U.S. FOOD & DRUG ADMINISTRATION

Investigator Responsibilities – Getting It Right During a Pandemic

FDA 2021 Clinical Investigator Training Course

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Office of Scientific Investigations
Office of Compliance, CDER
December 8, 2021

Disclaimer

- The contents of this presentation are my own and do not necessarily reflect the views and/or policies of the United States Food and Drug Administration or its staff.
- I have no personal conflicts of interests relevant to this presentation.

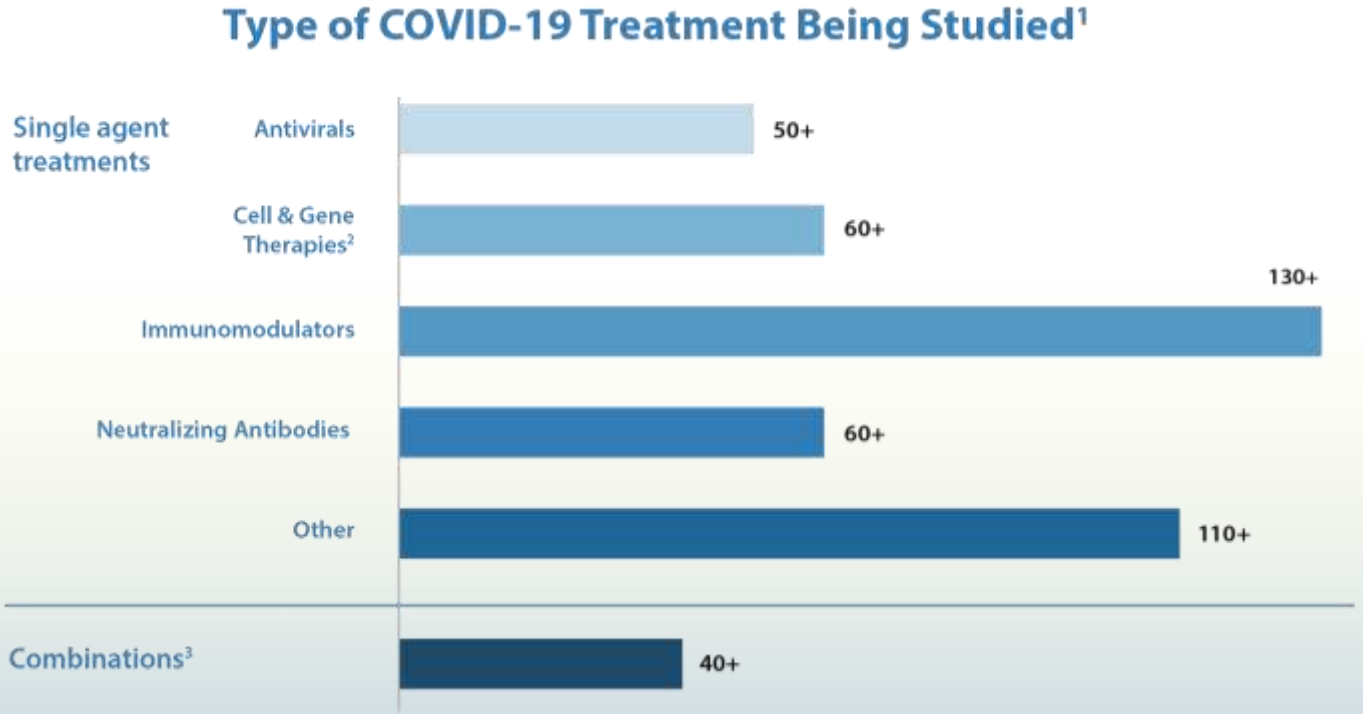
Learning Objectives

- Identify the federal regulations covering clinical research and clinical investigator obligations
- Discuss various methods that can be used to ensure compliance with federal regulations and study requirements
- Review acceptable clinical trial procedure adaptation in an emergent situation

Research as You Knew It

Welcome to a New World!

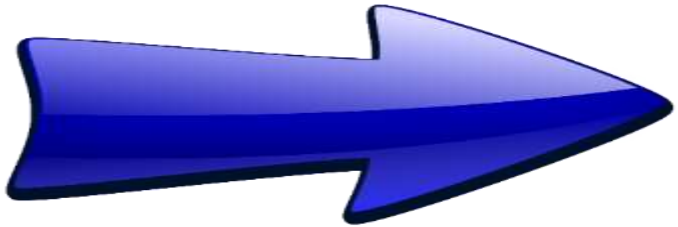
Coronavirus Treatment Acceleration Program



https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap

FDA Expectations of Clinical Investigators

- Adherence to Code of Federal Regulations
  - Knowledge of Clinical Investigator regulations
  - Understanding of Clinical Investigator responsibilities



National Archives and Records Administration

code of federal regulations

Clinical Trial Environment

Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations

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Guidance for Sponsors, Investigators, and Institutional Review Boards

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice (OGCP)

October 2018

https://www.fda.gov/RegulatoryInformation/Guidances/ucm623197.htm

Know the laws of your state

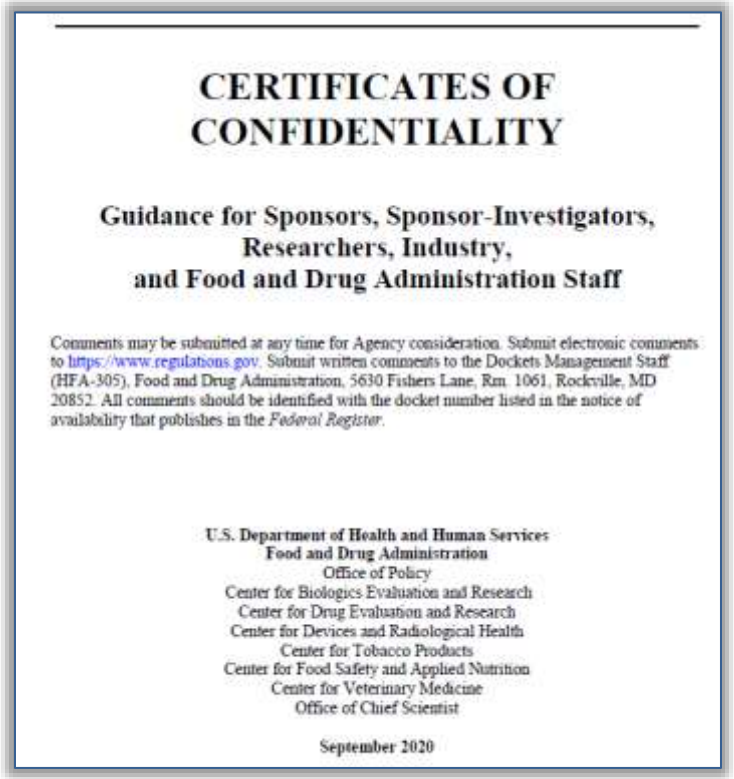
- ***Example***: *What is your state's medical assistant scope of practice and who is authorized to delegate tasks to the medical assistant*?

Answer: Depends on the applicable law of the state.

https://www.aama-ntl.org/employers/state-scope-of-practice-laws

Certificates of Confidentiality

- Certificates of Confidentiality must be issued for federally-funded human subject research that collects or uses identifiable, sensitive information. MANDITORY
- FDA may also issue discretionary Certificates of Confidentiality



CERTIFICATES OF CONFIDENTIALITY

Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff

Comments may be submitted at any time for Agency consideration. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Policy
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Center for Devices and Radiological Health
Center for Tobacco Products
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Chief Scientist

September 2020

Question

- *If you have obtained a Certificate of Confidentiality for your study, do you also need a Health Insurance Portability and Accountability Act (HIPAA) Privacy Authorization?*

YES

General Clinical Investigator Responsibilities

- Ensuring that an investigation is conducted according to
  - The signed investigator statement (**Form 1572**)
  - The investigational **plan**
  - Applicable **regulations**

[21 CFR 312.60]

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: March 31, 2022
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 Clinical Investigator

Address 1 | Address 2

City | State/Province/Region | Country | 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

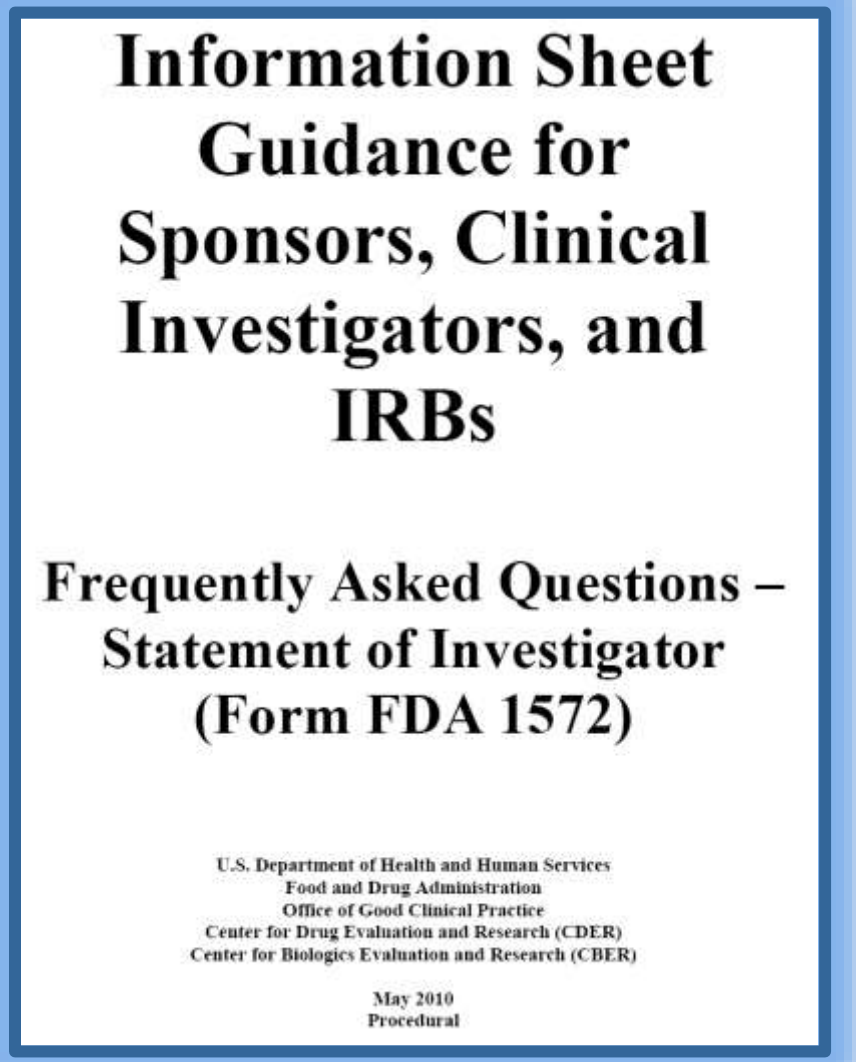
3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — CONTINUATION PAGE for Item 4



FDA

On the list of guidance documents being revised

Commitments on 1572

- Personally conduct or supervise investigation

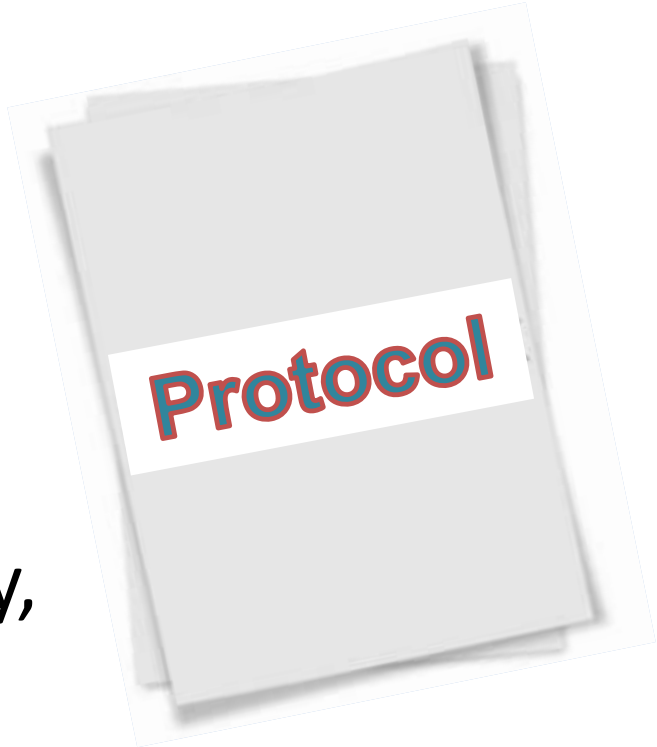
FDA regulations permit sponsors to transfer their responsibilities to contract research organizations (CROs) but do ***not*** permit clinical investigators to transfer their general responsibilities to CROs or site management organizations, sub-investigators, or study staff.

ICH E6(R2): Investigator

- The investigator is responsible for **supervising** any individual or party to whom the investigator delegates study tasks conducted at the trial site
- If the investigator/institution **retains the services of any party** to perform study tasks they should **ensure this party is qualified** to perform those study tasks and should implement procedures to ensure the integrity of the study tasks performed and any data generated

Commitments on 1572

- 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.



QUESTION

- *What is the #1 deficiency that FDA inspectors find at an investigator's site?*

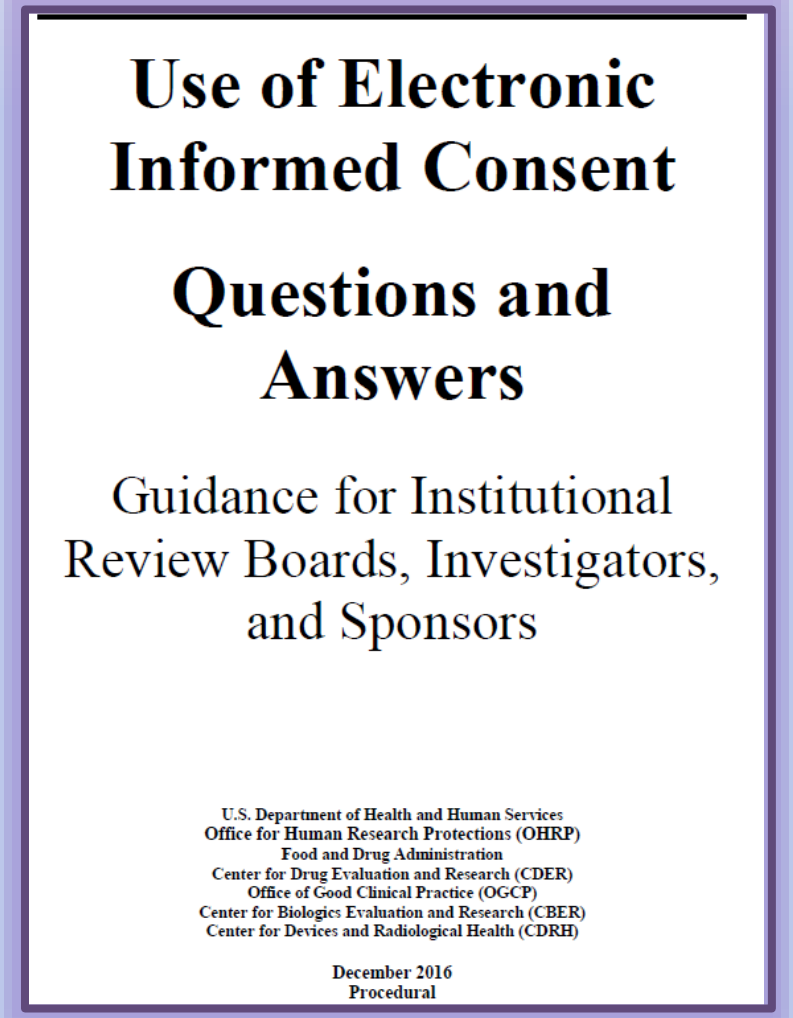
Answer: **NOT FOLLOWING THE PROTOCOL**

Commitments on 1572

- Ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations

Commitments on 1572

- Agree to inform any patients, or any persons used as controls, that the **drugs are being used for investigational purposes** and 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.



- The use of electronic systems and processes …including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, **to convey information** related to the study and **to obtain and document informed consent**.

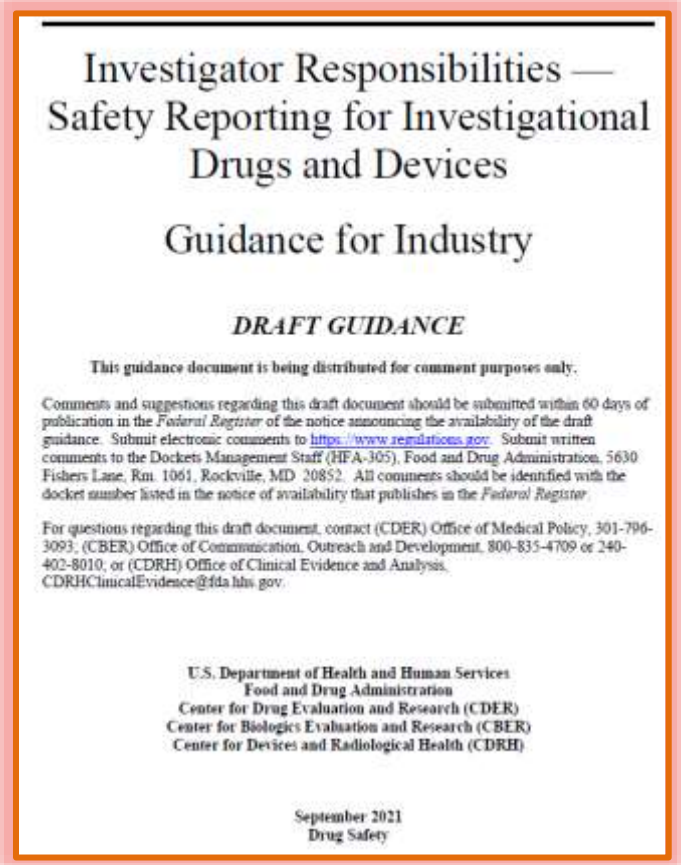
FDA's COVID MyStudies App

https://www.fda.gov/drugs/science-and-research-drugs/covid-mystudies-application-app

Commitments on 1572

- Agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. ***Have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.***

Recent Guidance



Investigator Responsibilities — Safety Reporting for Investigational Drugs and Devices

Guidance for Industry

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 electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, 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 (CDER) Office of Medical Policy, 301-796-3093; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Office of Clinical Evidence and Analysis, CDRHClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

September 2021
Drug Safety

Helps clinical investigators:

- Comply with the safety reporting requirements for IND studies under 21 CFR 312.64(b)
- Identify safety information that is considered an unanticipated problem involving risk to human subjects or others and that, therefore, requires prompt reporting to IRBs

Commitments on 1572

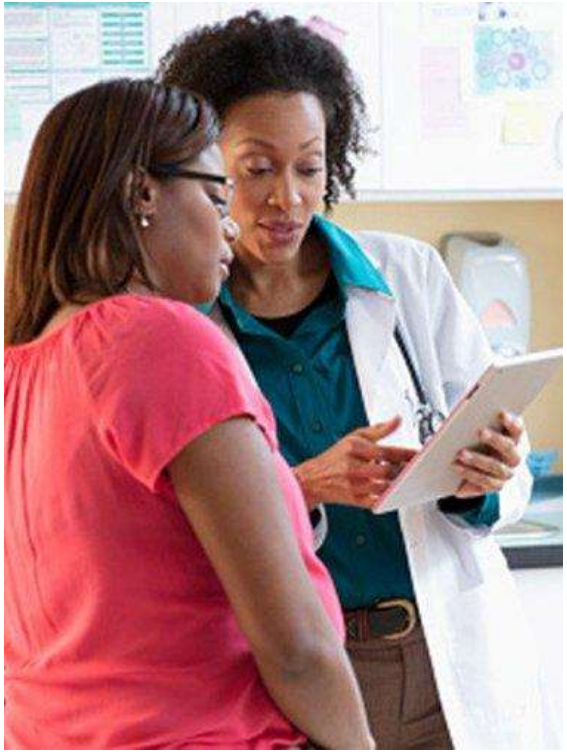
- Maintain adequate and accurate records (21 CFR 312.62) and make them available for inspection in accordance with 21 CFR 312.68

21 CFR 312.68

- "An investigator shall upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to **have access to, and copy and verify any records** or reports made by the investigator…"

ICH E6(R2): ALCOAC

- Source data should be **a**ttributable, **l**egible, **c**ontemporaneous, **o**riginal, **a**ccurate, and **c**omplete ... Changes to source data should be traceable, should not obscure the original entry and should be explained if necessary (e.g., via an audit trail).
  - *Makes this an explicit investigator responsibility*



Part 11 Compliance

- **Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations.**
  - **If a research site owns, controls, or operates its own systems with electronic FDA-regulated records, Part 11 applies.**

Electronic Signatures

- If sites are using electronic signatures on any of their essential records, Part 11 signature requirements also apply.
- Sponsor-investigators also need to remember to submit a certificate of intent to use electronic signatures to the FDA.

https://www.fda.gov/industry/about-esg/appendix-g-letters-non-repudiation-agreement

QUESTION

- *What considerations apply to the electronic systems used to generate electronic signatures on clinical trial records, including informed consent documents, during the COVID-19 public health emergency?*

ANSWER

- Electronic systems used to generate electronic signatures on clinical trial records, including informed consent documents, during the COVID-19 public health emergency **must comply with the requirements outlined in FDA regulations at 21 CFR part 11 (Part 11)** when applicable.

Guidance for Industry

Part 11, Electronic Records; Electronic Signatures — Scope and Application

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Food Safety and Applied Nutrition (CFSAN)
Center for Veterinary Medicine (CVM)
Office of Regulatory Affairs (ORA)

August 2003
Pharmaceutical CGMPs

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers

Guidance for Industry

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For questions regarding this draft document, contact (CDER) Cheryl Grandinetti or Leonard Sacks at 301-796-2500; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Program Operations Staff or Irfan Khan at 301-796-5640.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

June 2017
Procedural

14823dft.doc
06/20/17

Commitments on 1572

- Ensure **initial and continuing review by an IRB** and report all changes to research and unanticipated problems involving risks to subjects, not make any changes without IRB approval except where necessary to eliminate immediate hazards

- Comply with other requirements in 21 CFR 312

Investigator Responsibilities

- Record keeping and retention (312.62)

An investigator is responsible for:

- Maintaining adequate records of the **disposition of the drug**
- Accurate **case histories** that record all observations, and
- **Other data pertinent to the investigation** on each individual administered the investigational drug or employed as a control in the investigation

Question

- *For an IND study, if a research study drug is ordered through a computerized medication ordering system, does 21 CFR Part 11 apply to the physician's electronic signature for the research medication order?*

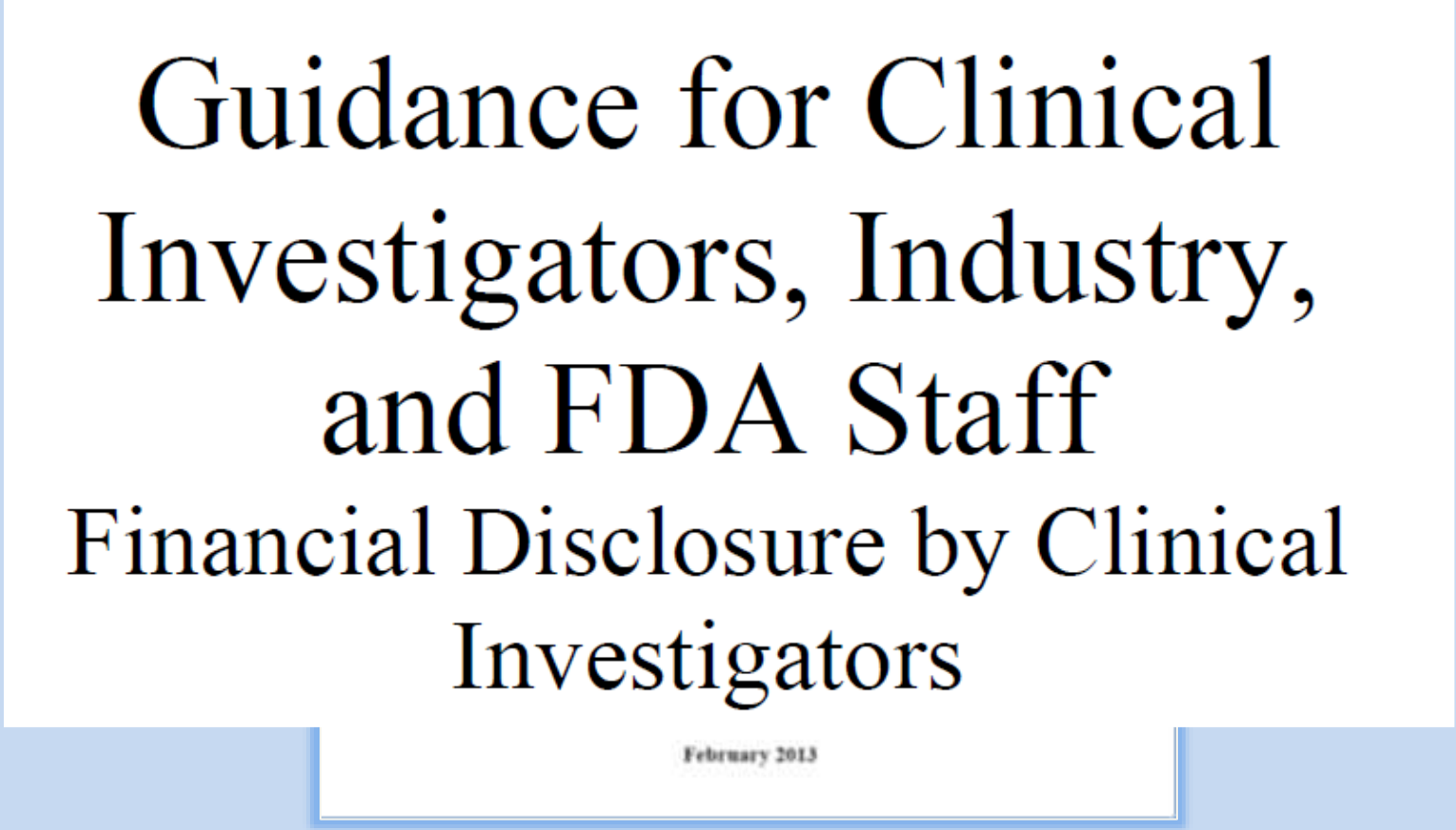
Answer: No. These signatures are not normally signatures required under FDA regulations in 21 CFR, so part 11 doesn't apply.

Responsibilities (cont.)

- Investigator reports (312.64)
  - Progress reports to sponsor (for sponsor's annual report to FDA)
  - Safety reports
    - Immediately report to the sponsor any serious adverse event, whether or not considered drug related, and must include an assessment of whether there is a reasonable possibility that the drug caused the event
    - Record nonserious adverse events and report them to the sponsor according to the timetable for reporting specified in the protocol

Responsibilities (cont.)

- Final report to sponsor
  - Shortly after completion of the investigator's participation in the investigation
- Financial disclosure reports
  - Sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under 21 CFR part 54
  - Promptly update as needed during the course of the investigation and for 1 year following study completion



FORMS FDA 3454 (Certification of no disclosable financial interests) and 3455 (Disclosure Statement [21 CFR § 54.4(a)]) are available on the Web at the following Internet address: **http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm**

Implement System to Detect and Correct Errors in Real Time

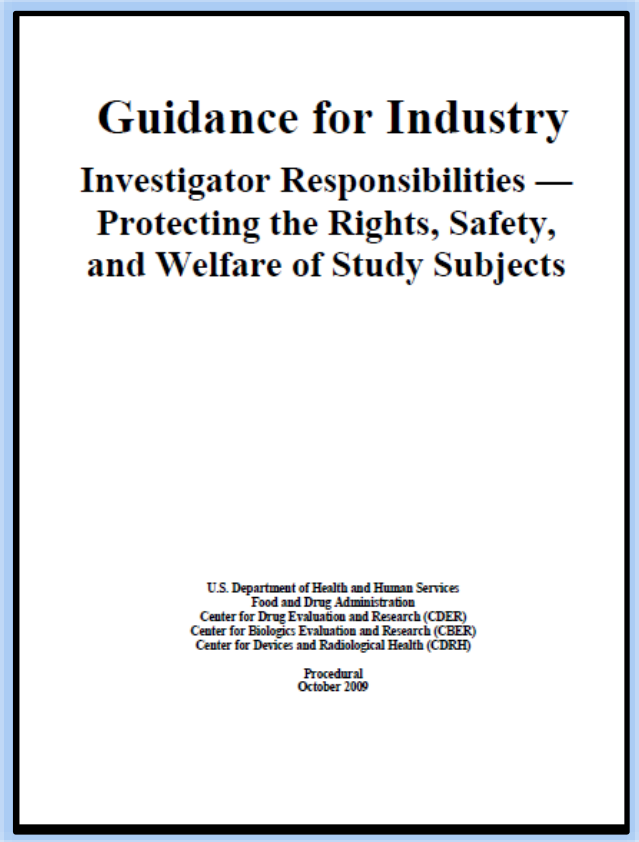
- Do real-time cleaning of the data
- Pay attention to monitoring queries and respond promptly ***Close loops***
- Audit trail of changes should make clear what was changed, who changed it, and why it was changed
- Evaluate need for system-wide corrections and training

Investigator Responsibilities

- An investigator is required to maintain investigation records for:
  - 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated
  - 2 years after the investigation is discontinued and FDA is notified if no application is to be filed or if the application has not been approved for such indication

Advise that you NOT destroy any records until the sponsor of the trial gives you permission.

Reference


Guidance for Industry

Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

Procedural
October 2009

- Outlines FDA expectations for study oversight
  - **Delegation** of study tasks
  - **Training** of study staff
  - **Supervision** of conduct of ongoing study
  - **Oversight of third parties** involved in the study (e.g., SMOs, outside labs specifically retained to conduct study assessments)

COVID-19 Guidance

Contains Nonbinding Recommendations

Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency

Guidance for Industry, Investigators, and Institutional Review Boards

March 2020

Updated on August 30, 2021

Engage Institutional Review Board

- Sponsors and clinical investigators are encouraged to engage with IRBs/IEC as early as possible when urgent or emergent changes to the protocol or informed consent are anticipated as a result of COVID-19

Safety Assessments

- Alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible, and are sufficient to assure the safety of trial participants

Keep Subjects Informed

- In all cases, it is critical that trial participants are kept informed of changes to the study and monitoring plans that could impact them

Efficacy Assessments

- Consult with the appropriate review division regarding protocol modifications for the collection of efficacy endpoints, such as use of virtual assessments, delays in assessments, and alternative collection of research-specific specimens, if feasible.

Missing Data

- It will be important to capture specific information in the case report form that explains the basis of the missing data, including the relationship to COVID-19 for missing protocol-specified information (e.g., from missed study visits or study discontinuations due to COVID-19)

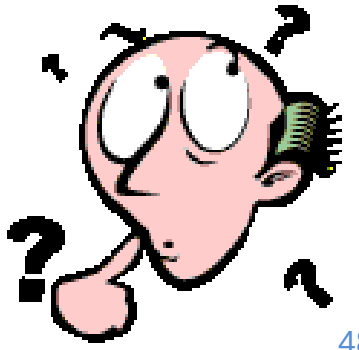
Investigational Products

- Certain investigational products, such as those that are typically distributed for self administration, may be amenable to alternative secure delivery methods.
- Existing regulatory requirements for maintaining investigational product accountability remain and should be addressed and documented.

QUESTION

- If a participant receives a vaccine or other medical product for the prevention or treatment of COVID-19 authorized under an Emergency Use Authorization (EUA), would FDA consider this receipt of an investigational medical product?

ANSWER: NO



Discontinuation of Investigational Product

- If there are individual trial participants for whom discontinuing the investigational product might present a substantial risk, ***the sponsor should consider amending the protocol, after discussion with the relevant review division,*** to limit investigational product use to those patients with apparent benefit and discontinue investigational product use to other participants.
- In all cases, if a trial participant is discontinued from an investigational therapy, it is important that there be appropriate management after discontinuation.

COVID-19 Testing

- COVID-19 screening procedures that may be mandated by the health care system in which a clinical trial is being conducted do not need to be reported as an amendment to the protocol even if done during clinical study visits unless the sponsor is incorporating the data collected as part of a new research objective

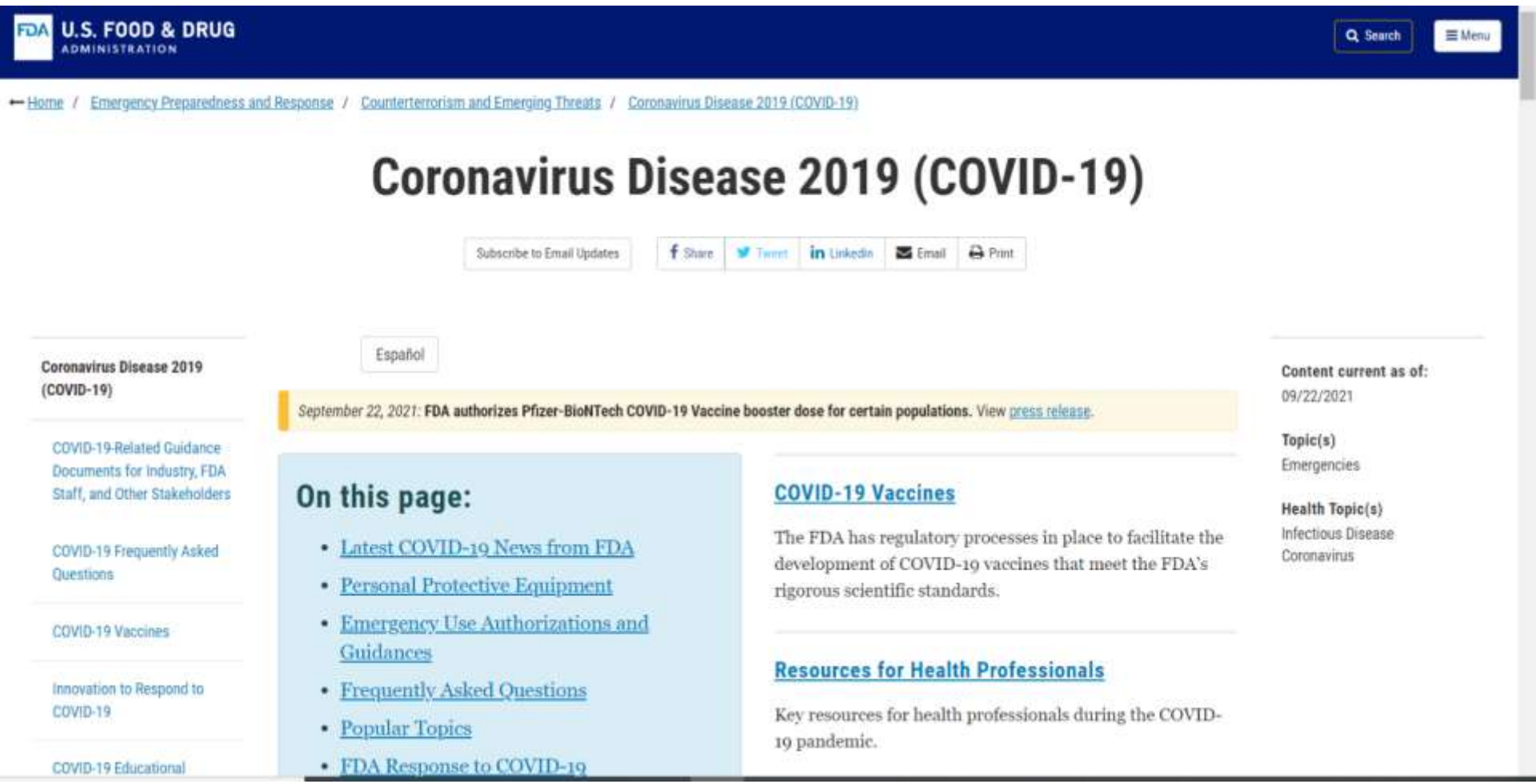
QUESTION

- If an investigator receives an IND safety report from a sponsor, is it acceptable to review only reports that the sponsor indicates will result in a change to the investigator's brochure, informed consent, or protocol?

ANSWER

NO.

It is not acceptable for an investigator to review only certain IND safety reports. FDA considers the review of all IND safety reports critical to fulfilling investigators' responsibility to protect the safety of trial participants in a clinical investigation.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COVID-19 Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders
COVID-19 Frequently Asked Questions
COVID-19 Vaccines
Innovation to Respond to COVID-19
COVID-19 Educational
September 22, 2021: FDA authorizes Pfizer-BioNTech COVID-19 Vaccine booster dose for certain populations. View press release.
On this page:
Latest COVID-19 News from FDA
Personal Protective Equipment
Emergency Use Authorizations and Guidances
Frequently Asked Questions
Popular Topics
FDA Response to COVID-19
COVID-19 Vaccines
The FDA has regulatory processes in place to facilitate the development of COVID-19 vaccines that meet the FDA's rigorous scientific standards.
Resources for Health Professionals
Key resources for health professionals during the COVID-19 pandemic.
Content current as of:
09/22/2021
Topic(s)
Emergencies
Health Topic(s)
Infectious Disease
Coronavirus

Sponsor-Investigator

- Investigator-Initiated Investigational New Drug (IND) Applications webpage
  - Brief explanations about various aspects of IND application submissions and procedures with links to guidances, references, and forms.

https://www.fda.gov/drugs/investigational-new-drug-ind-application/investigator-initiated-investigational-new-drug-ind-applications

Sponsor Responsibilities

- Sponsors are responsible for (21 CFR 312.50):
  - Selecting qualified investigators
  - Providing investigators with the information they need to conduct the investigation properly
  - Ensuring proper monitoring of the investigation
  - Ensuring that the investigation is conducted in accordance with the general investigational plan
  - Maintaining an effective IND
  - Ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks

Monitoring

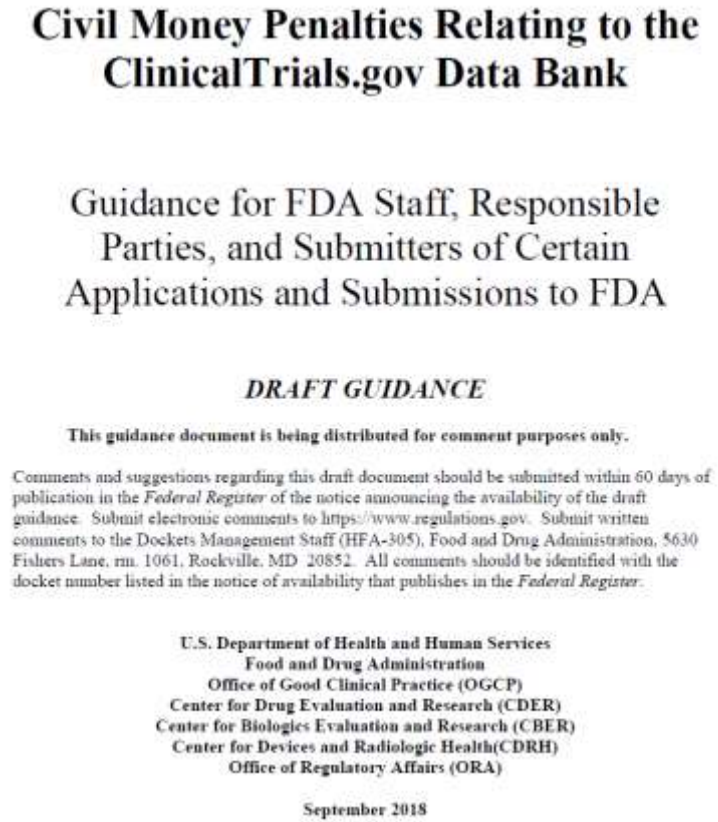
- **As a sponsor-investigator, YOU are responsible for monitoring your own study!**
  - FDA recommends that ***sponsor-investigators submit a brief summary to the IND to demonstrate that there is adequate monitoring of the clinical investigation*** to demonstrate the trial(s) are conducted in accordance with regulatory requirements, GCPs, and the protocol; that the rights and well-being of human subjects are protected; that data reporting, including safety reporting to the sponsor-investigator and the IRB, is accurate and complete; and that the sponsor-investigator has adequate oversight over the clinical investigation, as outlined in 21 CFR part 312, subpart D.

ClinicalTrials.gov

- **U.S. Public Law 110-85** (Food and Drug Administration Amendments Act of 2007/**FDAAA**), Title VIII, Section 801 mandates that a "responsible party" (i.e., the sponsor **or designated principal investigator**) register and report results of certain “applicable clinical trials”
  - Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, subject to FDA regulation
  - Trials of devices: Controlled trials with heath outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance required by FDA

    http://clinicaltrials.gov/ct2/manage-recs/fdaaa

Final Rule 42 CFR part 11



Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank

Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA

DRAFT GUIDANCE

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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 electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Good Clinical Practice (OGCP)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health(CDRH)
Office of Regulatory Affairs (ORA)

September 2018

The Final Rule clarifies and expands the regulatory requirements and procedures for submitting registration and results information for certain trials to ClinicalTrials.gov.

There are monetary penalties!

Noncompliance Letters

NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282(j)(5)(C)(ii)

VIA UNITED PARCEL SERVICE AND E-MAIL

August 31, 2021

Andrey Petrikovets, M.D.
1513 South Grand Avenue, Suite 400
Los Angeles, California 90015

Re: Notice of Noncompliance with the Requirements for Submission of Clinical Trial Results Information for "ICE-T Postoperative Multimodal Pain Regimen Compared to the Standard Regimen in Same Day Vaginal Pelvic Reconstructive Surgery: A Randomized Controlled Trial" (NCT03052816)
FDA Reference Number: CDER-2020-109

Dear Dr. Petrikovets:

The U.S. Food and Drug Administration (FDA) sent you a letter dated July 20, 2020, alerting you to potential noncompliance with the requirement to submit clinical trial results

https://www.fda.gov/media/151965/download

https://www.fda.gov/drugs/investigational-new-drug-ind-application/information-sponsor-investigators-submitting-investigational-new-drug-applications-inds

Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators

Guidance for Industry

DRAFT GUIDANCE

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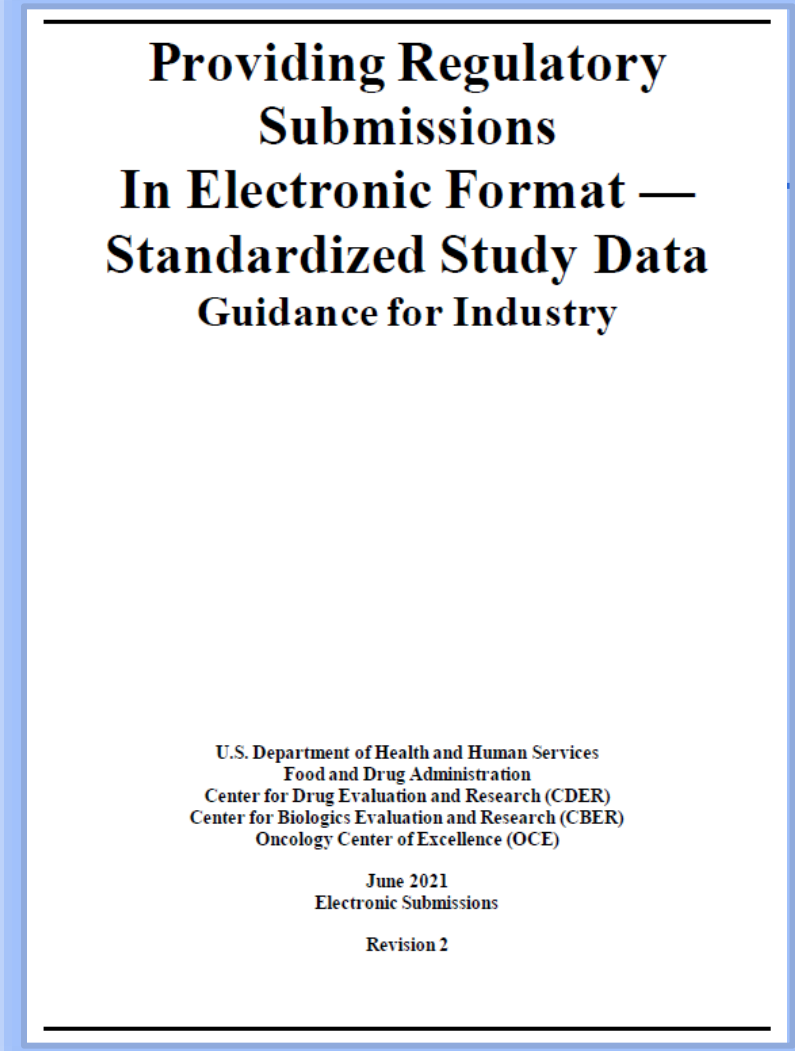
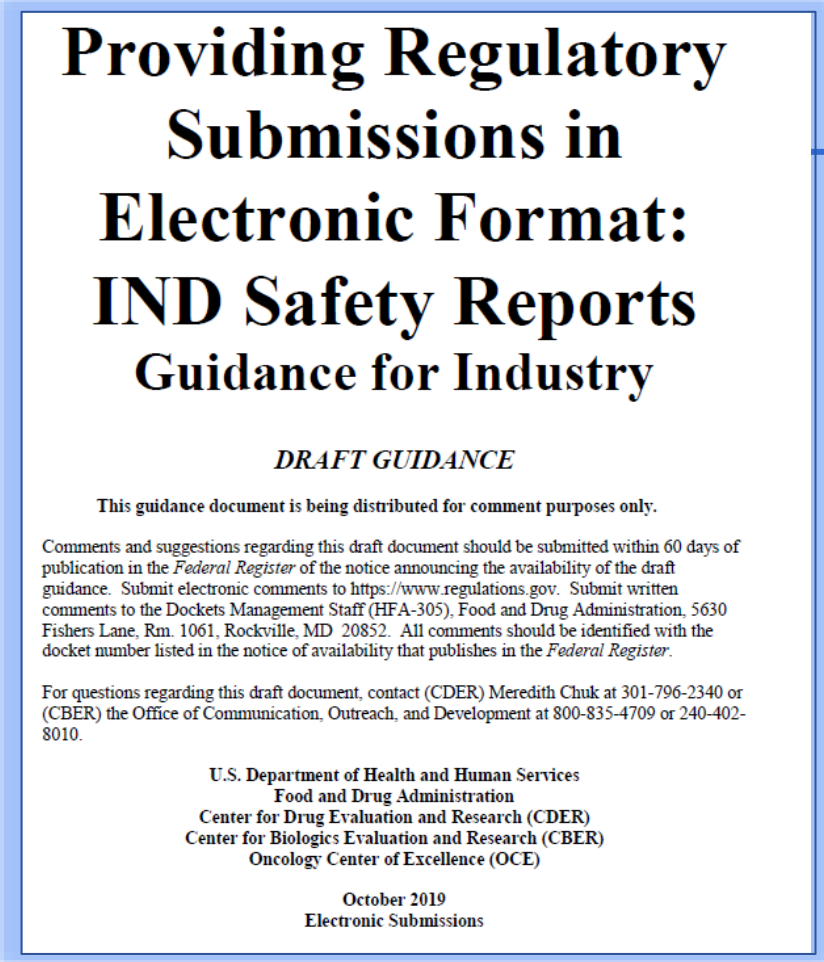
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2015
Procedural



FDA has exempted all submissions regarding noncommercial INDs (Research INDs) from the requirements.

- An IND for a product that is not intended for commercial distribution and includes investigator-sponsored INDs and expanded access INDs (e.g., emergency use INDs and treatment INDs).



Providing Regulatory Submissions in Electronic Format: IND Safety Reports

Guidance for Industry

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 electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, 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 (CDER) Meredith Chuk at 301-796-2340 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Oncology Center of Excellence (OCE)

October 2019
Electronic Submissions

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Preparing for an Inspection

- Makes sure your files are in order (subject files and regulatory files)
- Have the correct staff available
- Block off time at the beginning and end of the day for discussions with the inspector
- Have a copier available
- Correct any deficiencies, if possible, while the inspector is still at your site

What Can You Do Now?

- Know your patients ***Really know your patients***
- Step back and re-evaluate your electronic systems
- Be prepared for telehealth, remote monitoring, and other decentralized processes
- Be proactive – not reactive

Challenge Question #1

Which is <u>not</u> a responsibility of a clinical investigator:

A. Supervising individuals to whom the investigator delegates study tasks

B. Informing patients that the drugs are being used for investigational purposes

C. Ensuring initial and continuing review by an IRB

D. Registering and reporting results of applicable clinical trials to ClinicalTrials.gov

Challenge Question #2

Which of the following statements is NOT true?

A. Investigators are required to report to the sponsor serious and unexpected adverse events.

B. Investigators are required to report all "unanticipated problems involving risk to human subjects or others" to the IRB.

C. FDA regulations permit sponsors to transfer their responsibilities to contract research organizations (CROs) but do not permit clinical investigators to transfer their general responsibilities.

D. An investigator must permit FDA to have access to and copy and verify any records or reports made by the investigator.

E. A sponsor-investigator is responsible for monitoring their own study.

In Summary – Key Messages

- Clinical investigators play a critical role in ensuring high quality studies
  - All regulations and responsibilities of an investigator must be followed. ***You and staff should know them!***
  - FDA is available and has many resources to assist you if questions arise
- Establish at your site a culture that supports critical thinking and open dialogue
- At stake is public confidence and participation in clinical trials and, ultimately, the availability of safe and effective products

Final Message

You never learn it all… I don't care if you're the greatest, there's always something to learn.

Otis Rush,
blues guitarist

Question

- **Would it be possible to share any new FDA GCP-related efforts or guidance documents expected to be issued shortly?**

Yes, they are publicly posted. Below are a few examples.

CDER: https://www.fda.gov/media/134778/download

- Decentralized Clinical Trials
- Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products
- Investigator Responsibilities- Safety Reporting for Investigational Drugs and Devices
- Use of Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

FDA Sites of Interest

- Regulations: Good Clinical Practice and Clinical Trials
  https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials

- FDA Basics for Industry
  https://www.fda.gov/industry/fda-basics-industry

- Sign up for Updates
  https://www.fda.gov/industry/fda-basics-industry/stay-informed-fda-program-areas

FDA Sites of Interest

- Replies to Inquiries to FDA on Good Clinical Practice
  - Designed to simplify the search for copies of e-mail messages (including the original inquiry and associated replies) that have been submitted by the public to the Good Clinical Practice Program's gcp.questions@fda.hhs.gov e-mail account.

https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/replies-inquiries-fda-good-clinical-practice

Guidances of Interest

- **FDA Inspections of Clinical Investigators- Information sheet**

  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-inspections-clinical-investigators

- **Guidance for Industry-Investigator Responsibilities**

  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-protecting-rights-safety-and-welfare-study-subjects

General Information Sheets

- Charging for Investigational Products
- Cooperative Research
- Informed Consent, A Guide to
- Non-local IRB Review
- Payment and Reimbursement to Research Subjects
- Recruiting Study Subjects
- Screening Tests Prior to Study Enrollment
- Sponsor - Investigator - IRB Interrelationship
- Use of Investigational Products When Subjects Enter a Second Institution

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trials-guidance-documents

Thank you for your attention

Eleanor

Reporting to FDA

Drug studies:

Call 301-796-3150 Fax 301-847-8748

Email: CDER-OSI-GCPReferrals@fda.hhs.gov

(*Office of Scientific Investigations, Office of Compliance, CDER*)

Biologics studies (including gene therapy and vaccine studies):

Call 240-402-8010 Fax 301-595-1245

Email: ocod@fda.hhs.gov

(*Division of Communication and Consumer Affairs, CBER*)


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