Documentation

WINTER - ACADEMY FOR RESEARCH PROFESSIONALS

JANUARY 31, 2019

Presented by:
Christine Sinkey, CCRC, BSN
Department of Ophthalmology
Clinical Trials Specialist

Objectives:

- **Background**
- **Understanding Essential Documents**
- **Regulatory Binder Management**
- **Documentation & Record Keeping**
- **Electronic Documentation**
- **Resources**

Disclaimer Disclosure: No conflict of interest

Background

Elements of a “Quality” Clinical Study

- Scientifically valid and ethically sound experimental design
- Qualified and trained personnel
- Adequate monitoring
- Document management

- Current, complete, and accurate data collection
- Adequate protection of subjects – rights, safety, and well-being

Regulatory Oversight & Guidelines

IRB
Institution Review Board
https://hawkirb.research.uiowa.edu

OHRP
Office for Human Research Protection
https://www.hhs.gov/ohrp

CFR
Federal Code of Regulation
https://www.hhs.gov/ohrp/regulations-and-policy/regulations

ICH
International Council of Harmonization
https://www.ich.org

FDA
Food & Drug Administration
https://www.fda.gov

HHS
U.S. Department of Health & Human Services
https://www.hhs.gov

GCP
Good Clinical Practice
https://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/ucm155713.htm#FDARegulations

Research conduct is required to comply with laws, regulations and guideline by agency, local, state, federal and international guidance. Conduct may be required to follow GCP Guidelines depending on the trial, sponsor, location, and/or the government in which data from the trial is going to be submitted.
High standards may occur with overlap in the standards expressed in each. At the same time, each may also cover certain unique standards.

Background

Regulatory Oversight

Code of Federal Regulations (CFR)

21 CFR: 11, 50, 54, 56, 312, 314 and 45 CFR 46

International Council of Harmonization (ICH) Guidelines

E6 GCP

Provide Standards and Guidance in Conduct of Clinical Research

- Rights, safety, and well-being of subjects
- Roles and Responsibilities of Investigators and Research Staff
- Study conduct and protocol management
- Safety reporting
- **Documentation and Record Keeping**

Essential Documents

- **Documents** that “individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced”

- “Serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and the **applicable regulatory requirements**”

- Minimum list of **Essential Documents** can be found in ICH GCP E6(R2) Section 8.

TIP: Documentation should “**stand on its own**” in telling the “**story**” of the study. The PI is responsible for all protocol activities including the maintenance and storage of the study documentation, but must rely on the research coordinator and research team to comply with the guidance.

Section 8 ICH E6 GCP

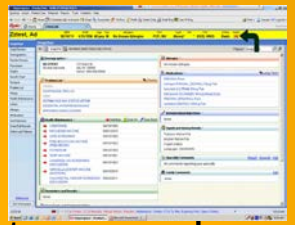
Source Documentation

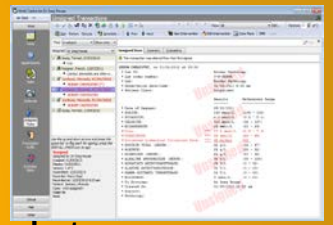
Section 1.52 ICH E6 GCP

Original documents, data, and records

Examples:

- Original paper clinical visit note by a clinical licensed professional
- Electronic Medical Record (EMR) notes or reports scanned into the EMR from outside medical offices
- Test results printed from an institutional EMR
- Pathology reports and/or procedure(s) results
- Specific forms created by Clinical Research Unit to record mandatory process required by the protocol (i.e. PK sample statement log, patient drug diary, procedure orders)
- Any original source documentation or handwritten notes





*****TIP: All Source Documents - original or electronic - must have a signature and date, by the person creating the source. When applicable signed by the Principal Investigator (PI).***

Regulatory Binder

Binder has many different names!

Investigator Binder
Regulatory Binder
Study Binder
Investigational Site File (ISF)
Trial Master File (TMF)

Regulatory Binder

Purpose

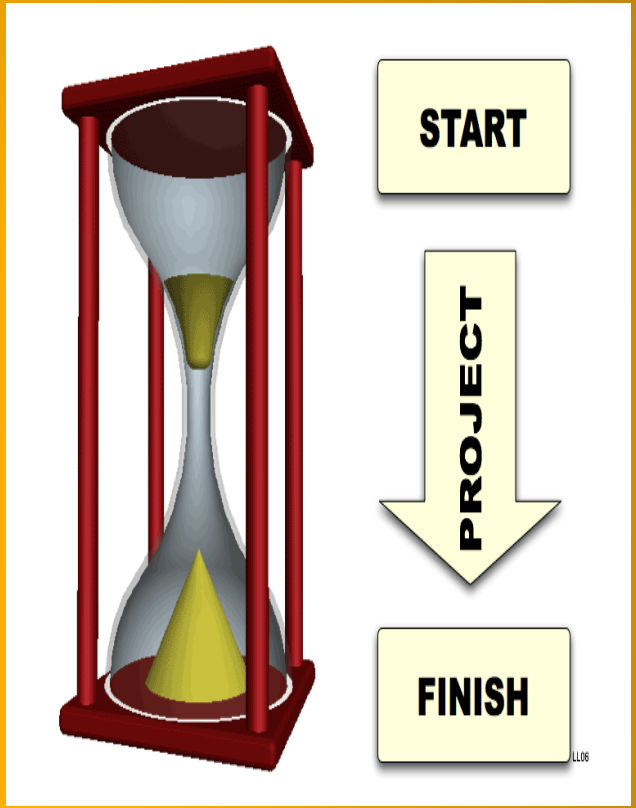
- **ORGANIZE** filing of study ***Essential Documents***
- **MANAGE** all aspects of the trial conducted at the site
- **EVALUATE** trial conduct and quality of data produced
- **DOCUMENT COMPLIANCE** by the investigator and sponsor to the standards / requirements of: FDA, IRB, NIH, Good Clinical Practice (GCP) and ICH
- **DOCUMENT** qualifications, credentials, and training

Section 8.1, 8.2, 8.3, 8.4 ICH GCP E6

Regulatory Binder

Essential Documents Timeline:

1. *BEFORE* **the study starts**
2. *DURING* **the conduct of the study**
3. *AFTER* **completion or termination**



TIP: Keep the binder current and up-to-date at all times

Regulatory Binder

Inspection and Monitoring Expectations

- **Data Integrity** - efficacy and safety data
- Evidence of subject **Rights, Safety, and Welfare** are protected
- **Compliant** conduct with applicable regulations and requirements
- **Availability -** for inspection and copying (e.g. FDA, Sponsor, CRO)
- **Retain -** for appropriate length of time
- **Preserve -** independently at clinical site and meets regulatory requirements

POLL QUESTION:

Who can conduct an inspection/or monitor your research study?

1. Institutional Review Board (IRB)
2. Joint Office for Research Billing (JOC)
3. Sponsor/Clinical Research Organization (CRO)
4. Department of Health and Human Services (OHRP)
5. Food and Drug Administration (FDA)
6. Cooperative Group/NIH
7. Grant Accounting/Billing
8. VA Research Compliance Officer (RCO)
9. All of the above
10. Only 1, 3, and 5

ANSWER: #9

Regulatory Binder

- **Investigator** maintains at clinical site
- Store binder in a **safe, secure location** ONLY accessible to research study team
- Subject-specific documentation and information (e.g., signed consent forms, test results, and completed case report forms, should be maintained separately in a subject binder/file.
- Document locations of other information, if located separate from regulatory binder (note-to-file or log)
- **NEVER** discard old versions of documents!

Regulatory Binder

Best Practice Recommendations

- Organize and order the sections to facilitate easy use and reference
- Store study documents in ***Reverse Chronological Order***
- Place newest items within a section at the front

Multi-site Studies: The Lead Site may *choose* to *customize* a **Checklist** for the study and provide to all participating sites.

Regulatory Binder *Checklist of Essential Documents*

TABLE OF CONTENTS

- ❑ Protocol & Amendments
- ❑ Protocol Training Logs
- ❑ Informed Consent Documents/Patient Information
- ❑ IRB Documentation Approvals/Correspondence
- ❑ Curriculum Vitae (CVs)
- ❑ Investigator Qualification Documentation
- ❑ Clinical Investigator Brochure (IB)
- ❑ FDA Documents
- ❑ Financial Disclosure Forms (FDF)
- ❑ Study Communications/Correspondence Site-Sponsor-Governing
- ❑ Delegation of Authority Log/Roles and Responsibilities / Signatures
- ❑ Clinical Research Training/Certifications
- ❑ Screening/Enrollment Logs
- ❑ Signed Consent Documents
- ❑ Investigational Product/Device Accountability Logs
- ❑ Specimen Tracking Log
- ❑ Serious Adverse Event (SAE)/Safety Reports/ Unanticipated Event
- ❑ Data Safety Monitoring Documents
- ❑ Study Protocol Deviation Forms
- ❑ Clinical Site Monitoring Visits
- ❑ Notes-To-File (NTFs)
- ❑ Case Report Forms (blank master copies)
- ❑ Subject Logs

Protocol & Amendments

- ❑ IRB-approved protocol
- ❑ IRB-approved protocol amendments
- ❑ Signed principal investigator (PI) signature pages for all protocol versions
- ❑ Log of protocol changes

Protocol Signature Page
Acknowledgement of Receipt

Confidential

A Multicenter, Double-Masked, Placebo-Controlled, Efficacy and Safety Phase 1 Study of XYZ-001

Edition Number: Version H
Dated: 08 August 2017

Investigator's Confirmation of Receipt

I have read the protocol and agree to conduct this trial in accordance with all stipulation of the protocol with applicable laws and regulations and in accordance with the ethical principles outlined in the Declaration of Helsinki

Dr. Andrew Research — Signature
September 28, 2017 — Date

Investigator's name and address (stamp/handwritten):

Dr. Andrew Research
University of Mars
100 Star Wars Drive
Orbit, Galaxy NNN

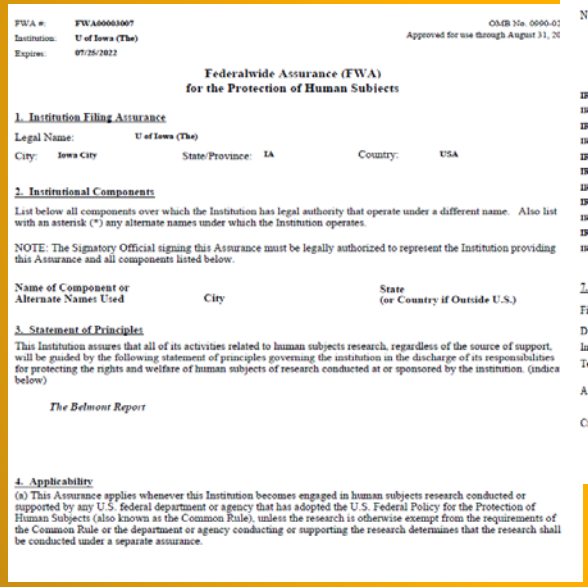
Tool Revision History:

Version		
Number	**Date**	**Summary of Revisions Made:**
4.0	09JUL2010	First published version
4.0	15MAY2011	Tool Summary Sheet title adjusted; remains v4.0 and footer version date remains the same
5.0	16SEP2011	Revisions incorporated and requirements notes added
6.0	11OCT2011	Medical license references revised and IRB Registration marked as optional
7.0	20JUL2012	Administrative edits and changes to reflect updates to Intramural Binder Tabs
8.0	12SEP2014	Removed IoR tab and revised Signed Consent Documents tab; updated hyperlinks; and completed administrative/clarifying edits

IRB Documentation

- ❑ IRB Federal Wide Assurance Number
- ❑ Updated IRB Roster *(optional)*
- ❑ IRB Registration *(optional)*

Link to OHRP Database - FWA & IRB Registration:
https://ohrp.cit.nih.gov/search/IrbDtl.aspx



FWA #: FWA00003007
Institution: U of Iowa (The)
Expires: 07/25/2022
OMB No. 0990-02
Approved for use through August 31, 20

Federalwide Assurance (FWA)
for the Protection of Human Subjects

1. Institution Filing Assurance

Legal Name: U of Iowa (The)
City: Iowa City State/Province: IA Country: USA

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)

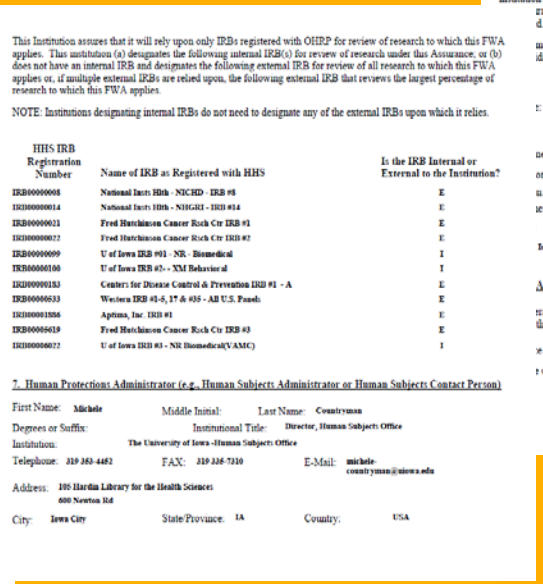
3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

The Belmont Report

4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.



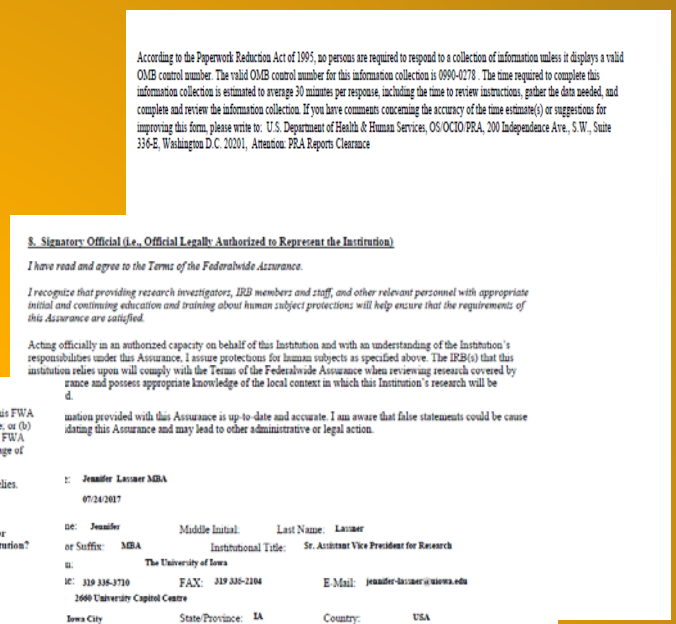
This Institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies. This institution (a) designates the following internal IRB(s) for review of research under this Assurance, or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Is the IRB Internal or External to the Institution?
IRB00000005	National Inst Hlth - NICHD - IRB #5	E
IRB00000014	National Inst Hlth - NHGRI - IRB #14	E
IRB00000021	Fred Hutchinson Cancer Rsch Ctr IRB #1	E
IRB00000022	Fred Hutchinson Cancer Rsch Ctr IRB #2	E
IRB00000099	U of Iowa IRB #01 - NR - Biomedical	I
IRB00000100	U of Iowa IRB #2- - NM Behavioral	I
IRB00000183	Centers for Disease Control & Prevention IRB #1 - A	E
IRB00000533	Western IRB #1-5, 17 & #35 - All U.S. Panels	E
IRB00001586	Aptima, Inc. IRB #1	E
IRB00005619	Fred Hutchinson Cancer Rsch Ctr IRB #3	E
IRB00006022	U of Iowa IRB #3 - NR Biomedical(VAMC)	I

7. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Michele Middle Initial: Last Name: Countryman
Degrees or Suffix: Institutional Title: Director, Human Subjects Office
Institution: The University of Iowa -Human Subjects Office
Telephone: 319 353-4482 FAX: 319 335-7310 E-Mail: michele-countryman@uiowa.edu
Address: 105 Hardin Library for the Health Sciences
600 Newton Rd
City: Iowa City State/Province: IA Country: USA



According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0278 . The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance

8. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of the Federalwide Assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by
rance and possess appropriate knowledge of the local context in which this Institution's research will be
d.

mation provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause
idating this Assurance and may lead to other administrative or legal action.

: Jennifer Lassner MBA
07/24/2017
me: Jennifer Middle Initial: Last Name: Lassner
or Suffix: MBA Institutional Title: Sr. Assistant Vice President for Research
n: The University of Iowa
r: 319 335-3710 FAX: 319 335-2104 E-Mail: jennifer-lassner@uiowa.edu
2660 University Capitol Centre
Iowa City State/Province: IA Country: USA

Approval

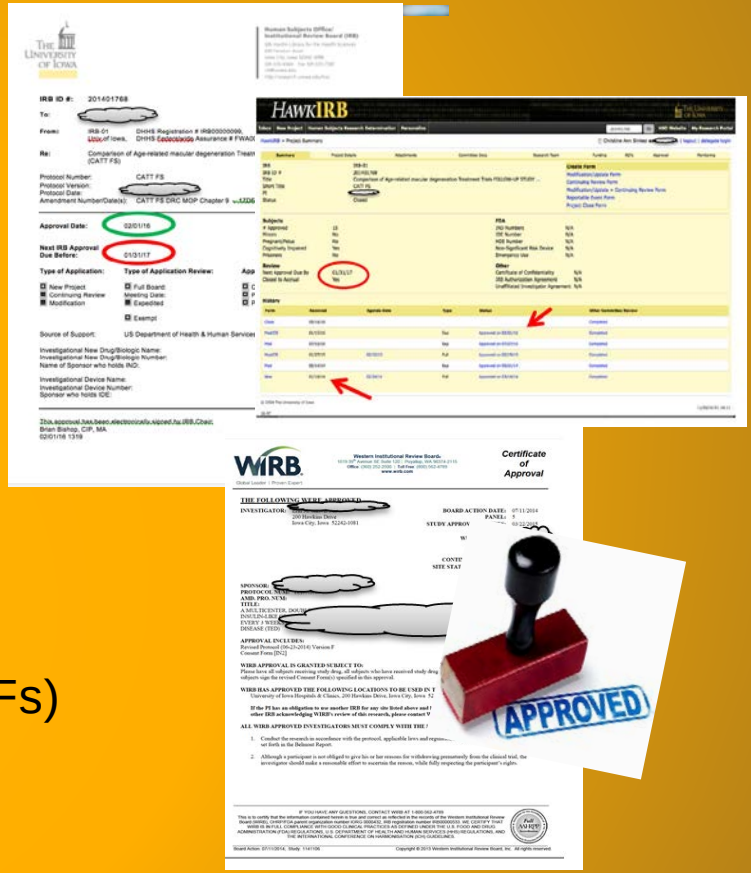
ralwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to the above Institution is hereby approved.

e Number: FWA00003007 Expiration Date: 07/25/2022
t of HHS Approving Official: Gail Holloway Date: 07/25/2017

https://hso.research.uiowa.edu/sites/hso.research.uiowa.edu/files/FWA_Expires7.25.22.pdf

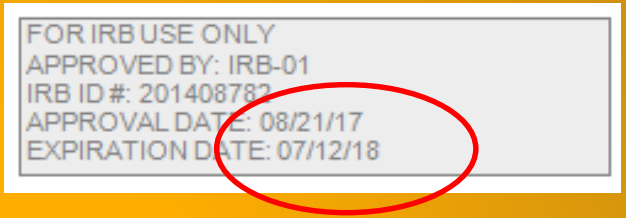
IRB Approvals & Correspondence

- Original IRB New Project application / submission
- IRB approval letters
- IRB Annual Continuing Reviews
- Project closure notification
- IRB-approved advertisements, brochures
- IRB-approved Participant Information Sheets
- IRB-approved blank Case Report Forms (CRFs)



Informed Consent Documents

- IRB-approved/stamped ***(clean copy)***:
  - Consent documents
  - Consent summaries
  - Assent documents
  - Short form consents for non-English speakers/readers



**Note: Keeping a log of Informed Consent Form versions can be helpful

- Retain **all original, *signed*** consent documents:
  - Current IRB approved/stamped version
  - Consent modification (e.g., protocol amendments requiring new version)
  - **Even if the subject withdraws consent or screen fails!**
- Store in **one** location - subject folder or separate binder
  - If stored separately, document the location in a Note-To-File

Investigator Qualification Documentation

- Up-to-date **Curriculum Vitae (CV)** for **principal investigator (PI) and subinvestigator(s)**
  - Include institution address, name, and date in header; with original signature and date in upper right hand corner
  - Institution address, name, and licensure need to ***mirror*** the information on the **FDA 1572**
- Current clinical **professional licensure** (dental, medical, nursing, pharmacy, etc.) for PI and co-investigators, if licensed
- **Update** CV and documents as the licensures expire or qualifications change

Andrew A. Research, MD
University of Mars
100 Star Wars Drive
Orbit, Galaxy NNN

Dr. Andrew Research
September 28, 2017

April 28, 2017

I. EDUCATIONAL AND PROFESSIONAL HISTORY

A. Institutions Attended, Postgraduate Medical Education, Certification and Licensure

1. 1995 University of Mars, Orbit, Galaxy NNN B.S., Biochemistry
2. 2001 University of Saturn, Medical Center, Saturn, NNN. M.D.
3. 2002 University of Earth, Medical Center, No Mans, Land
   Internal Medicine Internship
4. 2002-2005 University of Earth, Medical Center, No Mans, Land
   Fellowship
5. 2005-2016 Pluto Medical License#11111 South
   2016-present Medical License#AlphaBeta11

B. Professional and Academic Positions

1. University of Pluto, Medical Center, Lunar, Universe
   Employed Physician (2005-2016)
2. University of Pluto, Medical Center, Lunar, Universe
   Instructor (2006-2016)
3. University of Mars, Medical Center, Orbit, Galaxy NNN
   Employed Physician (2016-present)

Investigator's Brochure (IB)

The Investigator's Brochure (IB) is a **document that summarizes previous findings and data,** both clinical and nonclinical, on the investigational product(s) that are relevant to the study:

- Mechanism of action, potential risks
- Clinical pharmacology-peaks, AUCs, metabolites, drug interactions
- Safety information
- Toxicities – general, geno, carcino, and cardiac
- CMC-impurities, shelf life, substance uniformity
- Describes adverse reactions, the 'expected' adverse reactions associated with previous use of the investigational product
- Previous clinical trials and animal experiments

All **Investigator's Brochure (IB)** amendments and versions need to be saved during the entire trial

POLL QUESTION

Who signs the Form FDA 1572?

1. Clinical Investigator (a.k.a. Principal Investigator)
2. Sponsor
3. Coordinator
4. FDA
5. Laboratory
6. All of the above
7. Only 1

ANSWER: #7

The investigator's signature on this form constitutes the investigator's affirmation that he or she is qualified to conduct the clinical investigation and constitutes the investigator's written commitment to abide by FDA regulations in the conduct of the clinical investigations.

FDA Documents

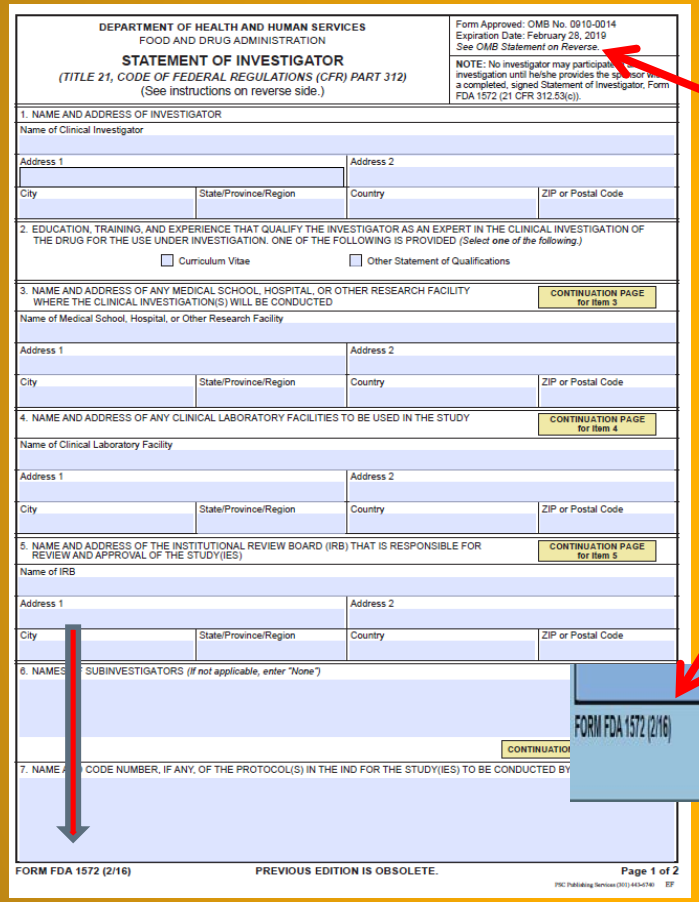
- ❑ **FDA Form 1571: Investigational New Drug Application (IND)**
- ❑ **FDA Form 1572: Statement of Investigator** for IND studies *(21 CFR Part 312)*
  - FDA Guidance https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf
- ❑ **FDA Form 3674: Certificate of Compliance with requirements of ClinicalTrials.gov Data Bank**
- ❑ **FDA Financial Disclosure Form** *(21 CFR Part 54)*
- ❑ **Investigator Agreement** for device studies *(21 CFR Part 812)*
- ❑ **FDA** approval or authorization letters
- ❑ **FDA Correspondence Log** *(if applicable)*

Watch expiration dates on bottom of electronic forms!

Go to **FDA website** for ***most current versions*** of FDA Forms to download:

https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm

Example Form FDA 1572: Statement of Investigator



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: February 28, 2019
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
Name of Clinical Laboratory Facility
Address 1 | Address 2
City | State/Province/Region | Country | ZIP or Postal Code

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — CONTINUATION PAGE for Item 5
Name of IRB
Address 1 | Address 2
City | State/Province/Region | Country | ZIP or Postal Code

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*
CONTINUATION

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY

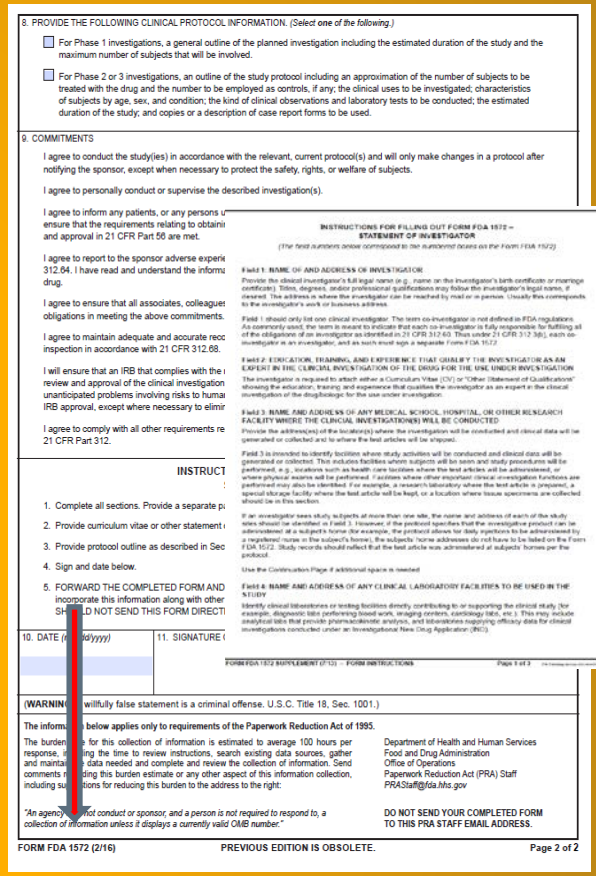
FORM FDA 1572 (2/16) PREVIOUS EDITION IS OBSOLETE. Page 1 of 2

ALWAYS CHECK

Expiration date

FDA WEBSITE
LATEST VERSION
1572 FORM

FORM FDA 1572 (2/16) PREVIOUS EDITION IS OBSOLETE. Page 1 of 2



8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select one of the following.)*
☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
☐ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS
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 u… ensure that the requirements relating to obtainin… and approval in 21 CFR Part 56 are met.
I agree to report to the sponsor adverse experi… 312.64. I have read and understand the informa… drug.
I agree to ensure that all associates, colleague… obligations in meeting the above commitments.
I agree to maintain adequate and accurate reco… inspection in accordance with 21 CFR 312.68.
I will ensure that an IRB that complies with the … review and approval of the clinical investigation … unanticipated problems involving risks to human… IRB approval, except where necessary to elimi…
I agree to comply with all other requirements re… 21 CFR Part 312.

INSTRUCT…
1. Complete all sections. Provide a separate p…
2. Provide curriculum vitae or other statement …
3. Provide protocol outline as described in Sec…
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND … incorporate this information along with other … SHOULD NOT SEND THIS FORM DIRECT…

10. DATE (…/dd/yyyy) | 11. SIGNATURE …

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

The inform… below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden … for this collection of information is estimated to average 100 hours per response, i… ding the time to review instructions, search existing data sources, gather and maint… data needed and complete and review the collection of information. Send comments r… ding this burden estimate or any other aspect of this information collection, including su… tions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency … not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

FORM FDA 1572 (2/16) PREVIOUS EDITION IS OBSOLETE. Page 2 of 2

INSTRUCTIONS FOR FILLING OUT FORM FDA 1572 – STATEMENT OF INVESTIGATOR

(The field numbers below correspond to the numbered boxes on the Form FDA 1572)

Field 1: NAME OF AND ADDRESS OF INVESTIGATOR
Provide the clinical investigator's full legal name (e.g., name on the investigator's birth certificate or marriage certificate). Titles, degrees, and/or professional qualifications may follow the investigator's legal name, if desired. The address is where the investigator can be reached by mail or in person. Usually this corresponds to the investigator's work or business address.

Field 1 should only list one clinical investigator. The term co-investigator is not defined in FDA regulations. As commonly used, the term is meant to indicate that each co-investigator is fully responsible for fulfilling all of the obligations of an investigator as identified in 21 CFR 312.60. Thus under 21 CFR 312.3(b), each co-investigator is an investigator, and as such must sign a separate Form FDA 1572.

Field 2: EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION
The investigator is required to attach either a Curriculum Vitae (CV) or "Other Statement of Qualifications" showing the education, training and experience that qualifies the investigator as an expert in the clinical investigation of the drug/biologic for the use under investigation.

Field 3: NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED
Provide the address(es) of the location(s) where the investigation will be conducted and clinical data will be generated or collected and to where the test articles will be shipped.

Field 3 is intended to identify facilities where study activities will be conducted and clinical data will be generated or collected. This includes facilities where subjects will be seen and study procedures will be performed, e.g., locations such as health care facilities where the test articles will be administered, or where physical exams will be performed. Facilities where other important clinical investigation functions are performed may also be identified. For example, a research laboratory where the test article is prepared, a special storage facility where the test article will be kept, or a location where tissue specimens are collected should be in this section.

If an investigator sees study subjects at more than one site, the name and address of each of the study sites should be identified in Field 3. However, if the protocol specifies that the investigative product can be administered at a subject's home (for example, the protocol allows for daily injections to be administered by a registered nurse in the subject's home), the subjects' home addresses do not have to be listed on the Form FDA 1572. Study records should reflect that the test article was administered at subjects' homes per the protocol.

Use the Continuation Page if additional space is needed.

Field 4: NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY
Identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an Investigational New Drug Application (IND).

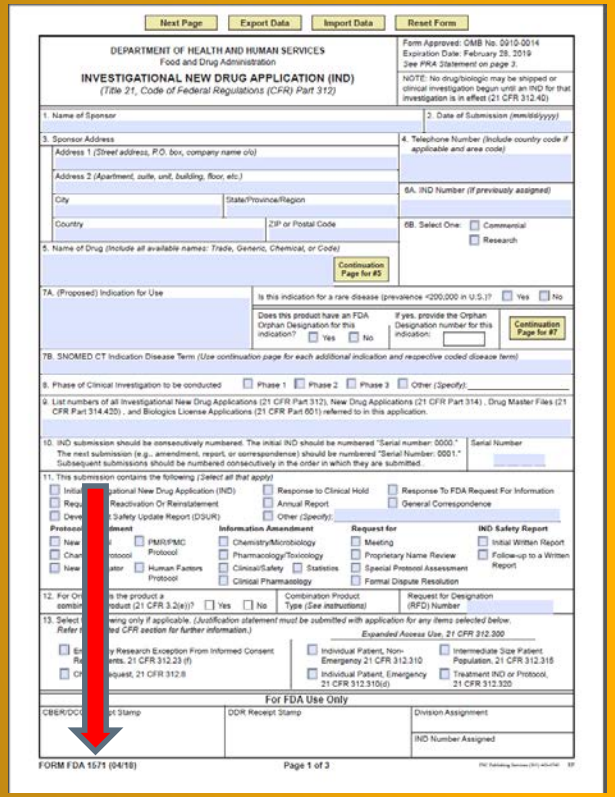
FORM FDA 1572 SUPPLEMENT (7/13) – FORM INSTRUCTIONS Page 1 of 3

www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm074728.pdf

Example Form FDA 1571:

FDA IND Application Number: Must accompany any amendments, annual reports, IND safety reports or general correspondence the sponsor submits to the FDA about the IND.

Form Fields have changed!!



NEW

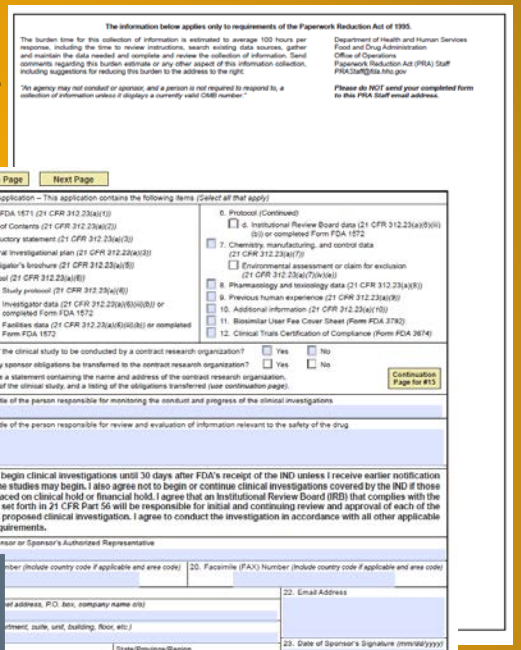
ALWAYS CHECK

FDA WEBSITE

for

LATEST VERSION

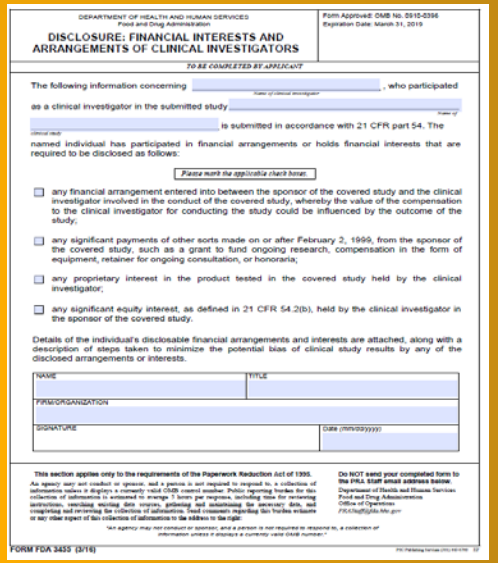
1571 FORM



https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083533.pdf

Financial Disclosure Forms (FDF)

- **Financial Disclosure Forms (FDFs)** certify the absence of certain financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to FDA, or to disclose those financial interests and arrangements to the agency and identify steps taken to minimize the potential for bias (21 CFR 54)
- Signed by the PI, sub-investigators, and each applicable research team member listed on the FDA 1572
- Protocol title and number should match the title and number listed on FDA Form 1572
- If any of the **five financial interest questions** are checked “Yes” a statement addressing the nature, amount of interest, arrangement or payment must be attached to the FDF
- Ancillary Disclosures:
  - **FDA Form 3410:** Confidential Financial Disclosure Report
  - **FDA Form 3453:** Certification: Financial Interests and Arrangements of the Investigators
  - **FDA Form 3455**: Disclosure: Financial Interests and Arrangements of the Investigators



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: March 31, 2019

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

The following information concerning _____ (Name of clinical investigator), who participated as a clinical investigator in the submitted study _____ (Name of clinical study) is submitted in accordance with 21 CFR part 54. The named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes

- ☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;
- ☐ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
- ☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;
- ☐ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

NAME	TITLE
FIRM/ORGANIZATION	
SIGNATURE	Date (mm/dd/yyyy)

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

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. Public reporting burden for this collection of information is estimated to average 1 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

"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 number."

Do NOT send your completed form to this PRA Staff email address below:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
PRAStaff@fda.hhs.gov

FORM FDA 3455 (3/16)

Link for additional information: http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf

Delegation Records

The principal investigator (PI) is responsible to maintain a ‘List” of appropriately qualified persons to whom significant trial-related tasks have been delegated (ICH section 4.1.5):

* Describe delegated study role tasks/supervision
* Identify training received/ongoing
* Identify dates of study involvement

Document evidence of three main points for delegating tasks:

1. Education
2. Experience (state licensures/curriculum vitaes-CVs)
3. Training of individuals to whom task are delegated

Records may include:

- Delegation of Authority (DAF)
- Delegation of Responsibilities (DOR)
- Delegation of Authority Log (DOA)

Delegation Of Authority Log (DOA)

or Delegation Of Authority Form (DAF)

- **The DOA is dictated by the ICH (under E6) and the FDA adapts as guidance.**
- **Log** of **Assigned Study Responsibilities** and descriptions signed/dated by the Principal Investigator (PI)
- **Documents PI delegation of trial related duties to other qualified and appropriately trained research study team members**
  - The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site.
- ***ALL*** Research Team Members should be on the IRB application:
  - **Start and Stop Dates of delegated duties**
  - **PRINTED** name, initials, & original signatures
  - **Descriptions of study responsibilities**

Delegation Of Responsibility (DOR)

Staff specific form that documents **Significant Trial Related Duties** that an individual research team member is responsible for.

- **Documents PI delegation of trial related duties to other qualified and appropriately trained research study team members**
  - The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site.

- Be sure to include **ALL** research team members on IRB application:
  - **START and STOP DATES of delegated duties**
  - **PRINTED** name, initials, & original signatures
  - **Descriptions of STUDY RESPONSIBILITIES**

Delegation of Responsibilities Log (DOR)

Example:

Delegation of Responsibilities Log

Investigator Name:	Protocol:	Site Number:

List staff to whom the Principal Investigator (PI) has delegated significant study-related duties.

Name	Responsibilities*	Initials	Signature	Start Date	End Date	PI Initials/Date

By initialing above, I, the PI, declare that during the conduct of the above study, I have delegated the following study-related activities:

*Responsibilities Legend		
1. Administer Consent	6. Randomize Subjects	11. Complete Study Forms
2. Screen Subjects	7. Dispense Study Drug	12. Provide Discharge Instructions
3. Obtain Medical History	8. Drug Accountability	13. Make Follow-up Phone Calls
4. Perform Physical Exam	9. Assess Adverse Events	14. Query Management
5. Determine Eligibility	10. Complete Source Documents	15.

Signature of Principal Investigator: _____ Date: _____

Version 4.0 - 2012-03-14

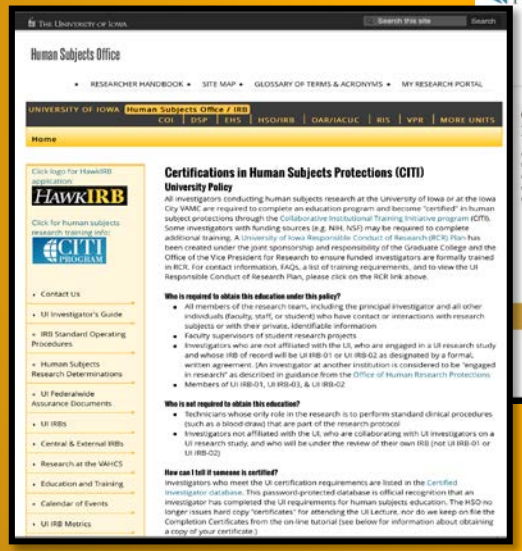
Page _____

Check if final page of log: ☐

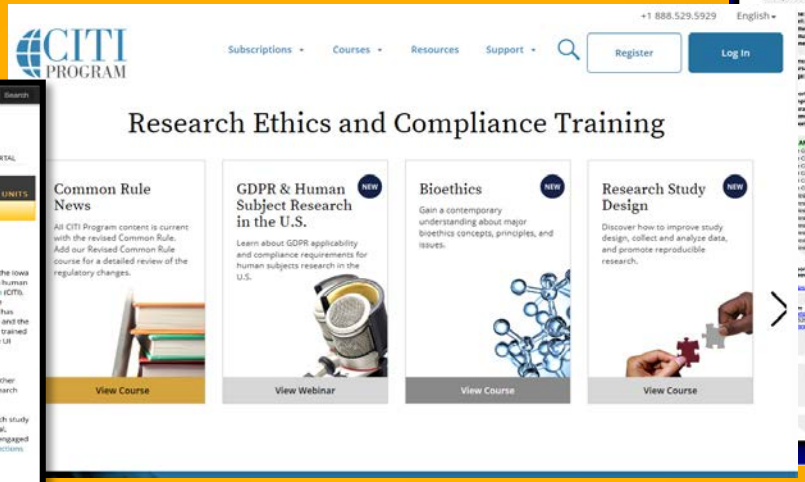
***TIPS: The form is a generic example of the DOR form your sponsor/CRO may provide. You will be required to maintain for each study at your site. The form must be updated on an ongoing basis throughout trials to reflect any staff changes.**

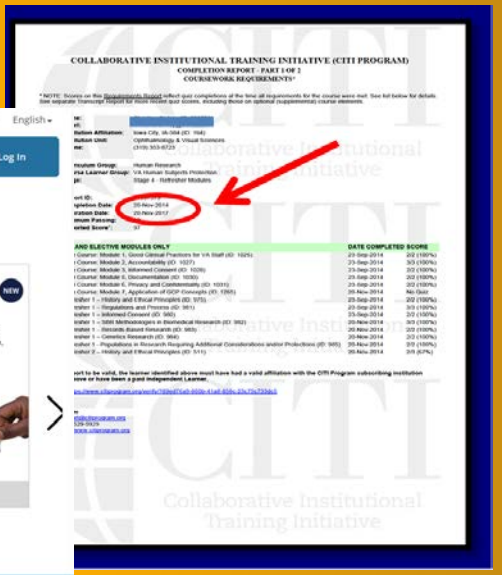
Research Educational Training

- Current training certificates for all study team members
  - Human Subject Protections (HSP)
  - Good Clinical Practice (GCP)



https://hso.research.uiowa.edu





https://www.citiprogram.org

Training Documentation

- Documentation of study-related training, specific Study:
  - Procedures
  - Certifications
  - Protocol training

- Study specific procedure
- Electronic Data Entry
- Training for shipping biologics (IATA) Dangerous Goods Training
- Electronic data entry
- **DOCUMENT THE TRAINING!!!**

**Note: Be sure to have a process in place to check qualifications / credentials

Example Training Log:

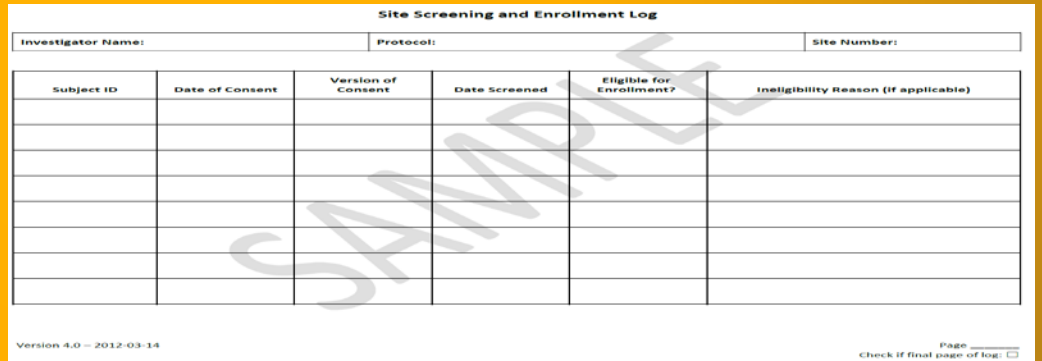
Training Log

Investigator Name:	Protocol:	Site Number:

Printed Name	Signature	Title of Training	Date of Training

Screening/Enrollment Log

- Used to document the consent and screening of all subjects and the outcome of each screening
- Contains subject's assigned study code, date screened, eligibility for enrollment and/or reason for screen failure
- **NO subject identifiers**
  - Tracked separately using a **Code List**
- Follow site Screening and Enrollment Plan for enrolled subjects (as per IRB application)
- May be paper or electronic



Site Screening and Enrollment Log

Investigator Name:	Protocol:	Site Number:

Subject ID	Date of Consent	Version of Consent	Date Screened	Eligible for Enrollment?	Ineligibility Reason (if applicable)

SAMPLE

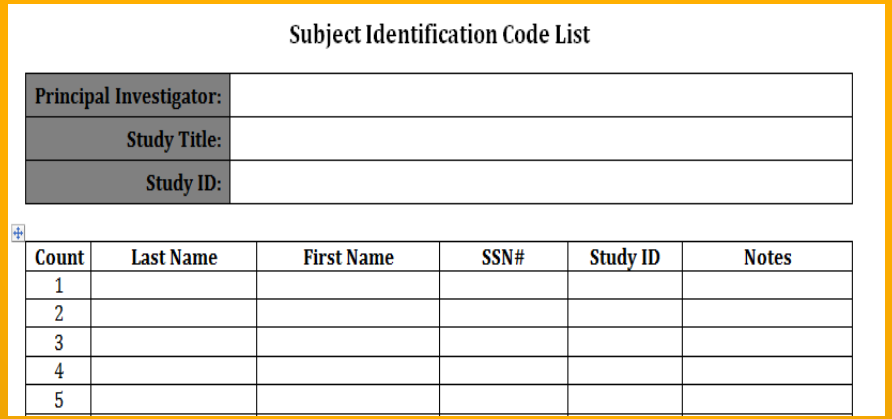
Version 4.0 – 2012-03-14

Page
Check if final page of log: ☐

Subject Identification Code List

- **Confidential List** of trial subject names

- Allows the Investigator/Institution to reveal identity of subject (ONLY)
- ***NEVER*** share with outside entities (e.g. Sponsor, CRO)



Subject Identification Code List

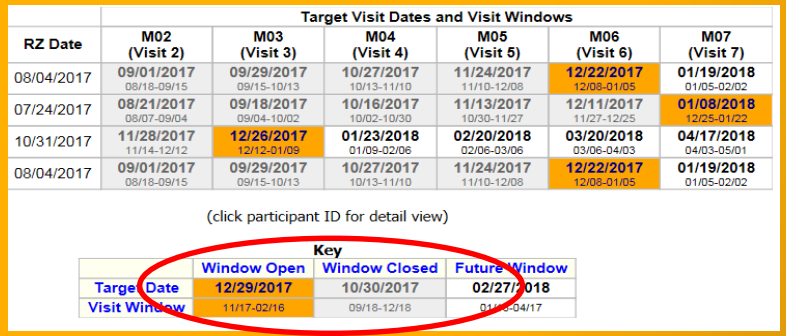
Principal Investigator:	
Study Title:	
Study ID:	

Count	Last Name	First Name	SSN#	Study ID	Notes
1					
2					
3					
4					
5					

Subject Visit Tracking Log

- Log of enrolled **Subject Visits**
- Used to track scheduled visits as per protocol **Target Visit Dates** (e.g. within visit windows)
- Reasons for **Early Termination (ET)**
- **Electronic Visit Log:** visit compliance with protocol-specific appointments/or procedure visit

Example:



RZ Date	Target Visit Dates and Visit Windows					
	M02 (Visit 2)	M03 (Visit 3)	M04 (Visit 4)	M05 (Visit 5)	M06 (Visit 6)	M07 (Visit 7)
08/04/2017	09/01/2017 08/18-09/15	09/29/2017 09/15-10/13	10/27/2017 10/13-11/10	11/24/2017 11/10-12/08	12/22/2017 12/08-01/05	01/19/2018 01/05-02/02
07/24/2017	08/21/2017 08/07-09/04	09/18/2017 09/04-10/02	10/16/2017 10/02-10/30	11/13/2017 10/30-11/27	12/11/2017 11/27-12/25	01/08/2018 12/25-01/22
10/31/2017	11/28/2017 11/14-12/12	12/26/2017 12/12-01/09	01/23/2018 01/09-02/06	02/20/2018 02/06-03/06	03/20/2018 03/06-04/03	04/17/2018 04/03-05/01
08/04/2017	09/01/2017 08/18-09/15	09/29/2017 09/15-10/13	10/27/2017 10/13-11/10	11/24/2017 11/10-12/08	12/22/2017 12/08-01/05	01/19/2018 01/05-02/02

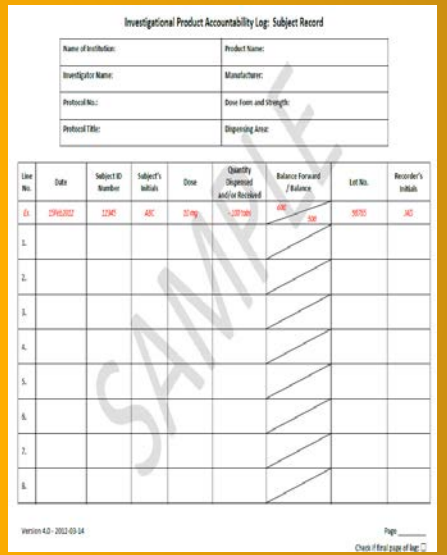
(click participant ID for detail view)

Key

	Window Open	Window Closed	Future Window
Target Date	12/29/2017	10/30/2017	02/27/2018
Visit Window	11/17-02/16	09/18-12/18	01/18-04/17

Investigational Product (IP) Accountability Records

- Documentation of IP delivery to the site, inventory at the site, use by each subject, return to site, return to sponsor or destruction
  - ❑ *Shipment Records*
  - ❑ *Receipt documentation*
  - ❑ *Stock (inventory) Record*
  - ❑ *Subject Dispense Record*
  - ❑ *Temperature logs*


Investigational Product Accountability Log: Subject Record

Name of Institution:	Product Name:
Investigator Name:	Manufacturer:
Protocol No.:	Dose Form and Strength:
Protocol Title:	Dispensing Area:

Line No.	Date	Subject ID Number	Subject's Initials	Dose	Quantity Dispensed and/or Received	Balance Forward / Balance	Lot No.	Recorder's Initials
Ex.	15Feb2022	12345	ABC	10 mg	-100 tabs	600 / 500	98765	JAS
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								

SAMPLE

Version 4.0 - 2012-03-14

Page _____

Check if final page of log: ☐

❑ Document location of records (e.g. Note-To-File in Reg Binder)

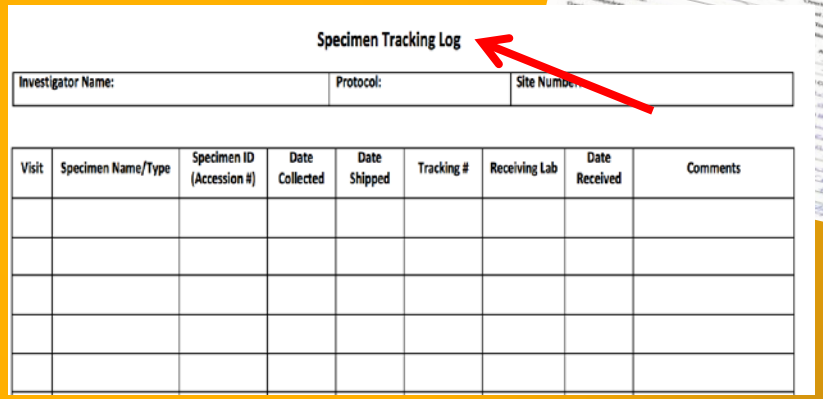
- **Investigational Drug Services** (IDS) maintain records (e.g. study product is blinded to the research team)

Clinical Laboratory Documentation

- ❑ Lab reference ranges
- ❑ Copy of lab certificates/accreditations (CAP, CLIA)
- ❑ PI determination of *clinical significance* for all lab reports along with PI signature/date
  - ❑ *i.e., clinically significant, nonsignificant, or abnormal*

Lab Specimen Tracking Log

- ❑ Specimen tracking log
- ❑ Shipping documentation
- ❑ Storage temperature logs
- ❑ Freezer inspection reports



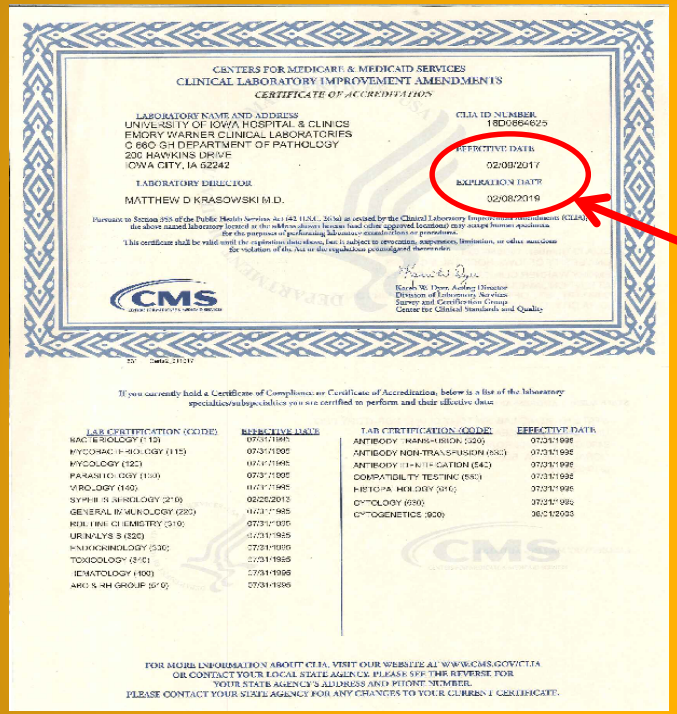
Specimen Tracking Log

Investigator Name:	Protocol:	Site Number:

Visit	Specimen Name/Type	Specimen ID (Accession #)	Date Collected	Date Shipped	Tracking #	Receiving Lab	Date Received	Comments

Clinical Lab Certificates

Examples: UIHC Pathology CLIA/CAP



CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS
UNIVERSITY OF IOWA HOSPITAL & CLINICS
EMORY WARNER CLINICAL LABORATORIES
C 660 GH DEPARTMENT OF PATHOLOGY
200 HAWKINS DRIVE
IOWA CITY, IA 52242

CLIA ID NUMBER
16D0664625

EFFECTIVE DATE
02/09/2017

LABORATORY DIRECTOR
MATTHEW D KRASOWSKI M.D.

EXPIRATION DATE
02/08/2019

Pursuant to Section 353 of the Public Health Service Act (42 USC. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon based solely upon its payment of user charges for the purpose of performing laboratory examinations and procedures.

This certificate shall be valid until the expiration date shown, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective dates

LAB CERTIFICATION (CODE)	EFFECTIVE DATE
BACTERIOLOGY (110)	07/31/1995
MYCOBACTERIOLOGY (115)	07/31/1995
MYCOLOGY (120)	07/31/1995
PARASITOLOGY (130)	07/31/1995
VIROLOGY (140)	07/31/1995
SYPHILIS SEROLOGY (210)	06/28/2013
GENERAL IMMUNOLOGY (220)	07/31/1995
ROUTINE CHEMISTRY (310)	07/31/1995
URINALYSIS (320)	07/31/1995
ENDOCRINOLOGY (330)	07/31/1995
TOXICOLOGY (340)	07/31/1995
HEMATOLOGY (400)	07/31/1995
ABO & RH GROUP (510)	07/31/1995

LAB CERTIFICATION (CODE)	EFFECTIVE DATE
ANTIBODY TRANSFUSION (520)	07/31/1995
ANTIBODY NON-TRANSFUSION (530)	07/31/1995
ANTIBODY IDENTIFICATION (540)	07/31/1995
COMPATIBILITY TESTING (550)	07/31/1995
HISTOPATHOLOGY (610)	07/31/1995
CYTOLOGY (620)	07/31/1995
CYTOGENETICS (630)	06/12/2003

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.

COLLEGE of AMERICAN PATHOLOGISTS

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

The College of American Pathologists certifies that the laboratory named below

University of Iowa Hospitals & Clinics
Emory Warner Clinical Laboratories
Iowa City, Iowa
Matthew D. Krasowski, MD, PhD

CAP Number: 1768801
AU-ID: 1183440
CLIA Number: 16D0664625

has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to November 20, 2019 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Chair, Commission on Laboratory Accreditation

President, College of American Pathologists

https://www.medicine.uiowa.edu/pathology/research/pathology-clinical-trials-support-core

Adverse Events Documentation

Adverse Events (AEs) / Serious Adverse Events (SAEs)

- ❑ SAE reporting forms and memos
- ❑ Correspondence, acknowledgement of reports of AEs
- ❑ Documentation that event was reported to IRB, Sponsor, regulatory authorities
- ❑ IND Safety Reports
- ❑ AE/SAE Log

Unanticipated Problems (UPs) / AEs of Special Interest

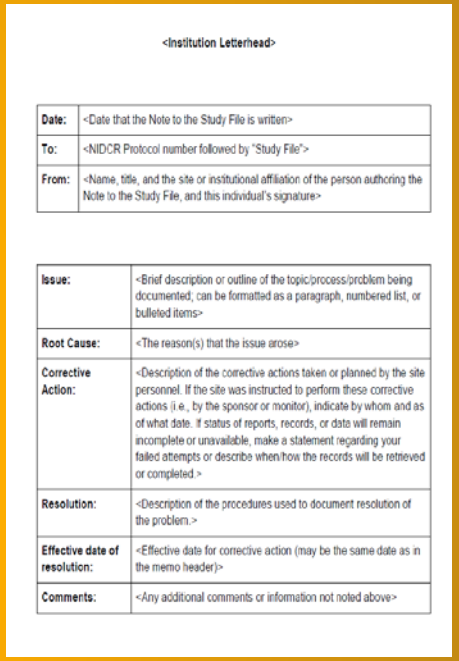
- ❑ Both UPs and AESI reports to IRB, Sponsor, FDA, and other regulatory authorities

Clinical Site Monitoring Visits

- **Monitoring Signature Log/Visit Record**
- Both **Monitor** and **Research Team Member** involved with the site visit must sign and date **Visit Log**:
  - Study Initiation Visit (SIV)
  - Interim Monitoring Visit (IMV)
  - Close-Out Visit
- File **original letter/email** announcing each visit
- File all visit correspondence
- **Follow Up Letter or report** documenting findings and action items
- Documentation that actions have been taken /issues have been resolved - signed off by monitor

Notes-To-File (NTFs)

- When used to document an issue in the conduct of the study or a discrepancy (e.g., missing data item or a missing date on a consent form) should include:
  - **Description** of the issue/discrepancy/or omission
  - **Root cause** for the issue/discrepancy/or omission
  - **Corrective** and **preventive actions** that have been taken to address the root cause
- Should be used “thoughtfully”
- When used properly a NTF can be a positive practice
- Document logistical problems or locations
- Document decisions made, instructions from the study sponsor, or problems experienced



<Institution Letterhead>

Date:	<Date that the Note to the Study File is written>
To:	<NIDCR Protocol number followed by “Study File”>
From:	<Name, title, and the site or institutional affiliation of the person authoring the Note to the Study File, and this individual’s signature>

Issue:	<Brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list, or bulleted items>
Root Cause:	<The reason(s) that the issue arose>
Corrective Action:	<Description of the corrective actions taken or planned by the site personnel. If the site was instructed to perform these corrective actions (i.e., by the sponsor or monitor), indicate by whom and as of what date. If status of reports, records, or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed.>
Resolution:	<Description of the procedures used to document resolution of the problem.>
Effective date of resolution:	<Effective date for corrective action (may be the same date as in the memo header)>
Comments:	<Any additional comments or information not noted above>

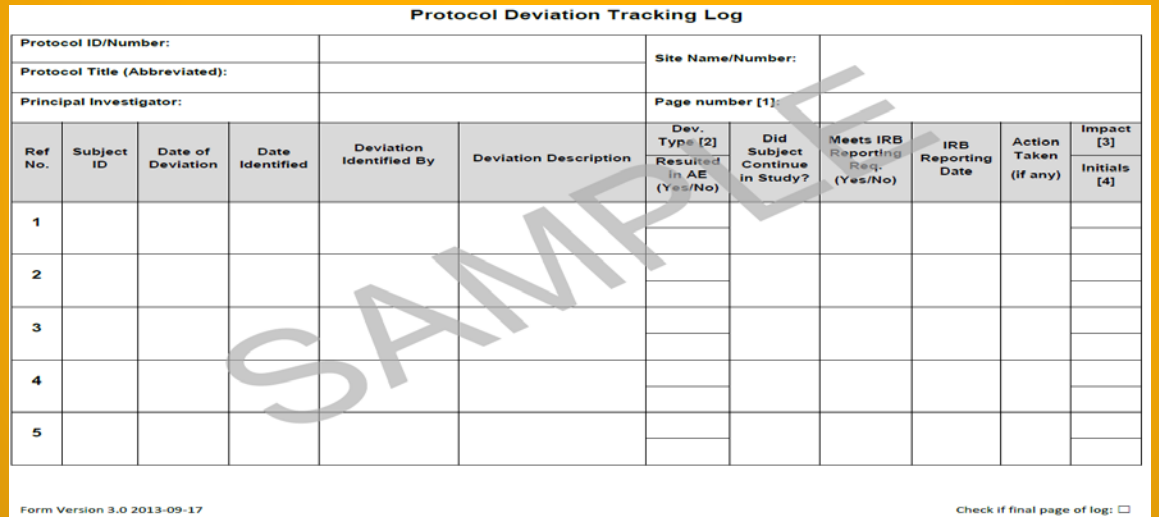
Discrepancy or Problem → **Action**

Notes-To-File (NTFs)

- Print on institution letterhead
- Authored, signed, and dated by an individual responsible for its content:
  - **Principal Investigator (PI)** for issues/discrepancies/deviations related to PI responsibilities
    - e.g., *human subject protection or data integrity* at the site
  - **An appropriately credentialed individual from the sponsor** for issues/discrepancies/deviations related to actions taken by the sponsor/monitor
    - e.g., clarification of a protocol section
- If applicable, send a scanned pdf to a **Data Management Center (DMC)**
- File **NTFs** in the site **Regulatory Binder**

Deviation Log

- Used to document all protocol **Deviations** that occur on the study
- **Deviations** – changes, divergence, or departure from the approved study design or procedures of the research protocol that have not been approved by the IRB and Sponsor
- Report all **Deviations** to IRB and Sponsor as per requirements



Protocol Deviation Tracking Log

Protocol ID/Number:						Site Name/Number:					
Protocol Title (Abbreviated):											
Principal Investigator:						Page number [1]:					
Ref No.	Subject ID	Date of Deviation	Date Identified	Deviation Identified By	Deviation Description	Dev. Type [2] Resulted in AE (Yes/No)	Did Subject Continue in Study?	Meets IRB Reporting Req. (Yes/No)	IRB Reporting Date	Action Taken (if any)	Impact [3] Initials [4]
1											
2											
3											
4											
5											

SAMPLE

Form Version 3.0 2013-09-17

Check if final page of log: ☐

Good Documentation Practice

- ✓ Document ***what is*** - and ***what is not*** – ***done***
- ✓ Provide reasons for any missed information
- ✓ Use of indelible **blue** or **black** ink on paper forms.
  - Reduces fading over time or ***smudging***
  - **No** pencils, felt-tipped markers or white-out

- ✓ No back or future dating – use of **current date** when entries are made.
- ✓ No **“ditto”** marks for repetitive data
- ✓ Instrument printouts: Adhere printout to Original Source Document; add initials and date where the printout is attached.
- ✓ Printouts sent for research data purposes need **coded, redacted, or de-identified**

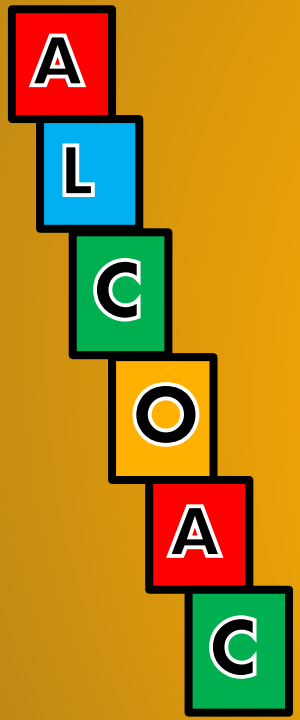
Good Documentation Practice

Correcting Information

- ✓ ***Errors happen***! **Corrections** are expected
- ✓ Single ~~***line through incorrect information,***~~ do not to obscure original data
- ✓ No writing over data (e.g. turning a 0 into a 9) - hides the original data
- ✓ Enter the **correct** information
- ✓ **Initial** and **date** when the **corrections** were made - *CAS 05/17/2018*
- ✓ Entries on study documents and changes to those entries should be made by study team members with the authority to do so as delegated by the PI

Good Documentation Practice

"ALCOA-C"



Attributable: to who created the record; sign & date

Legible: readable, clear, comprehensible, identifiable

Contemporaneous: record activity as events occur

Original: original source document

Accurate: exact, truthful, correct, verifiable date

Complete: capture all required data, no blank spaces

****Changes to source documents should be traceable.**

21 CFR 58.130 (e)
ICH GCP (R2) 4.9.0 & 8.1

Electronic Documentation and Data

- ✓ **Electronic Medical Records (EMR)** present **security**, and other legal challenges; know your institutional regulations at UIHC

- ✓ **Electronic Data Capture (EDC)** systems are being utilized for databases, electronic case report forms **(eCRF),** clinical monitoring, and maintaining regulatory documents

Examples: Medidata Rave, Orcale, InForm,

OmniComm, RedCAP

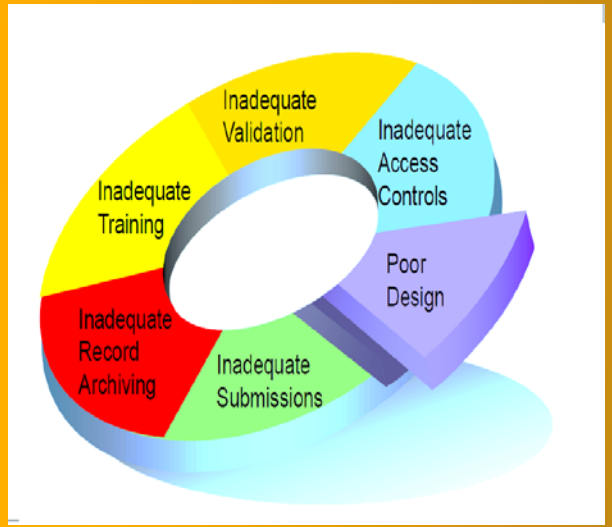
- ✓ **FDA guidance** (May 2016) for ***source data*** should be **ALCOA**

Electronic Data

21 CFR 11 FDA regulations for Electronic Records; Electronic Signatures

- **Validate Systems** to ensure accuracy, reliability, consistent performance, ability to discern invalid or altered records
- **Access Controls**: Internal security safeguards limit access, passwords, authorized users, automatic times log off
- **External Security:** protect records
- **Audit Trails:** track all changes; date/time
- **Document** computer education, training and experience

Commonly cited issues:



Documentation Resources

Websites and Links for more information

- https://nccih.nih.gov/grants/toolbox#startup
- Register the Clinical Trial(s) https://www.clinicaltrials.gov
- ICH E6 Guidance: https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf
- Electronic Code of Federal Regulations https://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl
- University of Iowa Resources – Human Subjects Office & HAWKIRB: https://hso.research.uiowa.edu
- Final Rule: https://www.nih.gov/news-events/news-releases/hhs-take-steps-provide-more-information-about-clinical-trials-public
- NIDCR's Toolkit for Clinical Researchers: https://nidcr.nih.gov/research/toolkit
- Office for Human Research Protections (OHRP): https://www.hhs.gov/ohrp/
- https://www.nidcr.nih.gov/research/human-subjects-research/toolkit-and-education-materials
- https://nccih.nih.gov/grants/toolbox/pdfs

THANK YOU!


Q&A
questions
answers
investigation
inquiry
ask
help
problem
query
info
confused
q&a
asking