UNC THE NORTH CAROLINA TRANSLATIONAL & CLINICAL SCIENCES INSTITUTE

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL NRP Network for Research Professionals

UNC OFFICE OF CLINICAL TRIALS

ORIENTATION FOR NEW CLINICAL RESEARCH PERSONNEL

MODULE 3

Presented by

NC TraCS Institute

UNC Office of Clinical Trials

UNC Network for Research Professionals

Online Logistics

- I will be monitoring the chat window for questions and will ask those questions to the presenter at the end of each talk, or during breaks in the conversation when the presenter invites questions.

- Slides will be emailed to everyone after the presentation, along with the evaluation link and any announcements.

- If you would like a certificate for ACRP/SOCRA credit, please complete the evaluation at the end of the presentation and send me an email – marie_rape@med.unc.edu

- Feel free to reach out to me either in the chat window or by email, I'm happy to help with anything you need.

Overall Agenda for Orientation

- **Module 1:** Introduction, NRP/ Education, and Office of Clinical Trials
- **Module 2:** IRB Processes, Conflict of Interest
- **Module 3:** GCP, Documentation, Informed Consent, Research Monitor Access
- **Module 4:** Contracts, Clinical Trial Agreements, Planning/Accounting of Funds, NIH Budgets, Billing Coverage Analysis
- **Module 5:** Recruitment, Study Start-up, Roles of Research Personnel, UNC Investigational Drug Services, UNC Device Policy
- **Module 6:** Introduction to RedCap, Investigator-Initiated Study Process, ClinicalTrials.gov, Documenting AEs & SAEs, IND and IDE studies

Good Clinical Practice & Study Documentation

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Clinical Research Associate; Pediatrics, Hematology/Oncology

NRP Steering Committee

Learning Objectives

Discuss Goals and Objectives of Good Clinical Practice (GCP)

Describe basic GCP principles that impact the investigator or research site

Discuss how GCP impacts documentation practices and trial management and document managment.

Describe the application of GCP principles through case scenarios

Summary/Learning Objectives Review

E6 Good Clinical Practice: Consolidated Guidance

- 1996: In an attempt to provide consistency among clinical trials, US, European Union, and Japan established a unified standard, called the International Conference on Harmonisation's "*Good Clinical Practice: Consolidated Guideline*," (ICH-GCP).

- Objective of "guidance is to provide a unified standard to facilitate mutual acceptance of clinical data by the regulatory authorities in these jurisdictions."

- E6 Good Clinical Practice: Consolidated Guidance recognized by industry sponsors as the **gold standard** for conduct of ethically and scientifically sound human subject research.

From the Introduction of Guidance for Industry, E6 Good Clinical Practice

Good Clinical Practice (GCP) Definition

Same definition for all stake holders (Site, Sponsor/CRO, IRB) (ICH 1.24)

Standard for the:

- Design (investigational plan; protocol)
- Conduct (how the study is carried out)
- Performance (investigator, sponsor, IRB, vendors)
- Monitoring (risk based, on site)
- Auditing (Internal, CRO, FDA)
- Recording
- Analyses
- Provides assurances that data and reported results are credible and accurate and that rights, integrity and confidentiality of trial subjects are protected

Topics Covered in ICH GCP

Describes:

- **Qualification of an investigator**
- Education and training of study staff
- Delegation of study-related tasks
- Requirement for IRB review
- Compliance with the protocol
- Responsibility for investigational product accountability
- Informed consent
- Safety reporting
- **Trial management & record keeping**
- **Data quality** and integrity, quality control
- **Essential documents** for a trial

Who Should Adhere to ICH E6 (R2) aka GCP?

- The general concept of GCP is essential for <u>any research study involving human subjects</u>.
- Whether conducting research involving a new drug or device, a behavioral intervention, or an interview/survey, Good Clinical Practice (GCP) provides investigators and study teams with the tools to protect human subjects and collect quality data.
- Following the ICH-GCP is one of the best ways to substantiate the quality of **any research study** and its resulting data.

Investigator Oversight

- Investigator ultimately responsible for conducting the trial
  - The investigator is responsible for demonstrating active supervision/oversight of persons with delegated tasks (Section 4.2.5)
  - The investigator is responsible for ensuring there are adequate resources to adhere to the protocol.
    - What could be some barriers?
  - Ensure research staff are qualified, capable and trained for their assigned trial-related tasks (Section 4.2.6)
    - Careful hiring and selection; additional documentation of training and implementation of procedures to ensure integrity of trial related procedures (SOPs/WIs)
  - Lack of PI oversight is a common finding on audits and inspections.
  - Consider a PI oversight plan

Good Data is the Life of a Study

- Inadequate and inaccurate records are another common finding on audits and inspections.
- Examples include:
  - Revisions on source worksheets were unclear
  - Failure to document dates related to serious adverse events
  - Failure to report adverse events accurately and correctly to the IRB
- Good data starts at the source! (pun intended)

Source Data and Source Documents

- All information in the original record necessary for the reconstruction and evaluation of the trial and includes:
  - clinical findings
  - observations
  - or other activities related to the progress of a clinical trial (Section 1.51)
- ***Original*** documents, data, and records
  - Source data are contained in source documents (original records or certified copies). (Section 1.52)
  - Records and reporting may be written or electronic
- "Source data should be attributable, legible, contemporaneous, original, accurate, and **complete**" (Section 4.9.0)
  - ALCOA-C

ALCOA-C

Attributable	**Who created or modified the record, when and why it changed** **Eg: Study staff who performed an assessment/procedure should sign or initial when documenting the event. If someone else is present that person should also sign or initial.**
Legible	The record and dates of an entry are clear and can be interpreted and understood.
Contemporaneous	The data are recorded in real-time, the data are observed, and records are signed (or initialed) and dated accurately. Eg: Late data entry should be noted. If study staff forgets to enter data in real time and must do it later, note this and include a date [and time] when entering the data.
Original	The record is original as it is captured, collected, or is an exact facsimile of the original. Eg: Study staff should not use pencil; use pen for originals. To make changes to an original entry, draw a single line through the error, then initial and date with an explanation for the correction. Also no correction fluid or writing over an original entry.
Accurate	The record is collected and recorded honestly and completely to demonstrate transparency.
Complete	Up-to-date and with no omissions.

Satisfying Requirements of ALCOA-C

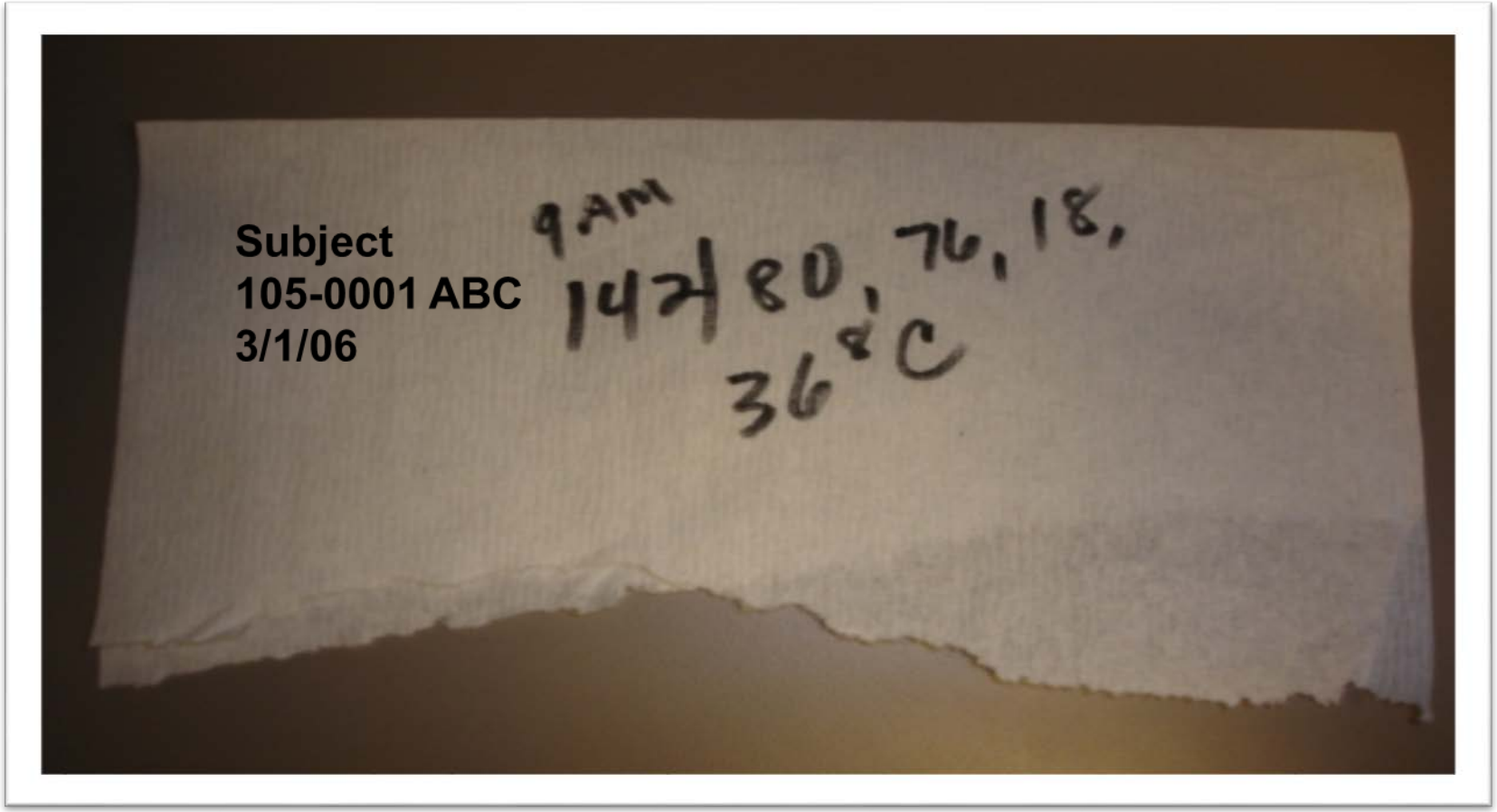
Ensure source documents/trial records (e.g., paper, electronic) contain clear details about the following:

- Who has made or updated the entry (i.e., the name of the doctor or signature or initials are present)
- When the entry was made or updated (i.e., the date is present)
- The entry is readable and understandable (e.g., it features clear handwriting and is void of non-standard abbreviations)
- The entry must be the first place the information was recorded (i.e., not transcribed from another document)
- The entry must reflect what occurred and when, including all the relevant details
- An audit trail tracing the changes made by whom, when, and why must be available

Types of Source Documents

- Medical history
- Hospital records
- Clinic & office charts
- Progress notes
- Lab notes
- Memoranda
- Meeting minutes
- Notes to file
- Phone records
- Subject diaries
- Questionnaires
- Subject files or records
- Drug dispensing records
- Recorded data from automated instruments (DynaMap, ECG, EEG,)
- X-rays, scans, MRIs

Example of a Source Document?



Important Events to Document

- The Consent Process (more than just signed consent form)
- Documentation of subject eligibility (inclusion/exclusion criteria)
- Study randomization, study drug adherence or non-adherence
- Completion of all protocol-required tests, procedures
- Missed visits, subject contacts, procedures, or examinations
- Protocol deviations & violations (notifications to IRB / sponsor and corrective actions)
- All subject contact – either via phone or in person (include date/time and reason for contact)
- Unanticipated problems or adverse effects and relationship to study intervention, severity, action taken and reporting to IRB
- Subject termination (withdraw of consent, lost to follow up, PI removal)

Source Data and Source Documents

- What is a Certified Copy and why do I need one?
- Definition:
  - A copy (irrespective of the type of media used) of the original record that has been **verified** (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original. {identical to the original in every aspect} (Section 1.63)
- A Certified Copy is a regulatory mechanism by which we can replace paper records with electronic ones and ensure the integrity of the contents.

Certified Copies of Source Documents

Things to Consider:

- Both FDA and GCP want source verified as an exact copy of the original
  - FDA = requires dated signature
  - GCP = allows for a validated process
- The person who made the copy should be the person who certifies the copy (can use a stamp or memo)
- Print outs of EHR records are not considered valid source data if not certified
- An electronic certified copy is a valid source
  - What happens if it is printed?
  - What if a valid original paper source is scanned?
- Regulatory compliant clone

Certified Copies of Source Documents (con't)

- Source housed within an electronic system is not automatically a certified copy if not Part 11 compliant
  - Access or Excel
  - An electronic signature is not automatically part 11 compliant
- Copies of wet ink regulatory documents provided to sponsors
  - Can these be used as a source document?
- Certified copies are necessary when original records are copied to a different media for archiving purposes and the originals are destroyed or if you want a copy as a substitute for the original records.
  - Develop clear SOPs to determine which study documents to certify and the method for certifying

Maintaining Regulatory Files - Essential Documents

- Purpose of Regulatory Files:
  - Organize essential documents
  - Allows research team to reference information that reconstructs the regulatory life of a study
  - Allows easy access to documents by monitor, auditor, IRB, FDA, OHRP
- Essential Documents for conduct of Clinical Trial should be maintained together (4.9.4)
  - The investigator/institution should take measures to prevent accidental or premature destruction of these documents
  - Tornado, hurricane, flooded research space

Maintaining Regulatory Files - Essential Documents

- Record Retention (8.1)
  - Written procedures in place describing procedures for records retention
    - Consider: Sponsor/Agreement, regulations, other countries (Canada)
  - Location of records when stored (estimated end of retention period)
  - Record retention in the event that company cease to exist, PI d/c affiliation with institution, retires, death
  - Will research related records in the electronic medical record be retained?
    - May need to confirm
- Principal Investigator ultimately responsible for maintenance of Regulatory Files, but task often delegated to other member of research team

Regulatory Files (Essential Documents)

- Signature logs (DOA and monitoring log)
- Screening/enrollment logs
- ✓ Protocol and amendments
- ✓ Investigator's Brochure
- Sponsor correspondence
- ✓ Training (GCP, Protocol etc.)
- ✓ 1572, Conflict of Interest, CV's, Licenses, Financial Disclosures

- ✓ IRB membership, FWA
- ✓ IRB approvals and correspondence
- AE log, SAEs
- IND Safety Reports
- ✓ Local Laboratory CLIA/CAP, normal values, Lab Dir. CV
- Temperature Logs
- ✓ Equipment & Calibration Records (equipment used for the purpose of research)
- Subject ID Code List

Templates Available for Documentation (UNC OCT)

- Delegation of Authority (Responsibility) Log
- Protocol Modification Tracking
- Adverse Event (UP) Tracking
- Protocol Violation Log
- Memo to File
- Progress Note Template
- Screening and Enrollment Log
- Telephone Log
- Investigational Drug or Device Accountability
- Consent Process Documentation

https://research.unc.edu/clinicaltrials/training/forms/research

Meet the Research Team

Investigator: Dr. Clark Kent

Research Coordinator: Jean Gray

Scenario 1: First Patient on a New Study

Dr. Kent and Jean are starting a new study for participants with Diabetes. They have their first participant in clinic today. Let's see what happens…

- On Tuesday Jean sent a copy of the consent document to the participant. When the participant arrives on Friday, Jean gets the participant to sign the consent document. Jean also reviews and signs the eligibility form and tells Dr. Kent the good news that they have their first participant on study.

Scenario 1: First Patient on a New Study

What needs to occur for Jean and Dr. Kent to be GCP compliant?

- ✓ Review of the consent with the participant, answer any questions, provide a copy (4.8.11) and document the informed consent process (4.8.10)
- ✓ A Medically qualified person (or PI) needs to confirm eligibility and provide documentation (4.3.1)

Some other things to consider:

- ✓ Were encounters with the participant whether via phone or email documented?
- ✓ Staff need to be qualified by education, training and experience; delegated tasks as appropriate and documented (4.1.5; 4.26)
- ✓ No demonstration of PI oversight – PI Oversight Plan (4.25)
- ✓ Could include written permission to inform the participant's PCP of the participants involvement in the study (4.3.3)

Scenario 2:
A New Sub-Investigator Joins the Team

Dr. Diana Prince

- Enrollment is going well and Dr. Prince is added to the team. She will be a Sub-Investigator on the study. Dr. Prince is an international expert in the treatment and diagnosis of diabetes and begins to enroll and see patients on the study.

Scenario 2:
A New Sub-Investigator Joins the Team

What needs to occur for Jean, Dr. Kent and Dr. Prince to be GCP compliant?

- ✓ Training on the protocol, drug and processes prior to participating or seeing pts (4.1.1, 4.1.2, 4.1.3)
- ✓ Dr. Kent is responsible for making sure that Dr. Prince is adequately informed about the protocol (4.1.5, 4.2.4)
  - ✓ Jean may facilitate, but Dr. Kent is ultimately responsible

Some other things to consider:

- ✓ Training must be ***documented*** on protocol, study procedures and IB
  - ✓ Electronic, paper etc…
- ✓ Will Dr. Prince's credentials absolve Dr. Kent from overseeing her work on the trial? (4.25)

Scenario 3:
A Pandemic Disrupts Study Activities

Research Coordinator: Jean Gray

- A few additional studies have been added to the team's portfolio. Soon after, a contagious viral respiratory illness affects the area and study activities are disrupted. What are some things that the study team can do to remain GCP compliant?

Scenario 3:
A Pandemic Disrupts Study Activities

GOAL: Ensure the safety and welfare of our participants, site research staff, and others while assuring data integrity/study compliance.

- ✓ Risk Identification: Identify risks to critical trial processes and data. Risks should be considered at both the system level (e.g., standard operating procedures, computerized systems, personnel) and **clinical trial level** (e.g., trial design, data collection, informed consent process). (5.0.2)
- ✓ Risk Evaluation: Evaluate the identified risks vs existing risk by considering: (a) The likelihood of errors occurring. (b) The extent to which such errors would be detectable. (c) The impact of such errors on human subject protection and reliability of trial results. (5.0.3)
- ✓ Risk Control: Decide which risks to reduce and/or which risks to accept. (5.0.4)
- ✓ Risk Communication: Document quality management activities (5.0.5)
- ✓ Periodically review (5.0.6)

Scenario 3:
A Pandemic Disrupts Study Activities

- ✓ Follow the protocol (as closely as possible) (4.5.1)
  - Another major audit finding
- ✓ During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware (4.3.2)
- ✓ If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, inform the regulatory authority(ies).(4.12)

Scenario 3:
A Pandemic Disrupts Study Activities

- ✓ The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects. (4.5.2)
- ✓ The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol. (4.5.3)
- ✓ The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favourable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted to the IRB, Sponsor and applicable regulatory authority(ies). (4.5.4)

Other Things to Consider for GCP Compliance

What else might the team need to be GCP compliant?

- ✓ May need to hire additional staff to provide support (4.2.3)
- ✓ If frequent deviations occur, will need appropriate and thorough documentation of the events surrounding the deviations and missed assessments. (4.5.3, 4.9.0)
- ✓ Adequate PI oversight (4.25)
- ✓ Is there enough structure/support infrastructure built into the team (SOPs, WIs, templates for source documentation, time management tools)
- ✓ Have a plan for electronic signatures and electronic copies

Other Things to Consider for GCP Compliance

- Quality management systems (sponsor & site) consisting of documented procedures: SOPs, protocol procedures etc. (5.0)
  - Responsible for ensuring and implementing a system to manage quality throughout all stages of the trial processes and at all sites

  Critical Standard Operating Procedures (Site)
  - Informed consent process
  - Recording management and reporting of adverse events
  - Storage and handling of clinical trial drugs
  - Handling of biological specimens
  - Equipment maintenance and calibration
  - Training of study personnel
- Investigator who is the Sponsor must adhere to requirements for sponsors and investigators (5.0, 5.2.2)

How did we do?

Were we able to….

- Identify GCP principles that impact the investigator or research site
- Understand how to apply GCP principles in a clinical study
- Analyze how a global Pandemic (or other circumstances) can impact GCP adherence.

Suggestions for Compliance

- Schedule regular meetings between PI and trial staff (with minutes)
- Put in place a PI oversight plan
- Perform quality control review of the data
- A medically qualified Investigator or Sub-investigator to sign off on Inclusion/Exclusion criteria
- A qualified investigator to determine the clinical significance for abnormal tests/procedures and follow up
- Document IP accountability and discussions regarding the use of the IP
- Maintain updated licenses/certifications; PI signs and dates the protocol and IB signature pages
- Develop and maintain training logs and delegation of authority logs
- File all IRB correspondence, approval letters with details of submission & ICF updates with clear versions
- Document the Investigator's acknowledgment of the protocol and subsequent amendments (protocol signature pages)
- Document/report any deviations from the protocol to the sponsor and the IRB

Questions?

Documentation / Compliance Video

And for a fun video on compliance, go to

- https://www.youtube.com/watch?v=wKsdMenonLw&feature=youtu.be

References

- ICH in Focus: ICH GCP E6(R2): Requirements and Challenges for Clinical Trial Sites; Spadoni, Sara; Clinical Researcher—February 13, 2018 (Volume 32, Issue 2)
- International Council for Harmonisation (ICH). 2016. “Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6 (R2).” Accessed March 25, 2019.
- CITI Program: Overview ICH GCP E6(R2) Integrated Addendum. Accessed March 25, 2019
- Getting on Board with ICH GCP E6(R2): Impact on Study Quality and Operations; Peterson, Jan; https://www.acrpnet.org. Accessed October 13, 2017

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Informed Consent in Research

North Carolina Translational and Clinical Sciences (NC TraCS) Institute

Catherine FB Barnes, BA, CCRP
Director of Education, RCMU
September 30, 2020

A Scenario…

You are conducting an informed consent discussion with a potential subject. The study involves the treatment of Amyotrophic Lateral Sclerosis with a new drug, injectable Sectroimab. Risks of the drug include transient ischemic attack and Raynaud's disease. You explain this to the subject during the discussion, and hope that the subject understands.

A Scenario…

What is Informed Consent?

What Elements Should be Included in Informed Consent?

How Do I Conduct Informed Consent Discussions?

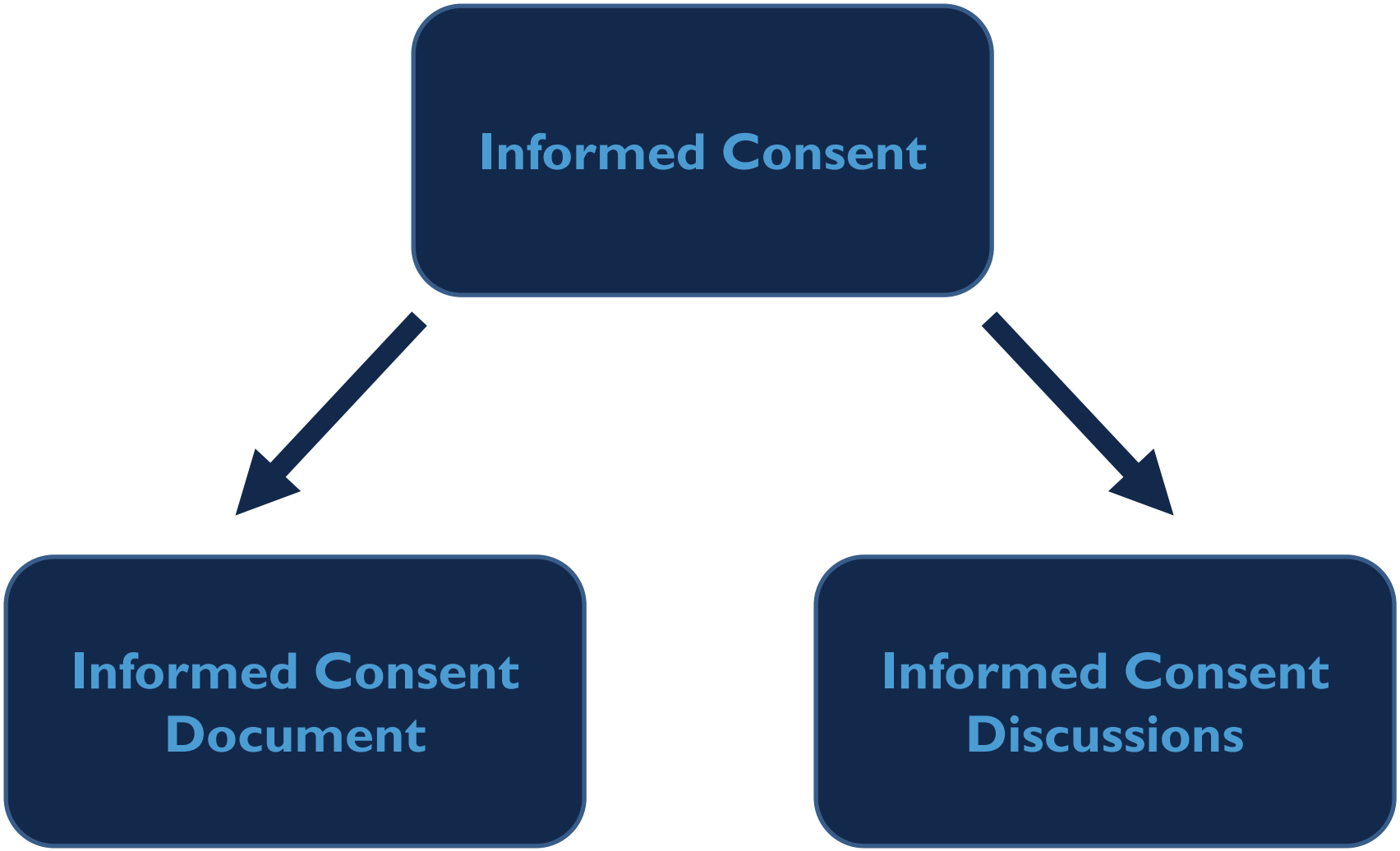
Scenarios

What is Informed Consent?

…is for subjects to understand their role as a "subject of research".

…is to explain the purpose of research to the potential subject, including what their role would be and how the trial will work.

The Purpose of Informed Consent…


Informed Consent
Informed Consent Document
Informed Consent Discussions

Why Do We Complete the Informed Consent Process?

Belmont Report:

Consists of the three basic ethical principles that underlie acceptable conduct in human research- respect for persons, justice, and beneficence.

Nuremberg Code:

One of the ten main points in this code is the requirement for informed consent of participants.

"The voluntary consent of the human subject is absolutely essential"

Informed Consent Document:

What Elements Should be Included?

Understandable to a person who is educated at an 8th grade level

Written in a language that the subject or representative understands

May not include any language where subject waives or appears to waive legal rights

May not include any language that releases any study team from liability or negligence

New Common Rule Requirement: Concise Summary

"Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research."

What is Included in an Informed Consent?

8 Elements are Required Per 45 CFR 46.116(b):

- That the Study Involves Research, and an Explanation of that Research
- Description of Risks and Discomforts
- Description of Benefits
- Alternatives to Participating in the Research
- Statement About Confidentiality Maintenance
- Statement About Treatment and Compensation for Injury
- Study Team Contact Information
- Voluntary Participation and Withdrawal Information
- *A Statement About Personal Health Information or Identifiable Biospecimens

If Applicable…

- Approximate number of subjects
- Statement that subjects will be informed about new information
- Additional costs that may result from participation
- That the research may involve risks that are unforeseeable
- Circumstances in which the investigator will end the subject's participation
- If the subject withdraws, the procedures that will be followed
- Clinicaltrials.gov statement
- Certificate of Confidentiality Statement
- A statement regarding that biospecimens may be used for commercial profit, and if the subject will share in the profit
- Whether research will involve whole genome sequencing
- Statement if whether clinically relevant research results will be disclosed to subjects

What about HIPAA?

HIPAA's purpose is to establish standards to protect individuals' protected health information (PHI), by…

Requiring appropriate safeguards to protect PHI

Setting limits and conditions on how we can use information without patient permission

Giving patients the ability to get a copy of their medical record, and request changes if applicable.

HIPAA Training

UNC **requires** online HIPAA training for new employees and annual renewal training:

https://privacy.unc.edu/protect-unc-\information/hipaa/hipaa-training/

HIPAA Authorization

A form that a research participant signs to "authorize" access to their PHI for research purposes. This is separate from the informed consent document.

Limited Waiver of HIPAA

…is granted by the IRB/privacy board, and allows access to key PHI in a limited manner (i.e. for recruitment purposes only). Usually followed by a full authorization.

Full Waiver of HIPAA

…is granted by the IRB/privacy board, and allows full access to PHI without a signed authorization. But the use/disclosure of PHI must involve no more than a minimal risk to the privacy of individuals.

If you don't have HIPAA (in some form)…

You can't look in someone's medical record **for any reason**

- Not for lab test results;
- Not to see if they've checked into a clinic;
- Not to verify medications;
- Not because you're curious about something;
- Not for feasibility;

If you need access to the medical record for you study- you must address HIPAA with the IRB through the IRB application.

Informed Consent Discussion:

Ensuring Subject Understanding

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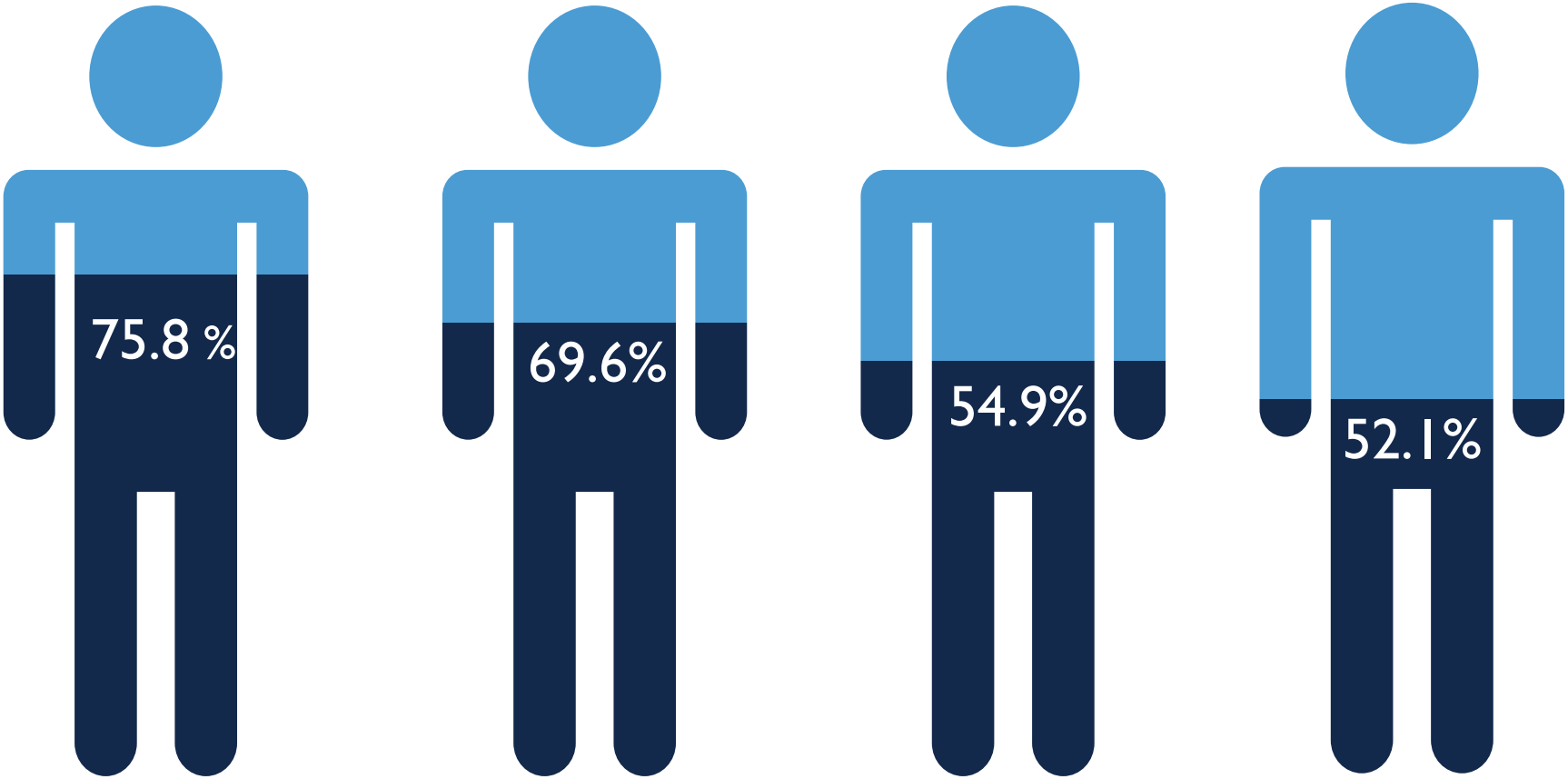
Remember the Scenario from Earlier?

- What was the drug?
- What was a risk?



Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. Tam, 2014

What is the Solution?

The 7 Questions:

1. Who?
2. Who (Part 2)?
3. What?
4. When?
5. Where?
6. Why?
7. How?

Who?

The Legal and Mental Capacity to Give Consent

O R

Legally Authorized Representative (LAR)

Who can be a LAR?

Court Appointed Legal Guardian

Healthcare Power of Attorney

Durable General Power of Attorney

Who (Part 2)?

Investigator Must Delegate Responsibility

Must Have Received Appropriate Protocol Training

Must Have Consenting Process Knowledge

Must Speak the Language of the Subject, or Have a Reliable Interpreter

What?

IRB Approved Consent

When?

Prior To….

- Conducting any procedures required by the research plan
- Entering a subject in a study
- Gathering any data about the subject

Where?


Read the Document
Consider Whether or Not to Participate
Subject must have the opportunity to…
Ask Questions
Receive All Responses to Questions

Why?

Remember the Purpose of Informed Consent?

The Purpose of Informed Consent…

…is for subjects to understand their role as a "subject of research".

…is to explain the purpose of research to the potential subject, including what their role would be and how the trial will work.

How?

- Minimize Coercion
- Pause to have the subject ask questions!
- Don't talk too quickly
- Remember that the subject may not understand

After Signing Consent…

Give the Subject a Copy of the Consent

Put a Copy of the Consent in the Medical Record (if applicable)

Don't Forget the Informed Consent Process Documentation!

This document is a record of the informed consent process. It states that best practices were followed during the informed consent discussion.

Questions?

What would you do if…?

A Patient Says No?

- Thank them for their time!
- Collect the consent form from them.
- Do not seem upset or disappointed.
- Do not try to convince them otherwise. If they say no, end the consenting process there.

A Patient Seems "On the Fence"?

- Remind them that research is voluntary.
- Assure them that they can withdraw if they'd like, at any time.
- Do not coerce or try to "sell" the study to the potential participant.

A Patient's Companion is Answering for Them?

- Be respectful to the companion, but try to change the conversation to be about the potential participant.
- Make sure the patient verbally says "yes" before continuing.

You Need Consent From Someone Who is Less Than 18 Years Old?

- You need to obtain **both** an **assent** (what the child signs) and **parental permission** (what the parent signs).
- The IRB allows for different assent forms for different age ranges (i.e. 15-17 years old), so ensure you have the correct assent.
- If your participant turns 18 during the study, you will have them re-sign a normal consent.

A Clinic Staff Member Needs to See the Patient?

- Let the clinic staff member see the patient as soon as they ask.
- Follow-up with the clinic staff member prior to leaving the room regarding when you can come back.
- You cannot do any study related-procedures or collect data until the consent is signed.

A Patient Agrees but You Don't Believe They Comprehend?

- Ask questions about the study to gauge understanding
- If they cannot answer your questions appropriately, then you can politely say that "the study isn't the right fit for you right now", "let's talk about this another time", etc.

Questions?

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Health Information Management's Role in the Research Process

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What Does HIM Do For You?

Research Consents

Research Monitor Access

What Does HIM Do For You?

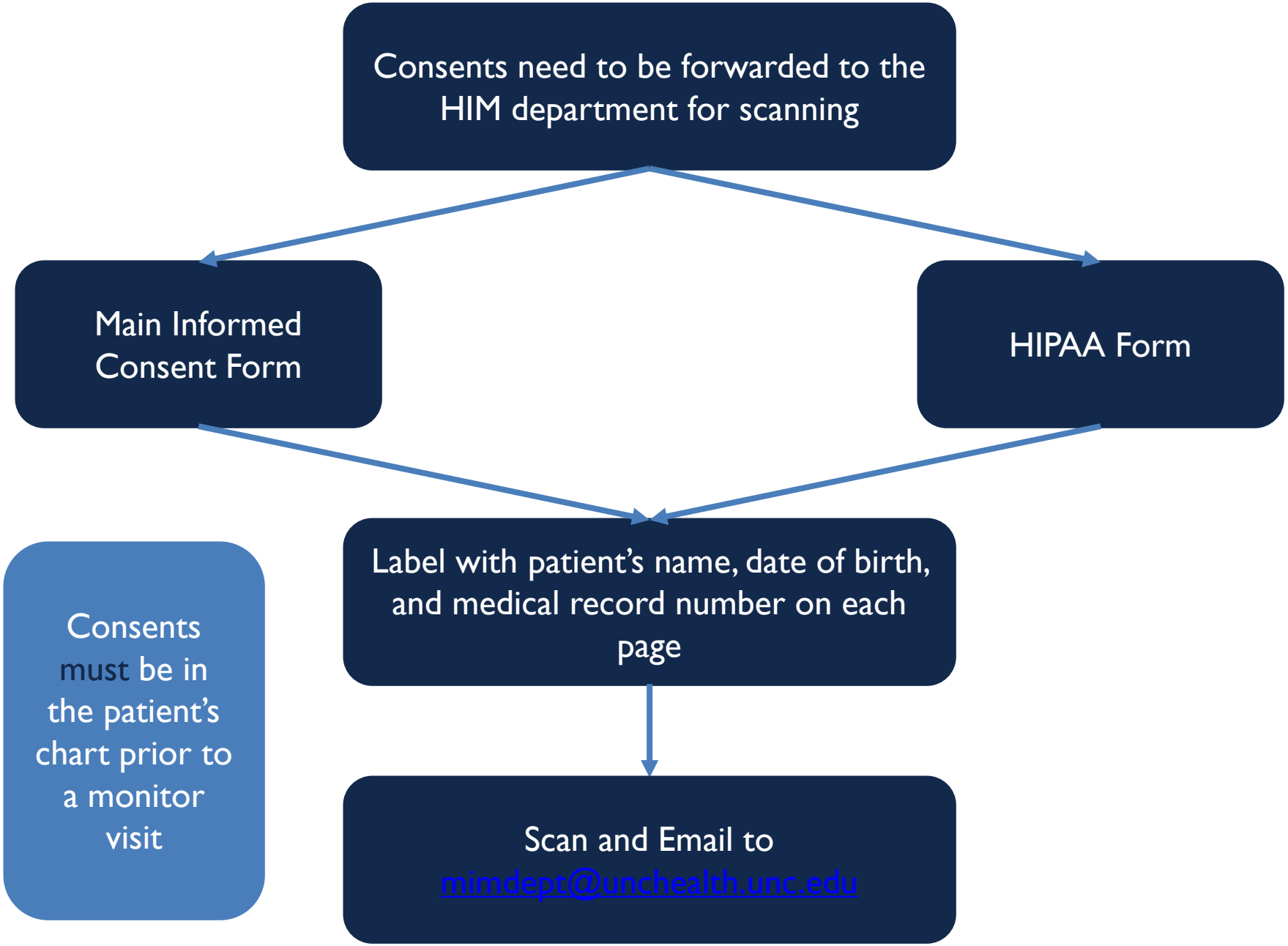
HIM Can…

…scan in research consents into patients' medical record

…validate submitted documentation to ensure compliance with regulatory guidelines

…act as an intermediary between ISD and the research team for monitor requests

Research Consents


Consents need to be forwarded to the HIM department for scanning
Main Informed Consent Form
HIPAA Form
Label with patient's name, date of birth, and medical record number on each page
Consents must be in the patient's chart prior to a monitor visit
Scan and Email to mimdept@unchealth.unc.edu

Research Monitor Access

What?

- Signed confidentiality statement
- Current UNC IRB approval letter
- Request for Research Monitor Access Form

When?

At least seven business days before the monitor visit, but no more than fourteen business days prior to the visit

To Whom?

HIM, emailing it to:
UNCHHimResearchRequest@unchealth.unc.edu

For all New Requests for Research Monitor Access, Submit…

Confidentiality Statement

What?

This document is an agreement that ensures confidential information is only used for legitimate job-related purposes.

When?

Present this document to the research monitor as soon as you can, usually at study-start up.

The document must be updated every year.

UNC IRB Approval Letter

What?

This letter can either be the UNC IRB approval letter, or an external IRB approval letter and UNC's letter ceding authority

When?

You will obtain these letters at IRB approval.

Request for Research Monitor Access Form

What?

This document gives the details about the monitoring visit, the patients that the monitor will be accessing (if less than 50). It must be signed by the PI.

When?

Fill this form out and submit with all other forms at least 7 business days prior to the monitor's visit.

HIM submits the request for access to ISD

HIM forwards the log-in access codes to the study personnel by email.


Login to your Epic account
You've got the access… now what?
Insert the patient information into the "patient" field
Open an in-basket message, choose "staff"
Type the monitor's username HIM has assigned into the "To" field

After the Visit…

Login to the monitor's account and click "done" on all in-basket messages

*To ensure that all messages have cleared, click "refresh"!

Questions?

Thank you!

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Joe Baker
Information Systems Specialist
Joseph.Baker@unchealth.unc.edu

Week 3
Evaluation Link:
https://go.unc.edu/orientwk3

OR

If you need a certificate of attendance, please email marie_rape@med.unc.edu after completing the evaluation survey.