Virginia Commonwealth University

VCU

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.

VCU

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.

VCU

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

VCU

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.
- Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs (http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0406-gdl.pdf)

“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

[redacted]

One of several recent FDA warning letters issued to Principal Investigators (PIs) who conduct FDA regulated studies includes the following citation:

> "Study coordinators who administered the informed consent, determined subject eligibility and dispensed study drug were not listed on the Form FDA-1572, Statement of Investigator, for protocols … By performing these significant study activities, the study coordinators should have been listed on the Form FDA 1572s as subinvestigators."

Additional guidance from CDER (FDA Division of Drug Information & Center of Drug Evaluation and Research) acknowledges that while completion of the 1572 form may seem difficult & confusing to research staff, it seems "crystal clear" to FDA personnel.

In response to a question posted on the internet, CDER discusses who to list in Box 6 of the 1572 form emphasizing the importance of the definition of a sub-investigator (http://www.nortonaudits.com/ask_the_experts). CDER defines a sub-investigator for purposes of the 1572 as follows:

> "… anyone that is a study team member or has contact with data collection or subject treatment should be on the Form FDA-1572. This would include all Clinical Research Coordinators." Whether to list an individual depends on the level of responsibility the individual has 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", CDER further explains that:

> Individuals responsible for explaining the study to subjects &/or qualifying study subjects SHOULD BE LISTED on the 1572 form.
>
> Individuals who merely ensure and observes signature of an informed consent by the subject (i.e., after the PI has explained the study and qualified the subject), he/she WOULD NOT have to be listed on the 1572 form.

To obtain additional clarification from the FDA regarding this topic, a member of the NCGS Regulatory staff telephoned the FDA and spoke with an FDA representative to confirm information contained in recent FDA warning letters and the CDER response referenced above. She asked whether persons who consent subjects in a clinical trial should be listed on the 1572 form. The FDA representative confirmed that persons who obtain consent should indeed be listed on the 1572 form and that the FDA views obtaining informed consent as a "critical study procedure" which is why "such a large portion of the regulations are devoted to the informed consent process."

While current Pfizer requirements leave the decision regarding who to list in Box 6 of the 1572 form to the discretion of individual PIs, the A5951001 study team recognizes this may be important information for all PIs to review in light of recent FDA updates on this topic and related citations in FDA warning letters pertaining to PI failure to list study coordinators on the 1572 form. Any future updates regarding this topic will be forwarded to research sites as they occur. Please see FDA guidance included with the newsletter for reference.

Email Chain From VCU Study Coordinator to FDA

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":

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

July 2008

http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0406-gdl-pdf

VCU

http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0406-gdl-pdf

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.

VCU

http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0406-gdl-pdf

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

  http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0406-gdl.pdf

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

http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/CRO/Policies_and_Procedures-SOPs/PM-411_Protocol_Specific_FDA_1572_Form.pdf

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

http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/Feature+Article/Investigators-and-Sites-Answers-to-Questions-about/ArticleStandard/Article/detail/77240

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

http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/US/A-Closer-Look-at-the-1572-Interpreting-the-FDAs-St/ArticleStandard/Article/detail/125562

VCU

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

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf

- FDA_Drug_Info

http://twitter.com/fda_drug_info

VCU