Form FDA 1572

Statement of Investigator

2012 HA Practical Workshop on Clinical Research Compliance

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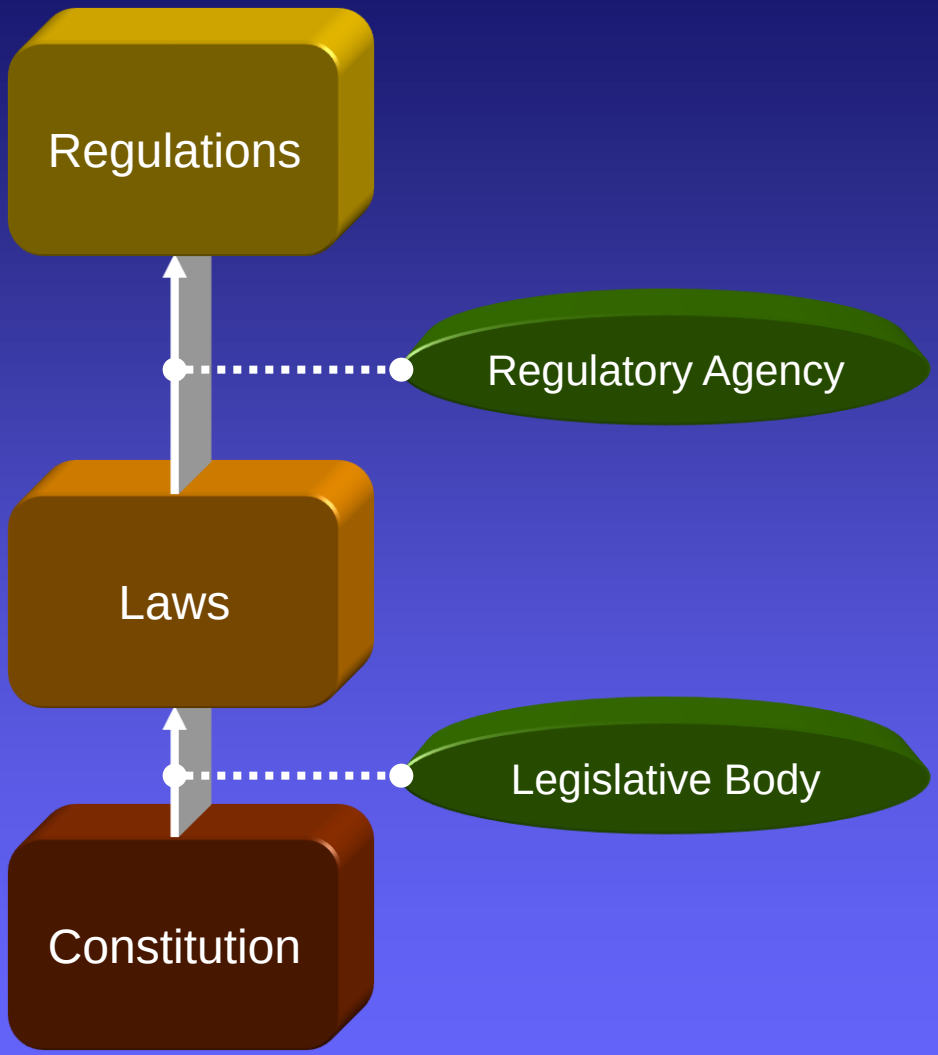
Form FDA 1572
Statement of Investigator

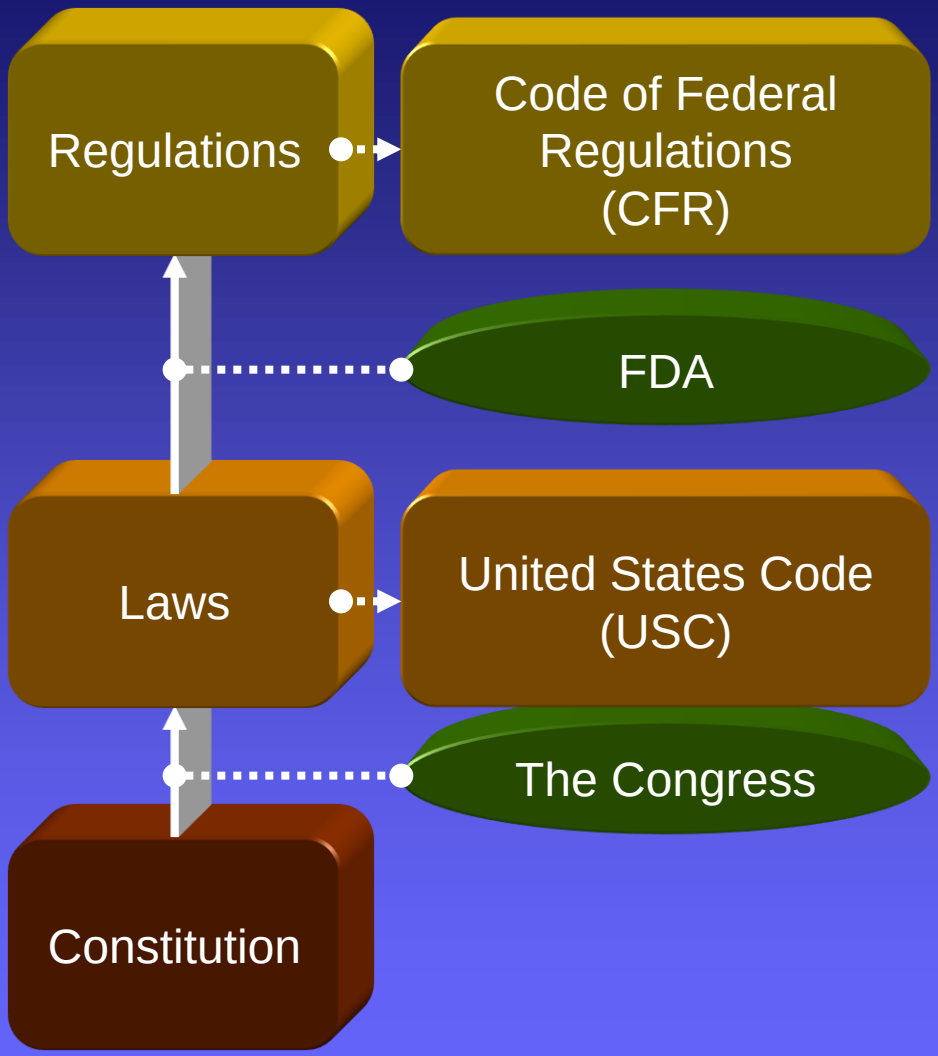
Highlights :

- Introduction to U.S. Laws and Regulations
- Highlights of Form FDA 1572

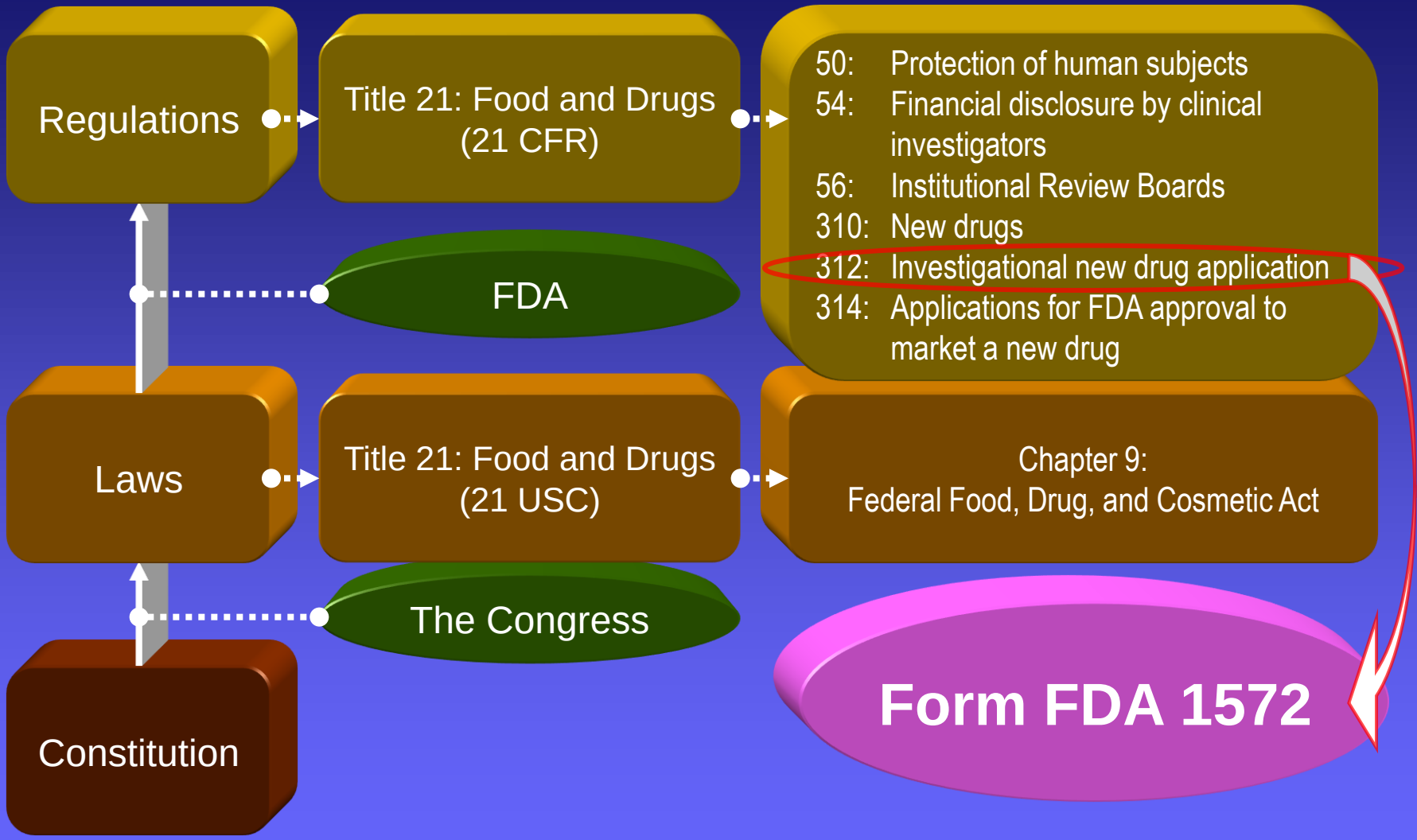
Laws and Regulations



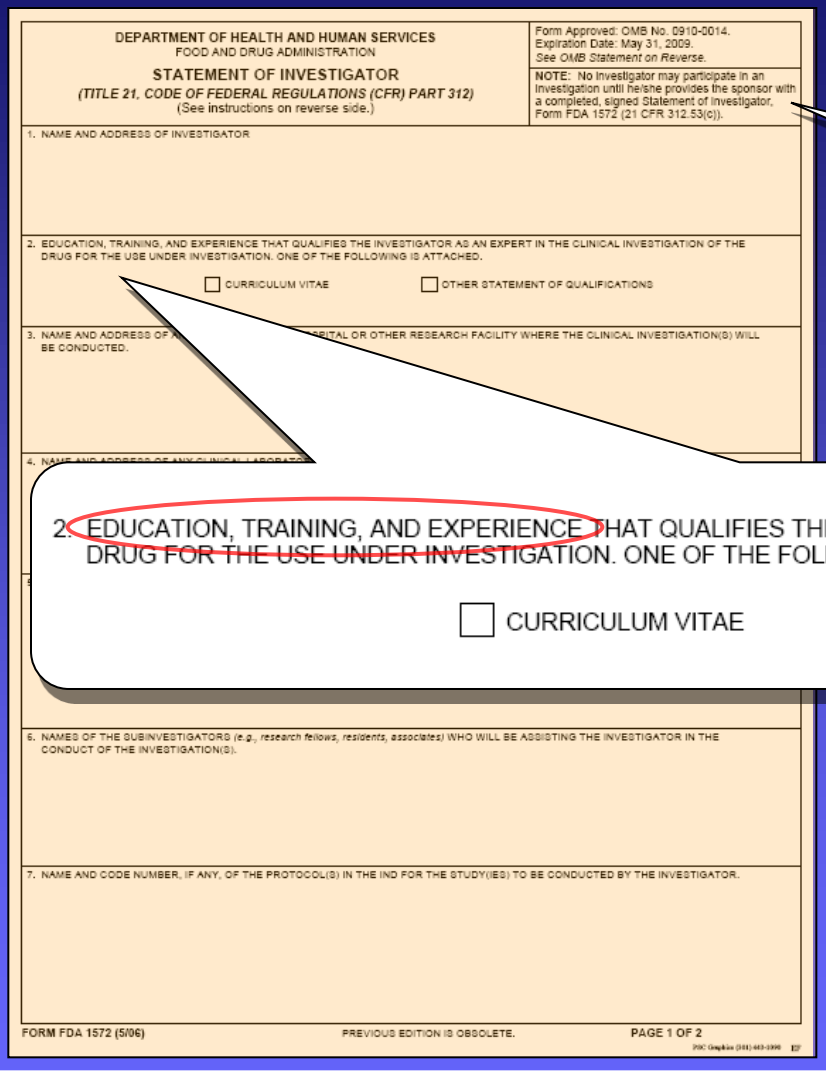
Laws and Regulations in the U.S. – USC and CFR



Laws and Regulations in the U.S. – USC and CFR



Highlights of 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: May 31, 2009.
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

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.

☐ CURRICULUM VITAE ☐ OTHER STATEMENT OF QUALIFICATIONS

3. NAME AND ADDRESS OF A ...SPITAL OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED.

4. NAME AND ADDRESS OF ANY CLINICAL LABORATO...

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

Form FDA 1572: Statement of Investigator

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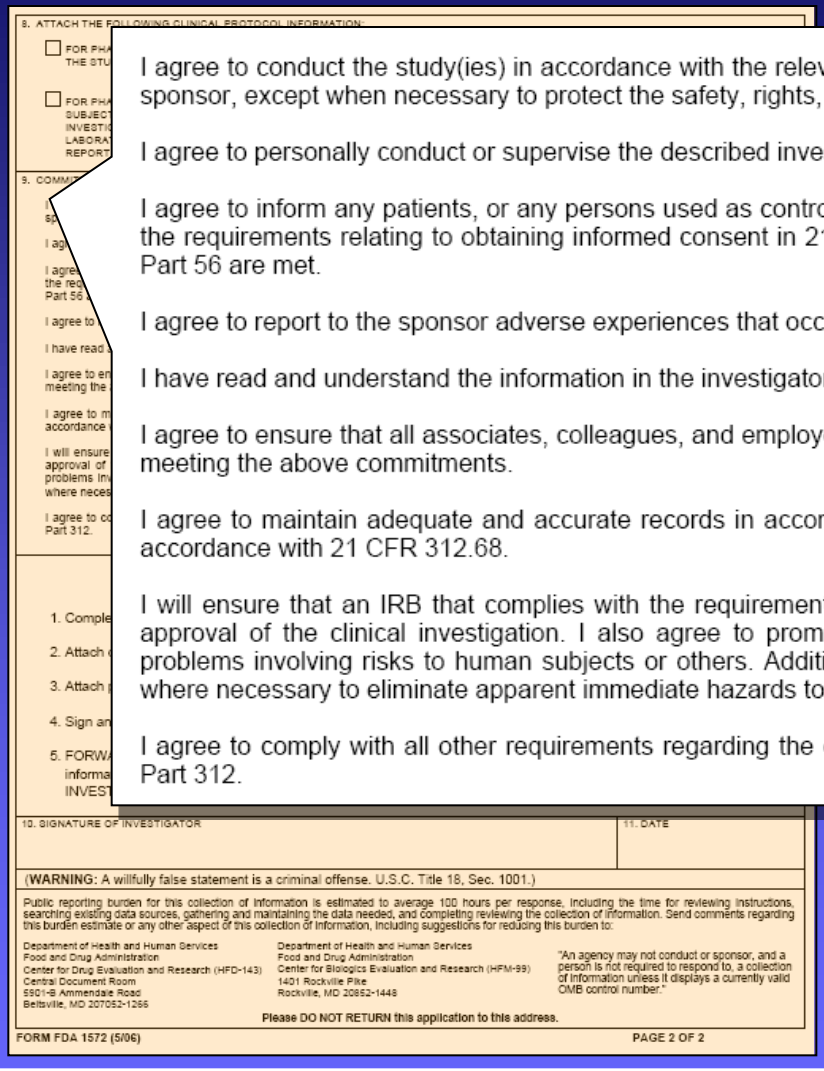
☐ CURRICULUM VITAE ☐ OTHER STATEMENT OF QUALIFICATIONS

- This form is only for drug trials linking to an investigational new drug application (IND).
- However, the U.S. FDA also has similar requirements for device trials (21 CFR 812.43(c)).

Highlights of Form FDA 1572



I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

10. SIGNATURE OF INVESTIGATOR

11. DATE

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

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 (HFD-143)
Central Document Room
5901-B Ammendale Road
Beltsville, MD 207052-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
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.

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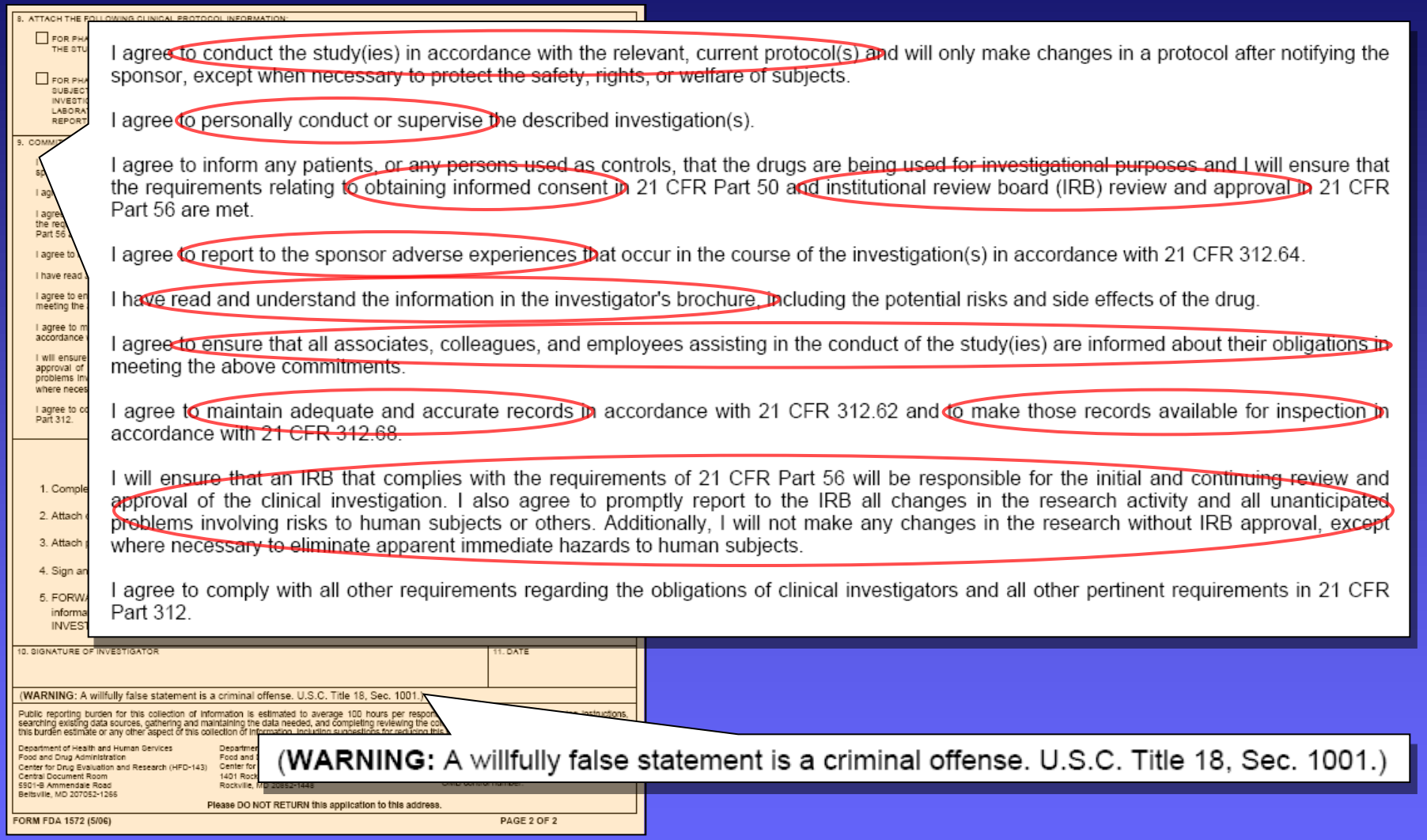
Highlights of Form FDA 1572



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Form FDA 1572

Disqualification and Debarment

Non-compliance with the requirements under the Form FDA 1572 may lead to:

Disqualification

Prohibition of or restriction on an investigator to receive investigational drugs or devices by the U.S. FDA (according to 21 CFR 312.70).

Owing to repeated or deliberate failure to comply with applicable U.S. regulatory requirements for clinical research or repeated or deliberate submission of false clinical research information to the FDA and/or sponsors.

Debarment

The order of prohibition of an organization or a person from submitting, assisting in submission of, or providing services in any capacity to any person in respect of submission of any drug application to the U.S. FDA (according to FFDCA Section 306) owing to conviction of a criminal act by the organization/person concerned.

FDA Website: Disqualification List

U.S. Food and Drug Administration

A-Z Index | Search | go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Inspections, Compliance, Enforcement, and Criminal Investigations

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Home > Inspections, Compliance, Enforcement, and Criminal Investigations > Enforcement Actions > Disqualified/Restricted/ Restrictions Removed/ Assurance Lists for Clinical Investigators

Enforcement Actions

- Disqualified/Restricted/ Restrictions Removed/ Assurance Lists for Clinical Investigators

Disqualified/Restricted/ Restrictions Removed/ Assurance Lists for Clinical Investigators

FDA regulates scientific studies that are designed to develop evidence to support the safety and effectiveness of investigational drugs (human and animal), biological products, and medical devices. Physicians and other qualified experts ("clinical investigators") who conduct these studies are required to comply with applicable statutes and regulations intended to ensure the integrity of clinical data on which product approvals are based and, for investigations involving human subjects, to help protect the rights, safety, and welfare of these subjects.

The following hyperlinked lists contain the names of:

1. All clinical investigators who have received a Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) since 1998 are listed. A NIDPOE informs the recipient investigator that FDA is initiating an administrative proceeding to determine whether the

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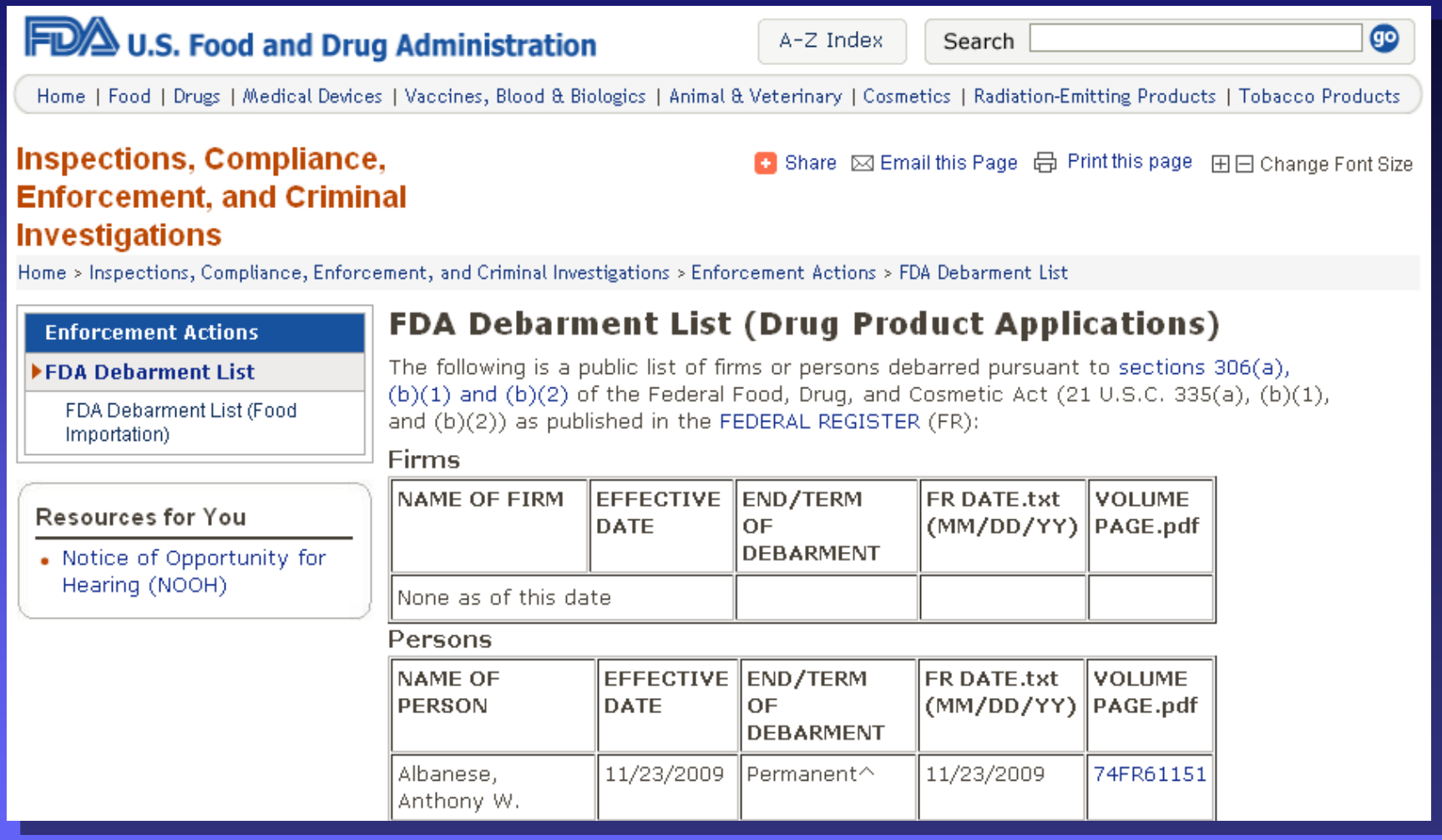
FDA Website: Debarment List



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Inspections, Compliance, Enforcement, and Criminal Investigations

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Home > Inspections, Compliance, Enforcement, and Criminal Investigations > Enforcement Actions > FDA Debarment List

Enforcement Actions

- FDA Debarment List
- FDA Debarment List (Food Importation)

Resources for You

- Notice of Opportunity for Hearing (NOOH)

FDA Debarment List (Drug Product Applications)

The following is a public list of firms or persons debarred pursuant to sections 306(a), (b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335(a), (b)(1), and (b)(2)) as published in the FEDERAL REGISTER (FR):

Firms

NAME OF FIRM	EFFECTIVE DATE	END/TERM OF DEBARMENT	FR DATE.txt (MM/DD/YY)	VOLUME PAGE.pdf
None as of this date				

Persons

NAME OF PERSON	EFFECTIVE DATE	END/TERM OF DEBARMENT	FR DATE.txt (MM/DD/YY)	VOLUME PAGE.pdf
Albanese, Anthony W.	11/23/2009	Permanent^	11/23/2009	74FR61151

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Highlights :

- Form FDA 1572 is a legal document required under the U.S. FDA regulation
- Investigators needs to understand the relevant U.S. FDA regulations and the implications
- Non-compliance with the commitments may lead to disqualification or debarment by the U.S. FDA