, after site contact attempts the Investigator(s) or Sub-Investigator(s) is unresponsive to the request, site must complete a Note to File. The NTF should include:
    - The date Investigator(s) or Sub-Investigator(s) was removed from the 1572
    - Employment end date (as applicable)
    - Reason(s) FD form was not obtained
    - Details regarding contact attempts (dates, method, etc.)
    - Documentation of contact attempts

Resources

- 21 CFR § 54 Financial Disclosure by Clinical Investigators
- 42 CFR § 50, Subpart F *Promoting Objectivity in Research*
- 45 CFR § 94 *Responsible Prospective Contractors*
- 21 CFR § 312.53 *Investigational New Drug Application*
- 21 CFR § 812.43*Investigational Device Exemptions*
- 21 CFR § 314.50 *Applications for FDA Approval to Market a New Drug*
- 21 CFR § 814.20 *Premarket Approval Application (PMA)*
- NIH HIV/AIDS Clinical Trials Networks *Financial Disclosure Policy and Procedure*
- DAIDS Financial Disclosure Guidance Process for Collection of Financial Disclosure by Clinical Investigators per 21 CFR 54.4
- OPCRO, DAIDS, Protocol Registration Manual
- DAIDS Policy #DWD-POL-CL-03.03 Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training Requirements
- FDA Guidance Financial Disclosure by Clinical Investigators
- FDA Form 3454 Certification: Financial Interests and Arrangements of Clinical Investigators
- FDA Form 3455 Disclosure: Financial Interests and Arrangements of Clinical Investigators

Reporting Financial Disclosure via HANC Online System

- The Office of HIV/AIDS Network Coordination (HANC) online FD is a separate requirement for some network members and ensures compliance with 42 CRF 50. If your disclosure is necessary you will be notified. Details regarding HANC online FD have not been covered in this presentation, but should you have any questions regarding the HANC disclosure you can contact MTN Regulatory at mtnregulatory@mtnstopshiv.org.

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