

# Recent FDA Guidance on FORM FDA-1572



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# FDA Guidance Documents

- Clarifies current FDA “thinking”
- Non-binding ... theoretically anyway!
- Minimum industry standard
- SOPs and industry practices may be stricter
- Drafts issued for comment. Some never finalized!
- Obama administration put new regulations on hold

# What is FORM FDA-1572?

- Statement of Investigator to FDA (via Sponsor)
- Criminal offense under FD&C Act (USC Title 18)
- Only studies conducted under an IND (21-CFR-312)

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.)

10. SIGNATURE OF INVESTIGATOR

**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)).

**(WARNING:** A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

# FDA-1572: Contents

- Name and Address of PI
- Education, Experience of PI
- Location of Research Site
- Location of Lab Facility
- Identify of IRB
- Names of Sub-investigators
- Protocol Title and Code
- PI Signature
- Attach CV, Protocol

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approved OMB No. 0910-0014 Expiration Date: May 31, 2009 See OMB Statement on Reverse
<b>STATEMENT OF INVESTIGATOR</b> (TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312) (See instructions on reverse side.)		<b>NOTE:</b> 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 312.63(c)).
1. NAME AND ADDRESS OF INVESTIGATOR		
2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFIES THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ATTACHED. <input type="checkbox"/> CURRICULUM VITAE <input type="checkbox"/> 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.		
4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.		
5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES).		
6. NAMES OF THE SUBINVESTIGATORS (e.g., research fellows, residents, associates) WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).		
7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR.		
FORM FDA 1572 (5-06)		PREVIOUS EDITION IS OBSOLETE. PAGE 1 OF 2
11. DATE		
<b>(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)</b> Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing/reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Central Document Room, 5901-B Annapolis Road, Beltsville, MD 20706-1206. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HF-109), 1401 Rockville Pike, Rockville, MD 20852-1448. "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Please DO NOT RETURN this application to this address.		
FORM FDA 1572 (5-06)		PREVIOUS EDITION IS OBSOLETE. PAGE 2 OF 2



# FDA-1572: Obligations

- Comply with protocol, FDA regulations, IRB requirements.
- Changes only with sponsor and IRB approval except where immediate intervention is required to protect subjects
- Ensure informed consent requirements met for all subjects including those used as controls
- Report adverse events
- Keep records and allow inspections
- Personally conduct and/or supervise, train staff.
- Read and understand protocol & investigator's brochure
- Ensure that IRB reviews and approves the study initially and on a continuing basis



# FDA-1572: FDA Guidance

- Sign only AFTER reading Protocol & IB
- Investigator does not have to be a physician/dentist
- FDA does not require a copy of the 1572
- Single-sided is fine
- No such thing as a co-investigator.
- Can have multiple PIs/site if accept full responsibility
- Sub-investigators do not have to provide CVs
- Date does not have to be written by PI, just accurate
- Form can be handwritten



# FDA-1572: Updates?

- Updates to the 1572 are not required, by FDA anyway
- CVs do not have to be signed, dated or updated

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Expiration Date: May 31, 2009.  
*See OMB Statement on Reverse.*

**FORM FDA 1572 (5/06) PREVIOUS EDITION IS OBSOLETE.**

# FDA-1572: Sub-investigators

- Directly involved in subject treatment or evaluation
- Direct or significant contribution to data
- Does not include ancillary or management staff

*List:*                      *Compounding Pharmacist, Surgeons,  
Study Coordinator, Neurologist*

*Don't List:*              *RegDoc Admin, Floor Nurse,  
Anesthesiologist, Pulmonary Tech*



# What about Non-US Sites

- Required if trial conducted under an IND!
- Central IRBs in U.S. can review non-U.S. Sites
- Alternatively, get an FDA waiver of IRB requirement
  - Independent Ethics Committee under ICH-E6
  - Attach to 1572, retain at site and in sponsor files

# www.Emissary.com



- [Recent Guidance on FDA Form-1572](#)
- [Review of FDA Inspections in 2007](#)
- [Surviving an FDA Site Inspection](#)
- [FDA versus ICH Regulations](#)
- [Historical Rise of Drug Regulation](#)
- [Time Management in Clinical Research](#)
- [The Adventures of SuperMonitor](#)

