Review of FDA Form 1572 and Financial Disclosures

Module 8 Topic 6

Form FDA 1572

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: August 31, 2011
See OMB Statement on Reverse

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Sponsor/Applicant/Submitter or Other

Address 1	Address 2	
City	State	ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

☐ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED

CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility

Address 1	Address 2

By Signing Form 1572…

- The Investigator is agreeing that he or she will personally conduct or supervise the described investigations
- To do this, the Investigator must be intimately involved with the study. Depending on the size of the staff, the qualifications of the staff members, and the complexity of the protocol(s), this involvement may vary according to the site and protocol
- The Investigator must have a full understanding of the protocol, as well as stay informed of all participant and site issues
- The Investigator should ensure procedures are established to escalate issues quickly when needed

FDA Form 1572: Eight Investigator Commitments

- Maintain protocol adherence
- Personally conduct or supervise
- Ensure informed consent of subjects
- Report adverse experiences

FDA Form 1572: Eight Investigator Commitments (contd)

- Provide training to sub-investigators
- Ensure adequate and accurate recordkeeping
- Ensure proper IRB/IEC review and reporting
- Comply with all regulatory requirements

Who Should be Listed as a Sub-Investigator on the 1572?

- The decision to list an individual as a sub-investigator depends on his/her level of responsibility-- whether he/she is performing significant clinical, investigation-related duties
- In general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on the 1572
- It is not necessary to include someone with only an occasional or ancillary role

When to Update the 1572 (U.S. Federal Regulation)

- According to U.S. federal regulation, the FDA Form 1572 must only be updated when a new protocol has been added to the IND or a new Investigator is added to the study. However, …

When to Update the 1572

- Within 30 days of any change in information, such as:
  - The Investigator of Record changes
  - A sub-investigator is added to the study or removed
  - At the time of continuing IRB/IEC review (if required by the local IRB/IEC)
  - A laboratory is added, removed or changed
  - Site location added, removed or changed

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

Reporting Financial Interests

- Goal: preserve objectivity of clinical research and the protection of human subjects
- Regulation: 21 CFR 54
- 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

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.

Demonstrating Compliance

- Individual FD forms must be completed, signed and dated before the relevant1572 form, to which the investigator/sub-investigator is being added, is finalized, signed and dated.

- The 1572 must be finalized, signed, and dated before the Investigator or sub-investigator adds their signature and start date to the DoA.

Note: The Investigator's or sub-investigator's DoA start date must be no sooner than the signature dates on their FD and corresponding 1572

When to Report: 4 Time Points

- Before an Investigator or sub-Investigator begins study activities (i.e., before final sign off by the IoR on the 1572 or DAIDS IoR Form).

- 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).

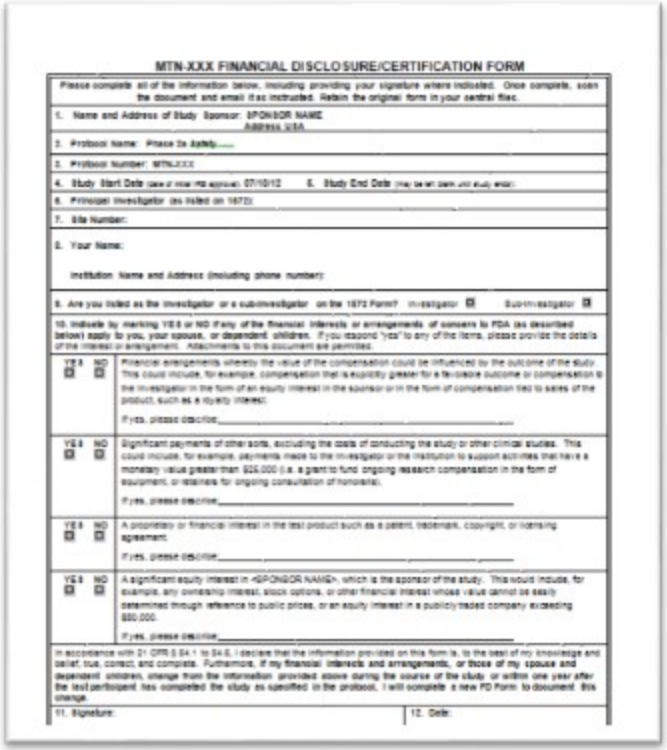
When to Report: 4 Time Points (contd)

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

- At the completion of all study-specific activities, that is, the date of the last follow-up for the study at that site.

How to Report Financial Disclosure

- A study-specific, Financial Disclosure Form can be found on the FDA website
- Definition of reportable financial interests (as per 21 CFR 54) and instructions for completion of the form will appear 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 1/2/3

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 subinvestigator on the 1572 Form? Investigator ☐ Subinvestigator ☐

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 or 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 §4.6, 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 from
- **Complete** the form – remember to sign and (hand) date it
- **File** the original, completed, signed and dated form in the study binder with the associated 1572 form

Being a Clinical Trial Investigator- Benefits

- **Professional Development** Remain at the cutting edge of specific area of therapeutic interest; meet other clinical trial investigators to exchange ideas and plan future collaboration; and gain comfort in working with drugs and processes not yet approved by the Food and Drug Administration (FDA)

- **Professional Recognition** Clinical trial investigators are often recognized as thought leaders within the professional community and may have the opportunity to become co-authors of articles for publication

Being a Clinical Trial Investigator- Benefits (contd)

- **New Revenue Stream** Clinical trials offer the opportunity for additional revenue

- **Role in the Evolution of Medicine** Clinical trial investigators can potentially bring breakthrough products to the market that could impact the health of people around the world