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

MTN-028: PK Trial of Two MK-2048A IVRs of Varying Dose Strengths

# 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
- Regulation: 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: 4 Time Points Sponsor: DAIDS

1. Prior to the date an Investigator or sub-investigator is added to the FDA Form 1572 and the date they begin their involvement in the study (i.e. the start date noted on the Delegation of Authority (DoA).

(*continued on next slide*)

# When to Report: 4 Time Points Sponsor: DAIDS

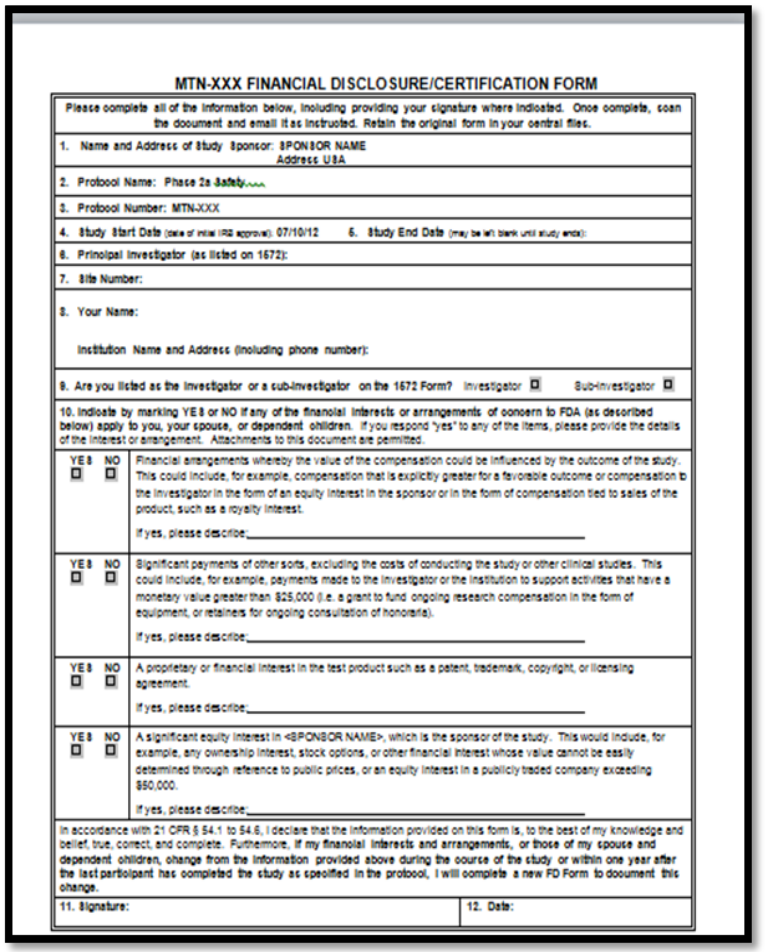
(*continued from last slide*)

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).
3. At the time an Investigator or sub-investigator is removed from the FDA Form 1572 or DoA.
4. At the completion of all study-specific activities, that is, the date of the last follow-up for the study at that site.

*At any additional times specified by the study sponsor.

# How to Report Financial Disclosure

- Blank study-specific Financial Disclosure Forms available on MTN website (www.mtnstopshiv.org )
  - Under "Studies", click on relevant study number, then click on "Study Implementation Materials", and look under "Other Tools/Templates".
  - 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 appear on the form itself.



**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.<br>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).<br>If yes, please describe:_____ |
| YES ☐ NO ☐ | A proprietary or financial interest in the test product such as a patent, trademark, copyright, or licensing agreement.<br>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.<br>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: |
|---|---|

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# Steps to Report Financial Disclosure

- Print the study-specific, Financial Disclosure Form.
- Complete the form in its entirety (items #1-10).
  - Remember to check all boxes, sign and date the form.
  - 'Study start date' = 1st IRB/EC approval for study as a whole.
  - 'Study end date' = last follow-up date for site.
- Upload a scanned copy of the completed, signed and dated form to the DAIDS Protocol Registration System.
  - Submit ALL scanned forms under "Other" submission category.
  - Identify the submitted items as Financial Disclosure forms.
- File the original, completed, signed and dated form in the study binder with the associated FDA Form 1572 or DoA.

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# What to do if unable to obtain Financial Disclosure(s)?

- Sites must contact investigator(s) and sub-investigator(s) for completion of FDs at required time points, even if staff no longer working at site
  - Must make at least two (2) attempts by different contact methods (e.g., phone, mail, email) over a two-week period
  - Must document these attempts
- If, after site contact attempts, investigator(s) or sub-investigator(s) are unresponsive, site must complete a Note to File
  - Must document reason(s) FD not obtained
    - If due to staff leaving site, must document departure date
  - Must document unsuccessful site contact attempts
  - Multiple staff may be included in one Note to File

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# Reporting Financial Disclosure via HANC Online System

- Per 42 CFR 50, only required of staff listed as Investigator of Record in FDA Form 1572 or DAIDS IoR Form
  - Also applicable to non-IND studies (e.g., MTN-015)
- Log in to fdcoi@hanc.info and submit statement
  - If already have a HANC account, annual solicitations will be sent via email
  - If do not have a HANC account or if it has been deactivated, notify MTN Regulatory for account (re)activation
    - Once account (re)activated, solicitation email will be sent

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