FDA Form 1572: 
What It Means & Who It Includes

Presented by
Judy Katzen, RN, MS
Trauma, Critical Care & Emergency General Surgery
And
Tamara Ponton, RN
Department of Anesthesiology
Objectives

- Define 1572
- Identify when it must be used
- Help identify who must be listed
“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))”
What is the FDA Form 1572?

- Form required for clinical trials involving investigational drugs and biologics.
- (Device studies require similar information – although not exactly the same – and no standard form: 21 CFR 812.100. However, both are known as the “Statement of Investigator”)
- An agreement signed by the principal investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.
- {FDA has OMB approval to use current form until 8/31/2011}.
- Most recent version is available online at www.fda.gov/opacom/morechoices/fdaforms/cder.html.
What information does the Form 1572 require? (page 1)

• Block 1: NAME AND ADDRESS OF INVESTIGATOR.

• Block 2: EDUCATION, TRAINING, AND EXPERIENCE OF INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ATTACHED.
  - CURRICULUM VITAE
  - OTHER STATEMENT OF QUALIFICATIONS

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

• Block 4: NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.

• Block 5: NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES).

• Block 6: NAMES OF THE SUBINVESTIGATORS (e.g. research fellows, residents, associates) WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).

• Block 7: NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR.
What information does the 1572 require? (page 2)

- Check off boxes for the phase of the protocol(s) being attached.
- Statements of commitments the investigator’s is promising to carry out.
- Signature of investigator
- Date
Requirements for Updating Form 1572 to Reflect New or Changed Information

If there are changes to information contained on the 1572 (e.g., an IRB address change, the addition of new subinvestigators, discontinuing the use of a clinical lab), the investigator should document the changes in the study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator.
Why this topic? Why now?

- Some sponsors, if they have not done so already, are beginning to request that study coordinators (SC) be included on the listing as an investigator.
“Block 6” of the 1572

6. NAMES OF THE SUBINVESTIGATORS (e.g. research fellows, residents, associates) WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).
Item Pfizer sent to sites participating in study A5951001 including PI @ VCU

One of several recent FDA writing classes focused on Principal Investigators (PIs) who conduct FDA-regulated studies included the following slide:

"Study coordinators...if they suspect the informed consent, determined subject eligibility, and informed study drug were not based on the data from FDA 1572 statement of investigator information...by performing these actions, study coordinators should be listed on the Form FDA 1572 as authorized.

Additional information from CBER (PDA Direct Information & Center for Drug Evaluation and Research) recommends that when completion of the 1572 form may seem difficult, instead of completing the form, a "credit card" to FDA might be submitted.

In response to a question posted on the Internet, CBER discussed how to list in Box 6 of the 1572 form for instructing the importance of the authorization of a sub-investigator (http://www.medicalburn.com). CBER defines a sub-investigator for purposes of the 1572 as follows:

"...where that in a study team meeting or the contact with data collectors, a subject assessment should be made. The Form FDA 1572, the "Protocol and Clinical Research Coordinator" (whether to list an individual depends on the level of responsibility and the involvement in the conduct of the study and in the evaluation of information obtained during the study.)

To clarify the meaning of "significant study-related duties", CBER further requires that:

- Individuals responsible for ensuring the study's conduct and quality study subjects should be listed on the 1572 form,
- Individuals who merely review and check the signature of an informed consent for the subject (e.g., that the PI has reviewed the study and signed the document) would NOT have to be listed on the 1572 form.

To ensure additional clarification during the call, the regulatory staff emphasized the FDA would provide a representative to explain information contained in recent FDA documents to the CBER response. The representative confirmed that persons who are not the study coordinator should not be listed on the 1572 form, but that the FDA would make sure the person is listed as a "clinical study coordinator". If the name of a potential investigator is included in the letter on the 1572 form and the FDA makes the investigator's name available, the FDA recommends filing the letter as a "clinical study coordinator".

While current FDA requirements have the decision regarding who to list in Box 6 of the 1572 form as the decision of individual PI's, the FDA A5951001 study team recognizes this may be important information for all investigators reviewing the study. Any future updates regarding this topic will be forwarded to research studies as they occur. Please contact FDA guidance with any comments or for reference.
From: Tamara L Ponton/FS/VCU [mailto:rstamara@vcu.edu]
Sent: Wednesday, November 11, 2009 10:36 AM
To: CDER DRUG INFO
Subject: study coordinators listed on 1572 for study drug clinical trials

Can you please direct me as to where i can get the most recent updated info regarding the 1572 form. I am doing a presentation on the 1572 form and should study coordinators be listed topic?

Can you tell me if you have any info as to the requirements of who should be listed. There is recent controversy on the topic of whether nurses and study coordinators should be listed and I can not find sufficient info on the website.

Thank you kindly,

"CDER DRUG INFO" <DRUGINFO@fda.hhs.gov>

11/12/2009 01:10 PM

To "Tamara L Ponton/FS/VCU" <rstamara@vcu.edu>
cc
Subject RE: study coordinators listed on 1572 for study drug clinical trials

Dear Tamara:
Thank you for your inquiry to the Division of Drug Information in Center for Drug Evaluation and Research at the Food and Drug Administration.

If the study nurse or coordinator is directly involved with the handling of subjects/subject data, it is generally recommended to include him/her on the 1572. It is clear we need better guidance on these 1572 questions and/or better instructions for completing the 1572 FDA regulations use the terms "investigator" and "sub-investigator":

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Email Chain From VCU Study Coordinator to FDA
Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs
Frequently Asked Questions - Statement of Investigator (Form FDA 1572)

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm.106 1, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document contact the Patricia M. Beers Block, Good Clinical Practice Program at 301 -827-3340 (Tel).

U.S. Department of Health and Human Services
Food and Drug Administration

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31. Should research nurses, other nurses, residents, fellows, office staff, or other hospital staff be listed in Block #6?

Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the data do not need to be listed individually. It is not necessary to include in this block a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (ICH E3 Section 6; http://www.fda.gov/cder/guidance/iche3.pdf).

If a number of staff residents on rotation participate in the study, a general statement regarding their planned participation may be included in Block #6.
32. Should pharmacists or research coordinators be listed in Block #6?

If a pharmacist is merely dispensing tablets and has no responsibility for preparing the test article(s) or evaluating or reporting data relative to the study activities, then it is not necessary to list the pharmacist. On the other hand, if the pharmacist will be compounding, labeling, monitoring and reporting test article compliance data, it would be appropriate to list the pharmacist in Block #6.

If a research coordinator is performing critical study functions and collecting and evaluating study data, the coordinator should be listed in Block #6. If the research coordinator is only transcribing data and maintaining study files, the coordinator does not need to be listed.
Links

• Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs

• Dana-Farber / Harvard Cancer Center Standard Operating Procedures For Clinical Research

• Investigators and Sites: Answers to Questions about Good Clinical Practice

• A Closer Look at the 1572: Interpreting the FDA's Statement of Investigator Form
Links

• Have questions about FDA 1572s?
  http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/Online+Extras/Have-questions-about-FDA-1572s/ArticleStandard/Article/detail/599035

• Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance

• FDA_Drug_Info
  http://twitter.com/fda_drug_info