Essential Documents – Understanding Your Regulatory Binder

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Objectives

- Define Essential Documents and the purpose of the Regulatory Binder
- Understand regulatory requirements and how to demonstrate compliance
- Describe Good Documentation Practice (GDP/ALCOA-C)
- Review best practices for maintenance

Key Definitions

Essential Documents	Documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced (ICH GCP 8.1)
Source Documentation	Original documents (or commonly known as certified true copies), data, and records where information is first captured (e.g: medical records, clinical and office charts, laboratory notes, etc.)
Case Report Forms (CRF)	A printed or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject
Key Personnel	Individuals who contribute in a substantive way to the development or execution of a protocol, or are involved in the consent process
Monitoring	The act of overseeing the progress of a clinical trial and ensuring that it is conducted in accordance with the protocol, SOPs, GCP, and any other regulatory requirements
Guidance	A statement of advice or instruction pertaining to practice (recommendation)
Regulation	Originates in an agency with either governmental or official authority and has the power of law

Applicable Regulatory Requirements & Guidance

ICH harmonisation for better health

ICH-GCP Sec. 8.2.2
Essential Documents for the Conduct of a Clinical Trial

FDA

21 CFR 312.62
Investigator recordkeeping and record retention

OHRP
Office for Human Research Protections

45 CFR 46 Protection of Human Subjects in Research (includes 5 subparts)

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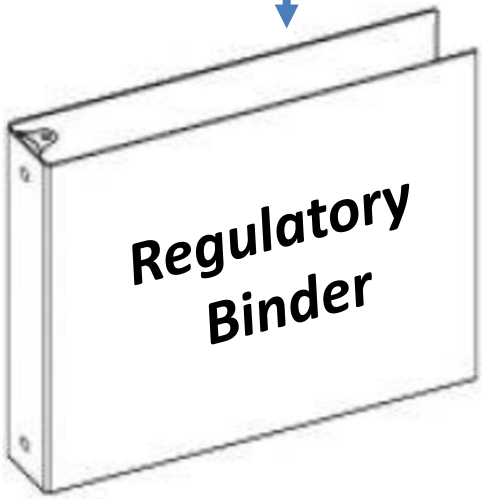
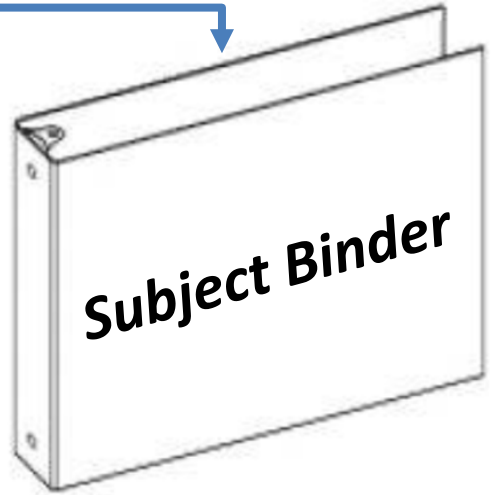
Relevant institutional policies and procedures

What is a Regulatory Binder?

- A framework for storing study-specific information, essential & regulatory documents
- AKA: Investigator Site File, Trial Master File, Study Binder, etc.

Essential Document Types

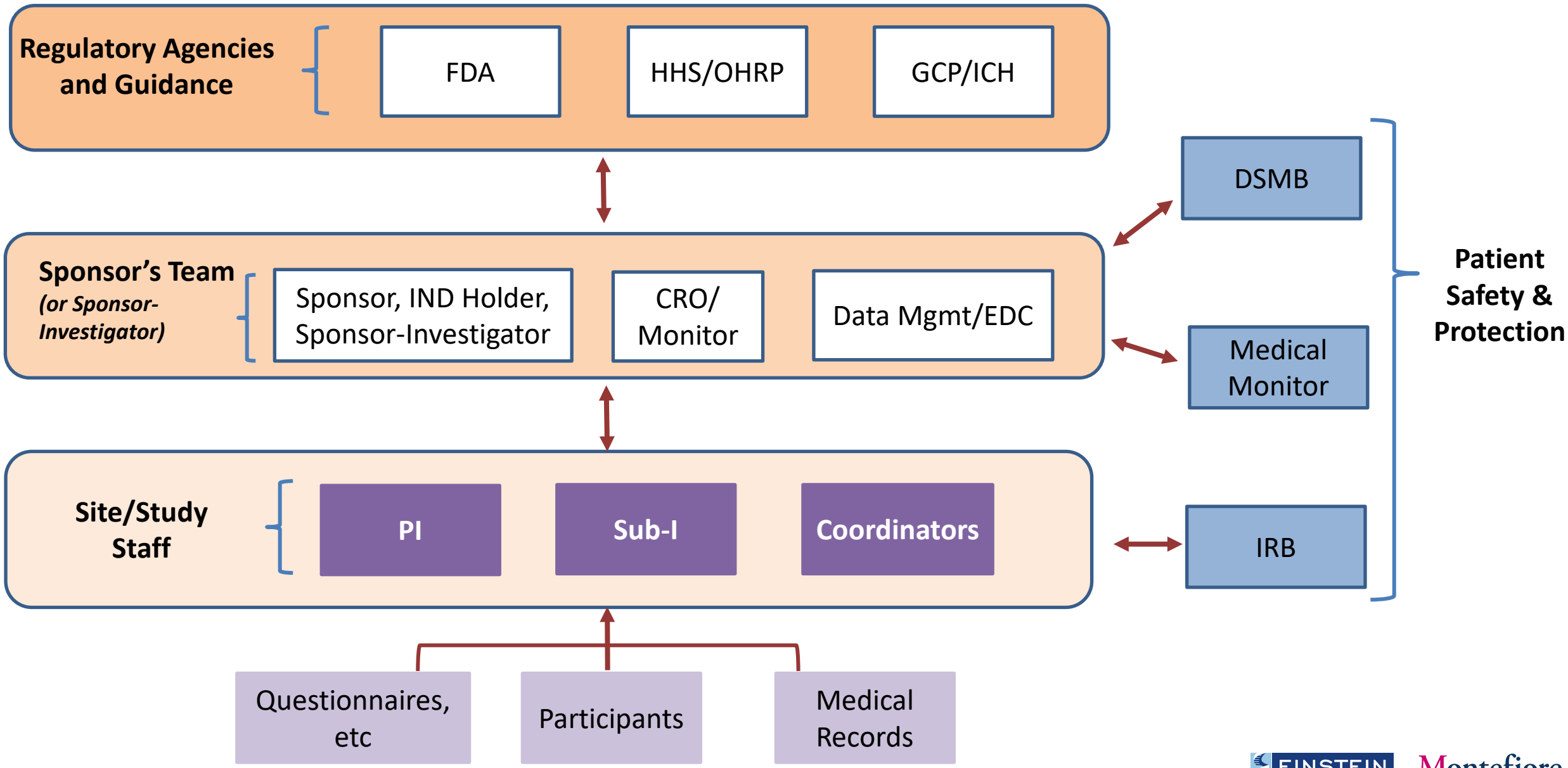




Study Specific: Documents other than participant files that substantiate the conduct of the study. Should be able to recreate the study from the study documentation.

Subject Specific: Data collected from/about individual patients; Should tell the story of the subject's participation in the study and the conduct of the study.

Where Do Essential Documents Come From?



Purpose of Regulatory Binder

Demonstrate Compliance	• Protect the rights, safety & welfare of the subjects • Adhere to regulatory & institutional requirements • Protocol adherence/compliance • Control of the investigational product • Event monitoring & reporting • Supervise the conduct of the investigation
Maintain Record Keeping	• Framework for organizing essential documents
Organization and Access	• Allows for ease of access to records (for study team & auditors) • Permits evaluation of study conduct and determine data quality

Investigator Responsibilities, FDA:
21 CFR 312.3(b)
21 CFR 812.3(i)

Purpose of Regulatory Binder

Show and Tell**……..**a method of organizing and maintaining Essential Documents in order to demonstrate compliance

☐	PI has selected qualified study staff and obtained/maintained appropriate documentation to support their qualifications	**CVs, Licenses, Training**
☐	Accountability of the Investigational Product	**Drug Accountability Log**
☐	Provided study team with the information needed to conduct an investigation properly	**Protocol Training Log and Slides**
☐	Monitored progress of study and informed IRB, sponsor and/or FDA of significant adverse effects	**IRB Submissions, Approvals, SAE Reports**
☐	Assured that the study is conducted in accordance with the investigational plan	**Protocol Training, Monitoring Logs**
☐	Maintained appropriate record-keeping and retention	**Filing is current, NTFs, clear documentation/notes**
☐	Maintained an effective IND or IDE - when applicable	**FDA Submissions**
☐	Ensured Trial Registration (clinicaltrials.gov) - when applicable	**CT.gov registration**

PI Responsibilities & Regulatory Binder Elements

DEMONSTRATE!

Investigator Responsibility	Adherence to regulatory and institutional requirements	Supervise the conduct of the investigation	Protocol Adherence, control IP, safety event monitoring & reporting
Regulatory Binder Purpose	Regulatory/Institutional Requirements	Study Management & Oversight	Compliance
Essential Documentation	○ IRB Submission ○ IRB Approval Letters ○ IRB Approved Docs. ○ IRB Correspondence ○ FDA Documents	○ Del of Authority Log ○ Staff Training Logs/ Certs. ○ Staff Qualifications: CVs, Lic., etc. ○ Team Meeting Minutes, slides, attendees	○ Informed Consent ○ Source Docs, CRFs ○ Event Reporting ○ Drug Accountability

YOUR PROOF

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Regulatory Binder Maintenance

- Establish at the beginning of a study
- Not always a single binder – BUT you **must know where to find individual files**
- Paper vs Electronic format (Complion eReg)
- Should be organized to facilitate **ease of use and reference**
  - Create tabs for each section, label spine with protocol number, PI name, and study site. Include a Table of Contents
- Files should be **kept up-to-date**, including all document versions (file in reverse chronological order)

Regulatory Binder Maintenance

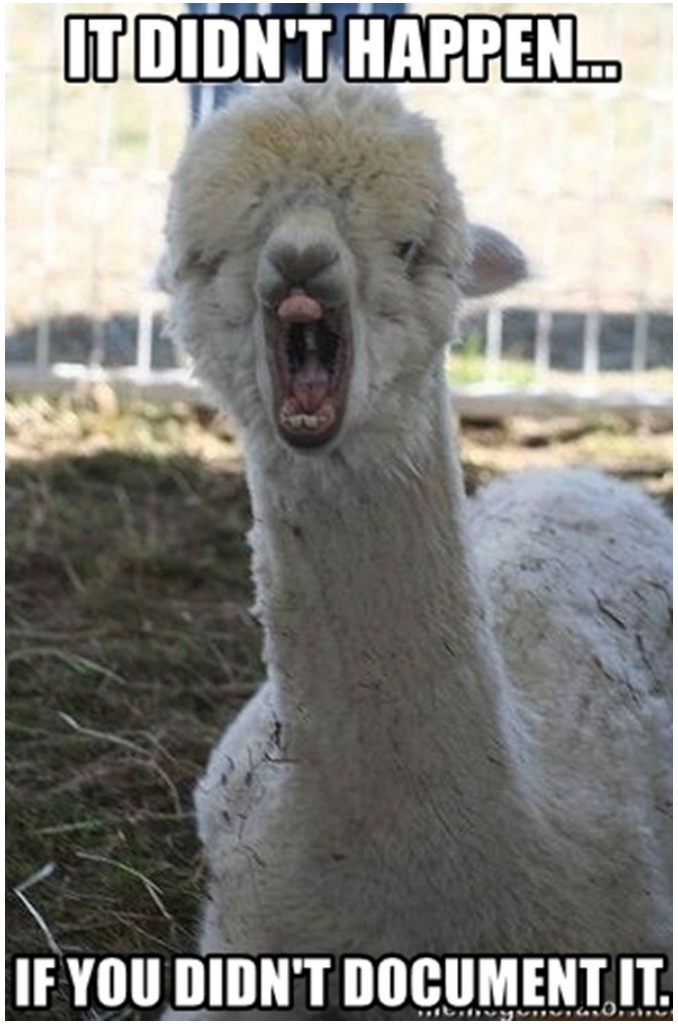
- Document in Pen **(never pencil)**
- If documents are maintained electronically, write a **Note-to-File** indicating the location and who maintains them.
- Store in a **safe and secure location** - accessible to study staff at all times.
- Should be reviewed throughout the study and is **subject to audit**.

Good Documentation Practice (GDP)

- Standards for creation and maintenance of study documents

- ***Telling the Story*** - study documents and data collection forms record the details of the subject's participation in the study

- Complete and accurate study documentation supports the fundamental principle of protection of study participant's safety, rights, and well-being.



Attributes of GDP: “ALCOA-C”

Attributable - it should be clear who has documented the data.

Legible - readable and signatures identifiable.

Contemporaneous - Data should be recorded, signed, dated at the time of conduct and dated with the current date (no predating or postdating).

Original – original or exact copy (the first record made by the appropriate person).

Accurate - accurate, consistent and real representation of facts.

Complete – ensure all fields are completed, even data that is not captured (“N/A”)

Essential Documents: Regulatory vs. Subject Files

Regulatory Binder Files
Protocol
IRB Documents
Consent Forms (clean/IRB approved)
CRF/Data Collection Tools
Sponsor/NIH/FDA documents
FDA documents
DSMB
Staff Training/Qualification
Clinicaltrials.gov Registration
Delegation of Authority/Resp. Log
Monitoring Log
Laboratory Documents

Subject Binder Files
Signed ICFs
Signed HIPAA
Completed Paper CRF
Completed Questionnaires/Diary
Telephone Correspondence
SAE Form

The Documents

General Study Documents	Investigational Product	Oversight	Event Reporting & Safety	Staff Training & Qualifications
Study Contacts Protocol Consent Template Case Report Forms Data Collection Tools Enrollment Log	Investigator Brochure Product Insert Accountability Log Temperature Log	IRB DSMB FDA Monitoring Visits Reports Audits	Protocol Deviations Log AE/SAE Log SAE Report/CRF	Delegation of Authority Log CVs Licenses GCP/HSR Training FDF COI Lab Certifications

General Study Documents

Study Protocol (all versions): Describes the study aims, research design, research site(s), plus all study-related activities and procedures.

- **File**
  - ✓Include signed Protocol Signature Page, if applicable
  - ✓May include Protocol Synopsis if a separate document
  - ✓Consider Protocol Versions log

- **Demonstrates**: PI understands procedures, updates; oversight

➢ **Guidance: GCP** 8.2.2; 8.3.2

General Study Documents

Consent Form (all versions) - Documents that information given to participants supports their ability to give voluntary informed consent

- **File**:
  - ✓Clean sponsor and IRB approved versions
  - ✓Translated versions
  - ✓Include consent process documents if IRB approved

- **Demonstrates:** Using most recently approved versions consistent with current protocol

➢ **Regulation: HHS**: 45 CFR 46.116; 45 CFR 46.117 & **FDA**: 21 CFR 50; 21 CFR 56

➢ **Guidance: GCP**: 8.2.3; 8.2.7; 8.3.2; 8.3.12

General Study Documents

Case Report Forms (CRFs) & Data Collection Tools: Original blank copies of all forms used to collect study data (e.g., case report forms, questionnaires, surveys)

- **File**
  - ✓Include version number/date – in the event that CRF/data collection sheets change during course of study.

- **Demonstrates:** Source document used to capture specific subject related information is current and approved

➢ **Regulation: FDA**: 21 CFR 312.53; 312.62

➢ **Guidance: GCP**: 8.3.14; 8.3.15; 4.9.3

General Study Documents

Enrollment Log: List of participant Study ID numbers, eligibility, enrollment status

- **File**
  - ✓Must be maintained securely at site, esp. if includes PHI
  - ✓NTF if not kept in binder
  - ✓Timely updating

- **Demonstrates:** PI is keeping track of enrollment/eligibility of participants

➢ **Guidance: GCP**: 8.3.20; 8.3.21

Example: Enrollment Log

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)

Investigational Product

Investigator Drug Brochure (IB): Scientific information about the investigational product; Informs the assessment of Adverse Events that may occur while patients are on treatment *(or Package Insert if the drug is already marketed)*

- **File**
  - ✓Should be readily available to all study staff - it is the your reference regarding drug and potential side effects.
  - ✓All approved versions of the IB or updated package inserts

- **Demonstrates:** PI has understanding of dose, dose frequency/interval, methods of administration and safety monitoring procedures.

➢ **Regulation: FDA** 21 CFR 312.55; 312.57; 312.62; 812.140

➢ **Guidance: GCP**: 8.2.1; 8.3.1

Investigational Product

Drug/Device Accountability, Temperature Logs and Shipment Docs: Documents the allocation of IP to patients; storage conditions; tracks receipt and compliance of product

- **File**
  - ✓Log in real time
  - ✓NTF if logs are stored elsewhere (blinding implications)
  - ✓File shipment receipts in reverse chronological order
- **Demonstrates:** PI control over IP management; oversight of how IP should be maintained & stored

➢ **Regulation: FDA**: 21 CFR 312.55; 312.57; 312.62; 812.140

➢ **Guidance: GCP**: 8.2.1; 8.3.1; 8.3.23

Investigational Product

Drug Storage Waiver: Document from Investigational Drug Service (IDS) aka Research Pharmacy signifying that investigator and site meets qualifications to store investigational product (IP) outside of pharmacy.

- **File**
  - ✓ Required for each MMC site – may have to request from different MMC pharmacy per site

- **Demonstrates:** PI control over IP management; Compliance with institutional drug oversight requirements.

➢ **Guidance:** Institutional Storage & Dispensing of Investigational Drugs Policy

Oversight

IRB Submissions: Initial Application, Continuing Review, Amendments, Reportable Events, Closure.

IRB Approvals/Acknowledgments: All approval letters/notifications and/or decisions

- **Demonstrates:** IRB has reviewed and approved the study & any protocol amendments prior to commencing any study procedures; patient facing documents have been approved; investigator has reported new information & safety-related events as they occur.

➢ **Guidance: GCP**: 8.2.7; 8.2.9; 8.3.2 - 8.3.4

Oversight

Monitoring Log: A log of sponsor's interim site monitoring visits, usually with the purpose of performing source data verification and review.

Monitoring Visit Report: Report of findings and requirements for corrective action.

- **File**
  - ✓ Update in real time; preferable at end of visit (sponsor/CRO rep. may oversee)
  - ✓ Monitor/study staff signatures
- **Demonstrates:** Evidence of Sponsor oversight and Investigator compliance with sponsor's Safety Monitoring Plan

➢ **Guidance: GCP**: 5.18.1-7; 5.19.1-3; 6.10

Example: Monitoring Log

Monitoring Visit Log

Investigator Name:	Protocol:	Site Number:

Name	Signature	Purpose of Visit	Date of Visit

Oversight

DSMB Submissions/Memos: Copy of all DSMB reports/memos; any correspondence (e.g. e-mails, letters, meeting minutes) with the DSMB and its members; Sponsor-Investigators will need to file a copy of the Data and Safety Monitoring Plan itself (IRB approved).

- **File**
  - ✓ Reverse chronological order
  - ✓ Memos should be filed and reviewed in the event of implications for study (IRB amendments, subsequent info/reporting needed, etc.)

- **Demonstrates:** PI is aware of decisions/communications related data integrity, validity, and subject safety.

➢ **Guidance: GCP** 8.3.10; 5.19.3; 6.8

Event Reporting

Protocol Deviations Log: Includes a record of all minor/major deviations from the approved protocol; major deviations should be reported to the IRB and Sponsor

- **File**
  - ✓Update in real time/at time of awareness
  - ✓Data will be submitted at IRB continuing review

- **Demonstrates:** PI oversight of protocol implementation and due diligence if/when events occurred outside the protocol

➢ **Guidance: GCP** 3.3.7, 3.3.8, 4.5.2

Event Reporting

[Serious] Adverse Event Log (AE/SAE Log): Tracks and ensures timely reporting of all applicable adverse events to the IRB.

- **File**
  - ✓ Logs should be updated as soon as possible after a reportable event occurs, preferably on the same day.
  - ✓ Data will be submitted to IRB at Continuing Review (some SAE's will be real time reportable events to the IRB)

- **Demonstrates:** PI oversight of participant safety and adherence to IRB, Sponsor and FDA requirements

➢ **Guidance: GCP** 3.3.8; 4.11; 5.17; 8.3.17

Event Reporting

Serious Adverse Event Forms/Reports: Includes correspondence, copies and acknowledgements of reports for internal SAEs reported to the IRB and Sponsor and FDA, as applicable

Unanticipated Problems reports to IRB –related to expectedness (not just seriousness

- **File**
  - ✓ Reverse chronological order

- **Demonstrates:** PI oversight of participant safety and adherence to IRB, Sponsor, and FDA requirements

➢ **Guidance: GCP** 3.3.8; 4.11; 5.17; 8.3.17; Institutional IRB Reportable Events Policy

Example: Adverse Event Log

Adverse Event Log

STUDY NAME

Site Name: _____

IRB # : _____

Principal Investigator:

_____

Severity	Study Intervention Relationship	Action Taken Regarding Study Intervention	Outcome of AE	Expected	Serious Adverse Event (SAE)
1 = Mild 2 = Moderate 3 = Severe 4 = Life-Threatening	0 = Not related 1 = Unlikely related 2 = Possibly related 3 = Probably related 4 = Definitely related	0 = None 1 = Dose modification 2 = Medical Intervention 3 = Hospitalization 4 = Intervention discontinued 5 = Other	1 = Resolved 2 = Recovered with minor sequelae 3 = Recovered with major sequelae 4 = Ongoing/Continuing treatment 5 = Condition worsening 6 = Death 7 = Unknown	1 = Yes 2 = No	1 = Yes 2 = No (if yes, complete SAE form)

Adverse Event	Start Date	Stop Date	Severity	Relationship	Action Taken	Outcome of AE	Expected?	SAE?

Staff Training/Qualifications

Delegation of Authority/Responsibility Log (DOA/DOR): Log detailing the study related roles of all IRB approved study staff as delegated by the PI.

- **File**
  - ✓Keep current with start and stop dates for all individuals
  - ✓Printed name, initials and original signatures

Demonstrates: PI oversight and proper delegation of task to appropriately qualified personnel; Tracking start-stop dates of individuals to correlate with IRB and Sponsor approvals –**ensure this is consistent!**

➢ **Guidance: GCP** 4.1.1; 8.2.10; 8.3.5

Example: Delegation of Authority (DoR)

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: _____

Staff Training/Qualifications

Curriculum Vitae (CV)/Licenses: CVs on file for all key personnel; Licenses for all clinicians and relevant professionals

- **File**
  - ✓ CVs should be signed, dated, and updated every 2 years
  - ✓ Licenses should be current –set reminders for expirations
  - ✓ If filed collectively for the dept./division/study team write NTF indicating the location

- **Demonstrates:** PI has chosen qualified and credentialed study staff

➢ **Guidance: GCP** 4.1.1; 8.2.10; 8.3.5

Staff Training/Qualifications

Good Clinical Practice (GCP)/Human Subjects Research (HSR): Documents completion of required GCP/HSR Training (usually CITI)

- **File**
  - ✓ For each staff member
  - ✓ GCP expires every 3 yrs.; HSR expires every 5 yrs.
  - ✓ Set reminder for expiration dates

Demonstrates: Compliance with institutional training requirements and general human subjects research training standards

➢ **Guidance:** Institutional Training and Education Policy

Staff Training/Qualifications

Protocol Training Log/Slides: Log of any protocol/procedure related training; can be sponsor or PI led.

- **File**
  - ✓Include signatures of all attendees
  - ✓Copies of slides/minutes as evidence of training

- **Demonstrates:** PI has ensured study staff have been trained on most current protocol and procedures.

➢ **Guidance:** Institutional Principal Investigator Responsibilities Policy

Staff Training/Qualifications

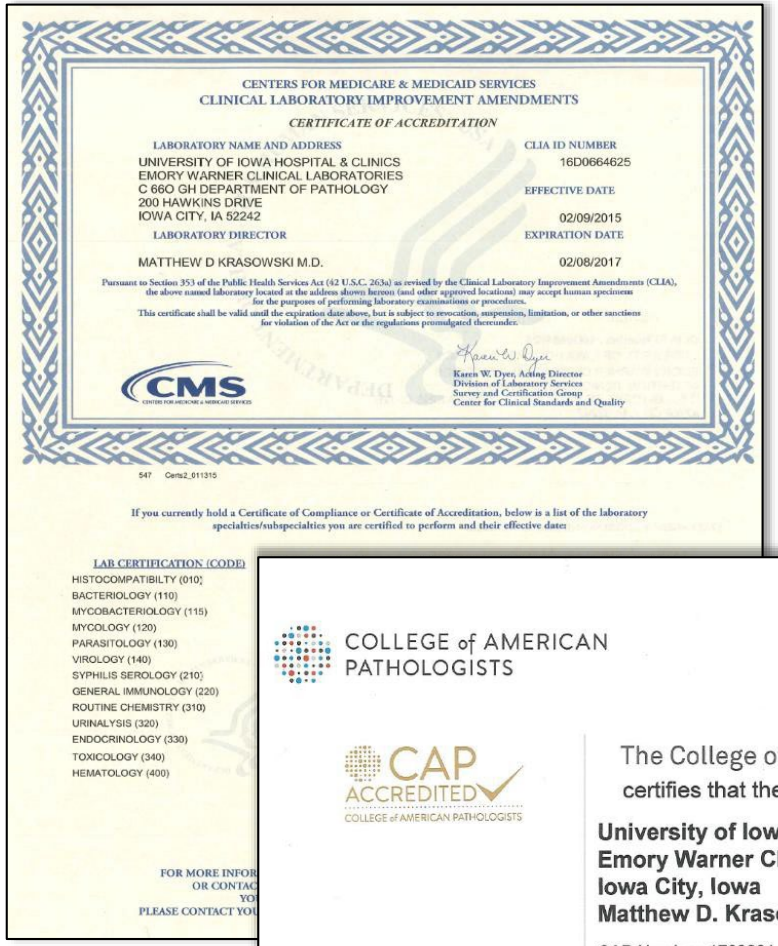
Laboratory Documents: Certificates of accreditation (if using diagnostic lab) - CAP/CLIA; Lab Director CV; Normal Ranges/Values; Specimen Log (if applicable)

- **File**
  - ✓ If lab documentation is filed separately or electronically, use NTF
  - ✓ Research labs typically do not have lab certifications, e.g., CLIA, CAP, and may not have "normal" lab values. If research labs are used, ensure that the lab director's CV.

- **Demonstrates:** Exhibits the competency of all lab facilities being utilized, and to support the reliability of test results.

➢ **Guidance: GCP** 8.2.11; 8.2.12; 8.2.14; 8.3.6; 8.3.7

Local Lab Certificates



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 66O GH DEPARTMENT OF PATHOLOGY
200 HAWKINS DRIVE
IOWA CITY, IA 52242

CLIA ID NUMBER
16D0664625

EFFECTIVE DATE
02/09/2015

LABORATORY DIRECTOR
MATTHEW D KRASOWSKI M.D.

EXPIRATION DATE
02/08/2017

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.
This certificate shall be valid until the expiration date above, 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

547 Certs2_011315

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)
HISTOCOMPATIBILTY (010)
BACTERIOLOGY (110)
MYCOBACTERIOLOGY (115)
MYCOLOGY (120)
PARASITOLOGY (130)
VIROLOGY (140)
SYPHILIS SEROLOGY (210)
GENERAL IMMUNOLOGY (220)
ROUTINE CHEMISTRY (310)
URINALYSIS (320)
ENDOCRINOLOGY (330)
TOXICOLOGY (340)
HEMATOLOGY (400)

FOR MORE INFOR
OR CONTAC
YO
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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

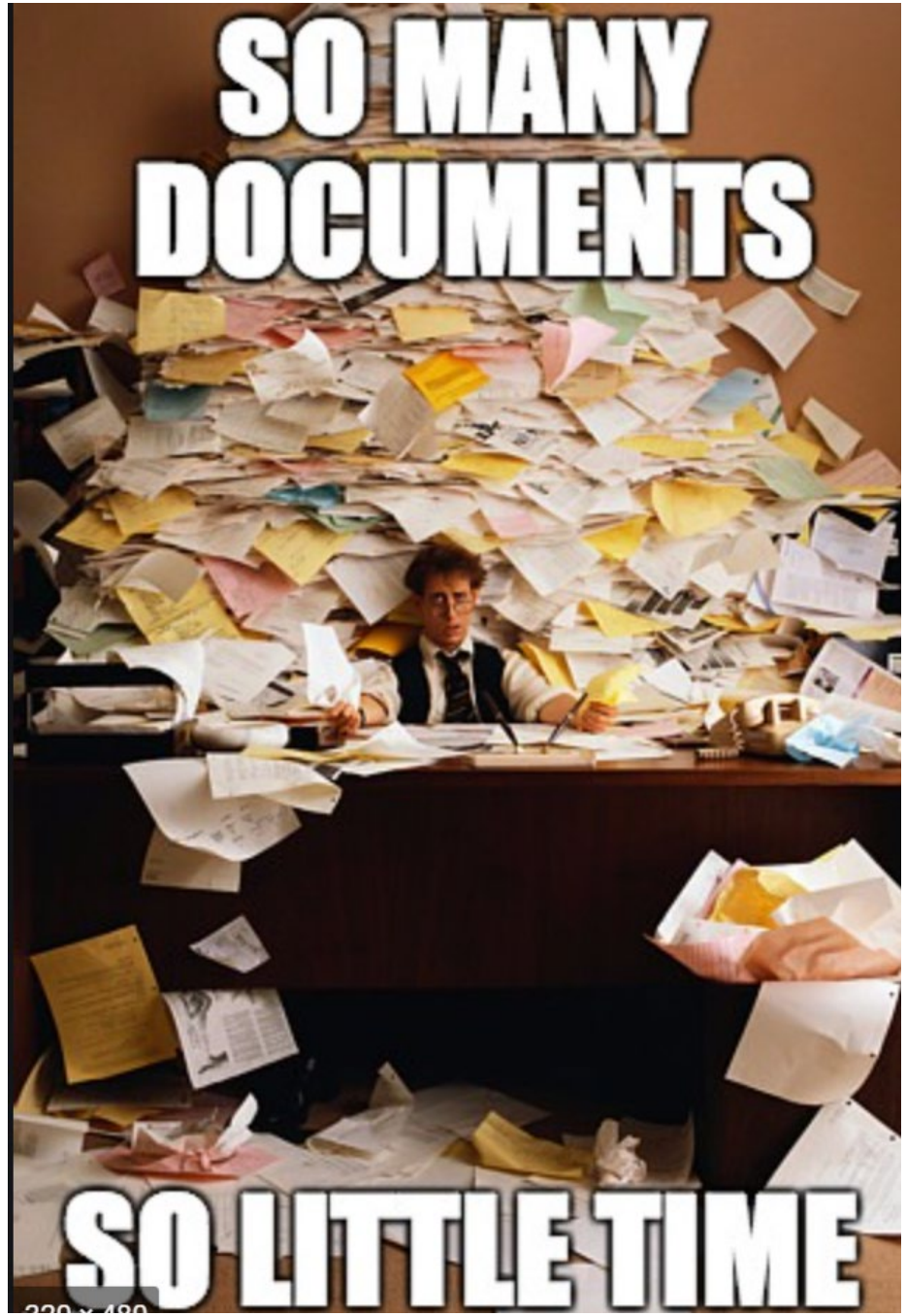
has met all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to November 20, 2017 to maintain accreditation.

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

- College of American Pathologists (CAP)
- Clinical Laboratory Improvement Amendments (CLIA)
- <u>Best Practice</u>: Set request schedule based on expiration date (q 2yrs)


SO MANY
DOCUMENTS
SO LITTLE TIME

Binder Requirements by Study Type

Human Subjects Research (Foundational)		Involves Labs		FDA Regulated
Protocol Study Staff (CVs, Lic.,Training, DOA) IRB Documentation Consent Forms Data Collection Tools Screening/Enrollment Log AE Monitoring & Reporting Monitoring/Auditing Clicaltrials.gov registration *(if applicable)*	+	CLIA/CAP Lab Normal Ranges Lab Director CV	+	***Industry Sponsored-*** FDA 1572 Drug/Device Info (Insert/IB) Accountability Logs Financial Disclosure IDS Drug Waiver *(per MMC guidance)* + ***Sponsor-Investigator (if PI holds IND) –*** FDA 1571/3674/3500a FDA Acknowledgment Letter FDA Submissions Clinicaltrials.gov registration

Do NOT include in your Regulatory Binder

- Study contract/budget information
- Participant information or protected health information (PHI)
  - Subject Binder
- Internal audit reports (IRB/Compliance)

Corrections to Source or Essential Documents

Error Noted	Do	Don't
Correction needed on original source document	• Make a single line through original entry and initial/date correction (with current date) • Keep original information clearly visible	• Scribble over mistake • Use White Out/Tape • Re-write over top of entry • Destroy originals • Alter past-dated notes (by writing alongside or adding to prior entries)
Missing data located at a later date	Incorporate into research record with current date	• Ignore/ leave blank • Backdate information

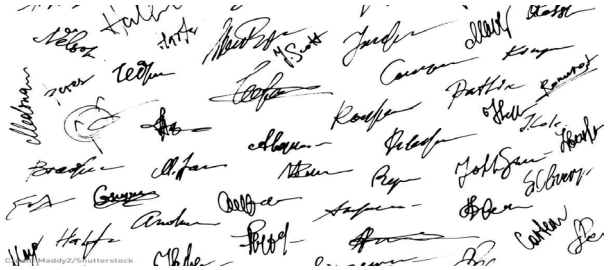
A - attributable
L - legible
C - contemporaneous
O - original
A - accurate
C - complete

Do

Don't

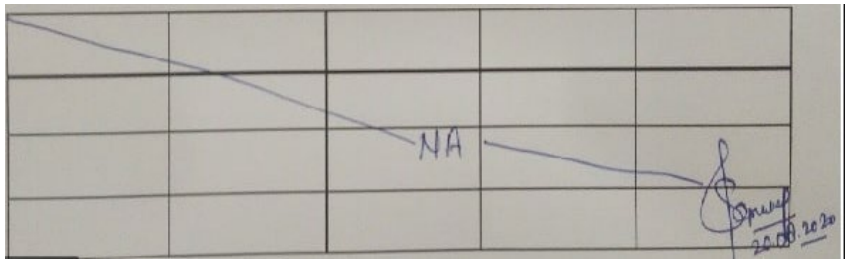
Attributable

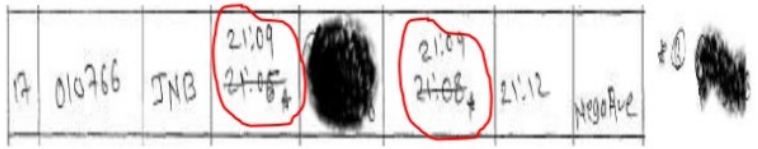
Activity (mCi)	Infusion Start Time (24 hr clock)	Infusion Stop Time (24 hr clock)
09.4	13:~~15~~	13:~~25~~



Not Legible

Completeness





Not Attributable

Attributable

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07 05 09 04 0D

Not Attributable

Note to File

- **Purpose**: May be used to correct errors, an explanation of departure from the protocol, or as a clarification of a process

- **How to Document**: Reasons for any departure and attempts to correct or prevent in the future should be included.

- **Create a template**:
  - Protocol Number & Title
  - Subject ID (if applicable)
  - Name of person completing form
  - Date
  - Description of the issue/problem and resolution

Example: Note to File Template

<Institution Letterhead>

Date:	<Date that the Note to the Study File is written>
To:	<protocol number followed by "Study File">
From	<Name, title, and site or institutional affiliation of 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 Actions:	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>

Stakeholders in Data Integrity

Industry
Data Offices

Data Safety Committee (DSC) Monitors

Industry
Clinical Research Associates and Monitors

Database Managers

Site
PIs, Clinicians & Coordinators

Stakeholders in Data Integrity

Site or Industry
Biostatisticians

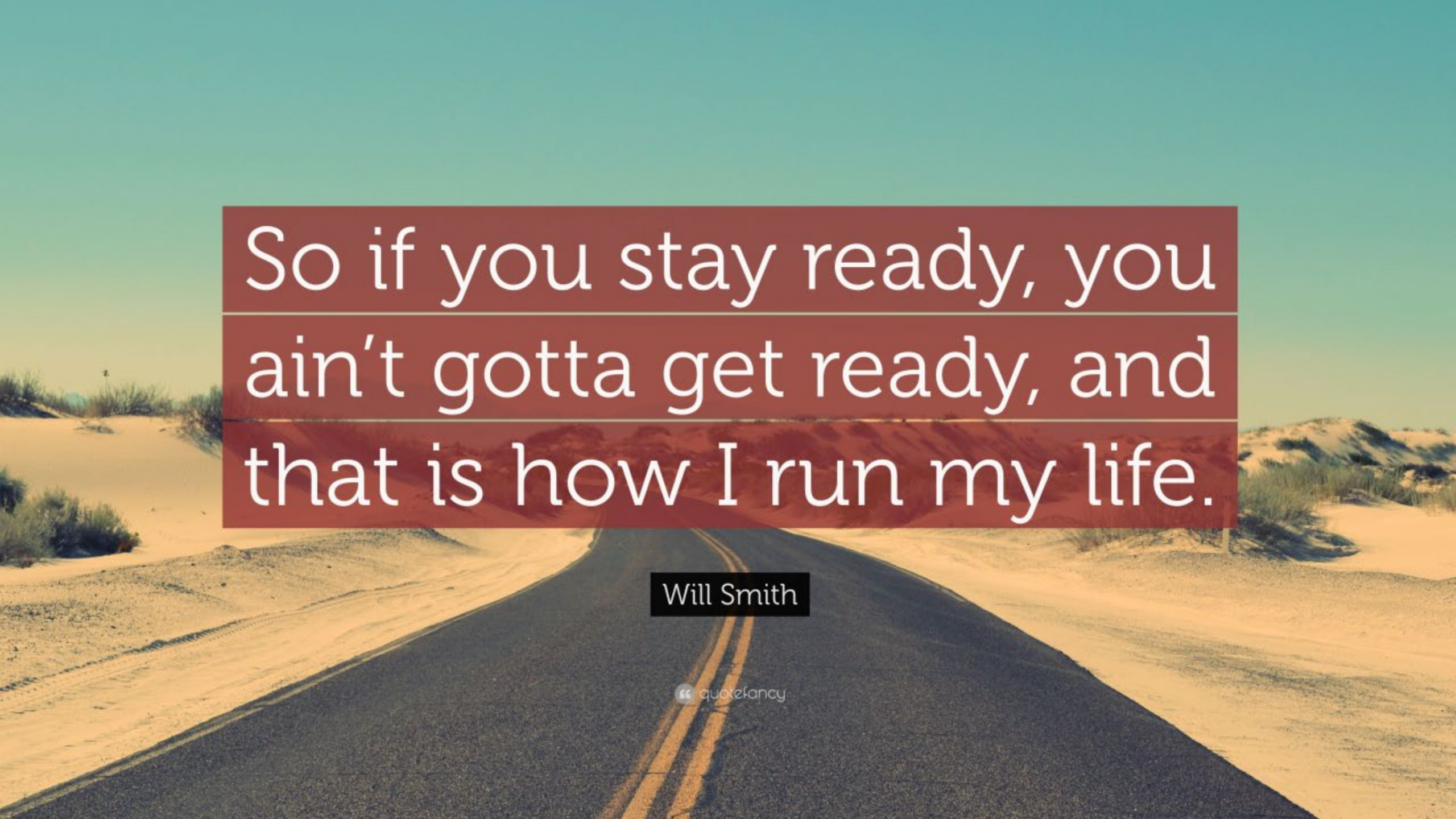
Tips for Successful Record Keeping

- Customize the Regulatory Binder to meet the specific criteria for your study
- Store binder in a secure location (e.g., locked file cabinet)
- Document and update materials in real-time
- File hard copy documents in reverse chronological order (most recent on top)
- Be consistent!
- Review documentation routinely
  - Use the IRB's Investigator Self-Audit tool as a guide
  - Address and resolve documentation issues immediately upon discovery

Tips for Successful Record Keeping

Mark your calendars!

- Documents expire (CVs, CITI Training, Licenses, etc.)
- Be ready for IRB Renewals/Progress Report Submission
- Prepare for Site Monitoring Visits


So if you stay ready, you ain't gotta get ready, and that is how I run my life.
Will Smith
quotefancy

Regulation & Guidance

HHS: 45 CFR 46- Protection of Human Subjects in Research
21 CFR 50 – Informed Consent for Human Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators

FDA: Part 312, Investigational New Drug Application
Part 812, Investigational Device Exemptions

OHRP: Guidance on Reporting Incidents

ICH: Good Clinical Practice, Guidance for Industry

General Policies

- Human Research Protection Program Policy
- Delegation of Authority Policy
- Principal Investigator Requirements
- Principal Investigator Responsibilities
- Disclosing Financial Conflicts of Interest to the Einstein IRB

➢ Einstein Office of Human Research Affairs: irb@einsteinmed.org, 718-430-2237

Other Policies & Guidance

Compliance and Reporting

Audit and Inspection Guidelines

Audit Policy

Conduct of Research

Research Record Retention Policy

Required Documentation for the Conduct of Research Involving Human Subjects

Investigational Drugs and Devices

Storage and Dispensing of Investigational Drugs

- Montefiore-Einstein Research Compliance: Clinicalresearch@Montefiore.org

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