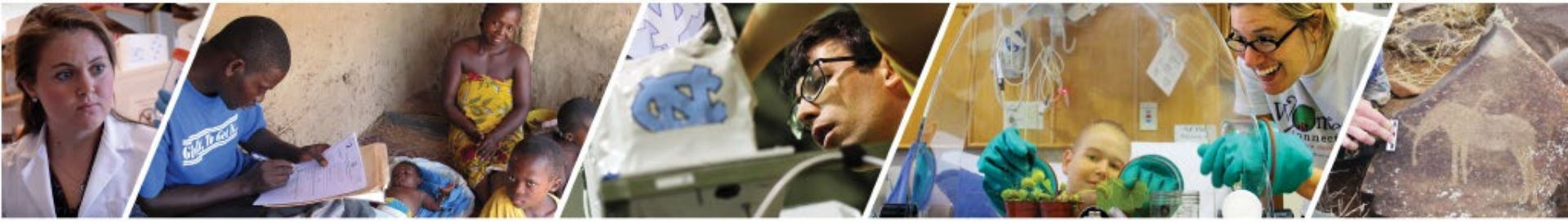
Essential Regulatory Documents



Office of Clinical Trials Quality Assurance Program

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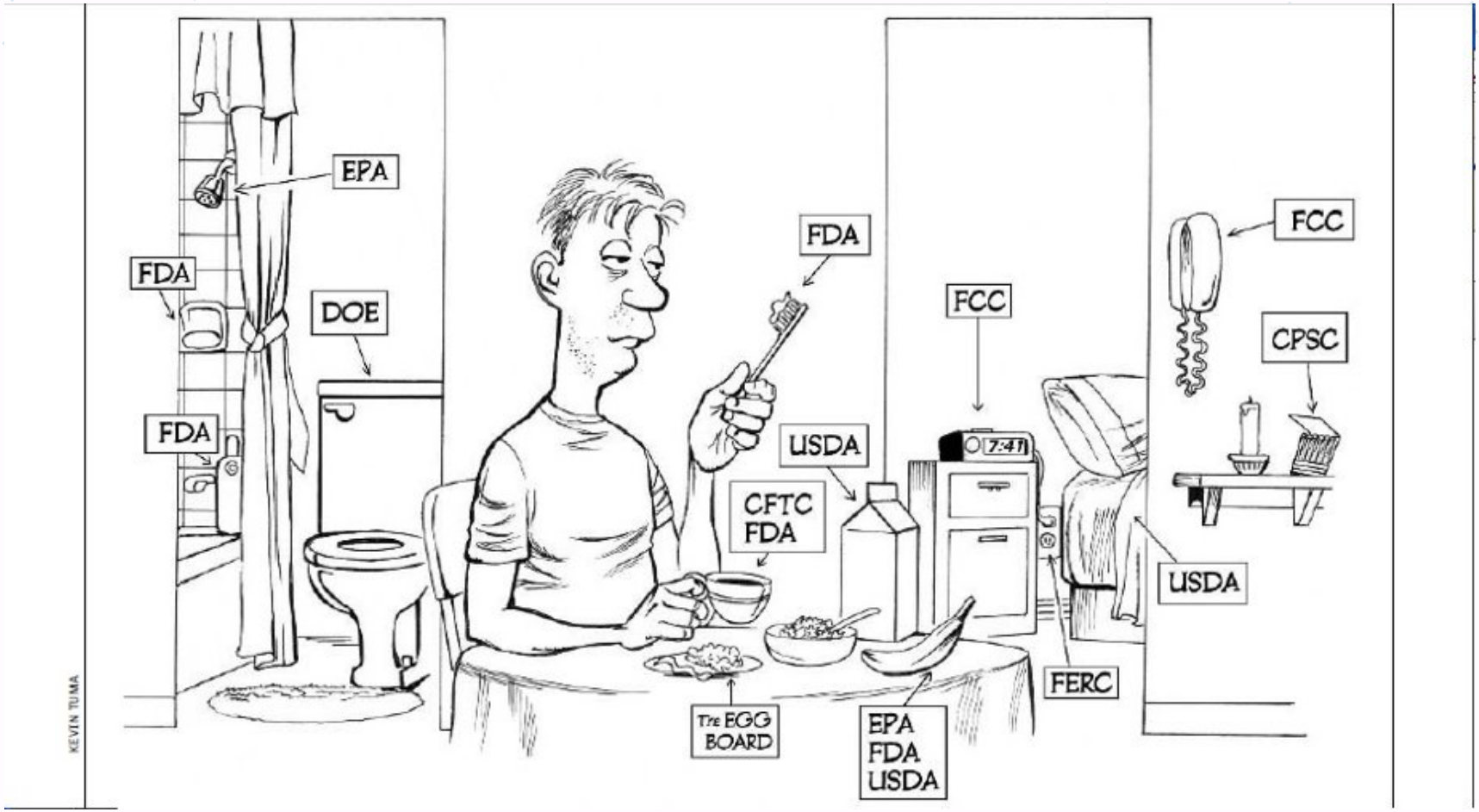
Mornings in the Regulatory World



Objectives

- Define Essential Documents in the context of Biomedical and Social/Behavioral clinical trial
- List the essential documents required at 3 timepoints during the trial

What Are Essential Documents?

Definition: the documents which individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced

(ICH GCP E6 (R2) 8.1)

What types of trials require maintaining essential documents?

- Federally funded (NIH) Trials

  Requirement as of January, 2017 – includes Biomedical and **Social/Behavioral Trials**

- FDA Regulated Trials

"A quality research site complies with the ICH GCP guidelines, the accepted international ethical and scientific quality standards for designing, conducting, recording, and reporting trials involving human participants."

American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites; R. Zion et al; Journal of Clinical Oncology; April 7, 2008

3 TIMEPOINTS

Prior to beginning the study

During the course of the study

After Completion of the study

Prior to Beginning the Study

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: April 30, 2015
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 Principal 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 PAGE – For Item 6

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

FORM FDA 1572 (7/13) PREVIOUS EDITION IS OBSOLETE. Page 1 of 2

IND trials – 1572 Statement of Investigator

IDE Trials – Investigator Agreement

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Documentation for Investigators and Sub-Investigators/Key Study Staff

Curriculum Vitae / Resume**

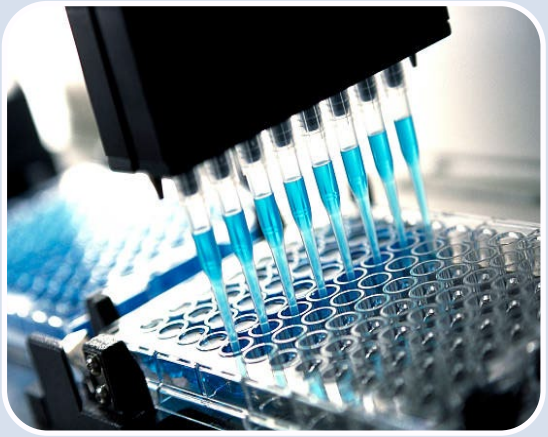
- Documents qualifications and eligibility to conduct trial

Licensure**

- Documents eligibility to provide medical supervision of subjects

Certifications**

- Documents qualifications to perform tasks as delegated



Initial IRB Approvals**

Approved Informed Consent Documents**

Approved Recruitment Materials**

Other Written Materials**

Initial Protocol**

Protocol Amendments**

Administrative Letters**

Investigator's Brochure/Package Insert/Device Information

CLIA/CAP For All Laboratories Used for the Study

CV of Medical Director

Normal Values/Ranges For Tests/Procedures Included in the Protocol

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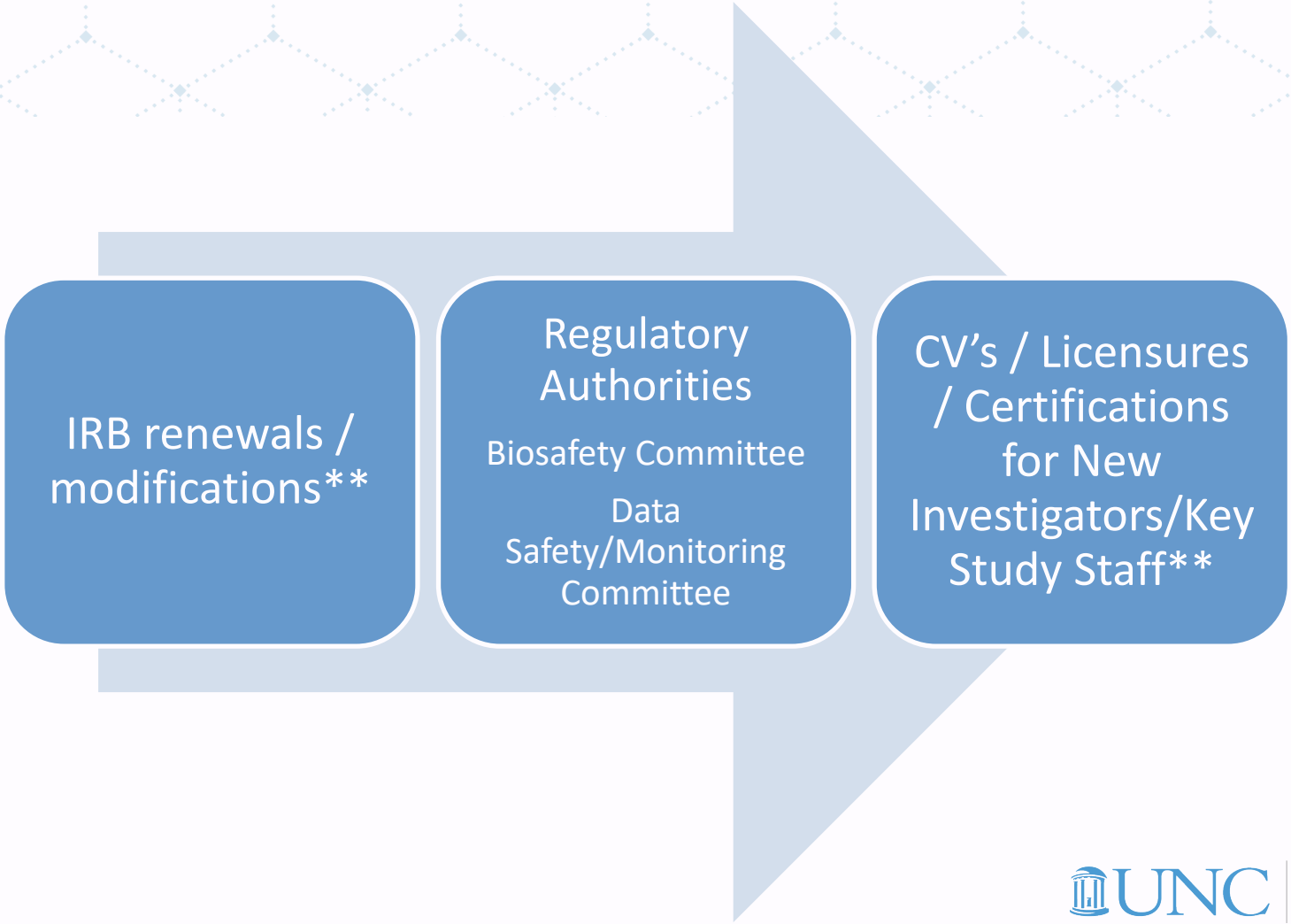
JUST A FEW MORE……

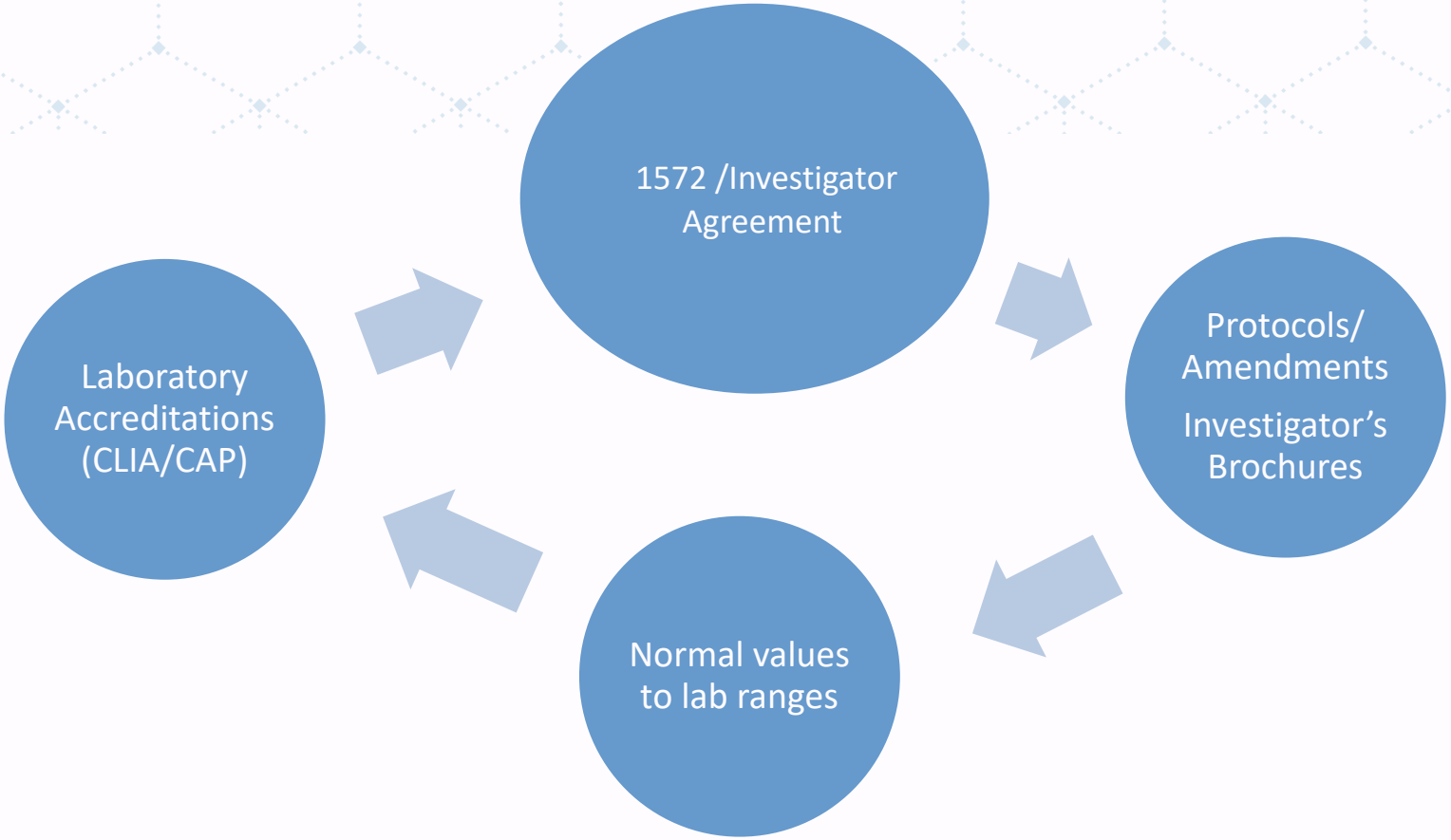
- Sample of Labels to be Attached to Investigational Products
- Investigational Product Shipping and Accountability Records
  - applicable for both drug and device studies
- Certificate of Analysis
- Procedures for Decoding Blinded Trials
  - used in case of emergency – doesn't break blind for oth
- Study Initiation Report**
  - Document questions asked during SIV!

During the Course of the Study

Update Files with:



Update:


1572 /Investigator Agreement
Protocols/ Amendments
Investigator's Brochures
Normal values to lab ranges
Laboratory Accreditations (CLIA/CAP)

Add Logs:

Subject

- Screening / Enrollment Logs**
- Subject ID Code Log**
- Adverse Event Logs**

Training

- Protocol/Amendments/Admin Letters**
- IB (Package Insert)
- Protocol Specific Procedures/CRF Completion**
- Human Subjects Protection/GCP**

Other

- Delegation of Tasks (Authority) / Signature Sheet**
- Protocol Deviation Logs**
- Retained Body Fluid / Tissue Samples**

INCLUDE

RELEVANT COMMUNICATIONS

- Letters
- Meeting Notes
- Telephone Calls/ Emails
- Monitoring Notifications / Follow Up Letters
- Memos to File

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Subject Documents Which are Considered Essential

- All Signed Informed Consent Documents

- Source Documents

SAFETY INFORMATION

Serious Adverse Events

- Report to sponsor and IRB
  - Reporting to IRB is dependent on their reporting requirements (UNC vs External IRB)

Unanticipated / Unexpected Adverse Events

- Report to Sponsor and IRB

Safety Information / Reports

- Sponsors Notify Sites

After Completion of the Study

STUDY COMPLETION

- ✓ Logs
  - ✓ Investigational Product Accountability / IP Destruction
  - ✓ Completed Subject Identification Code
- ✓ Copies of the Signed & Dated Case Report Forms
- ✓ Final Close-out monitoring report
  - ✓ Includes where site documents will be stored
- ✓ Close out of study with IRB
- ✓ Clinical Study Report / Data

Resources

- FDA Guidance on ICH GCP: https://www.fda.gov/files/drugs/published/E6%28R2%29-Good-Clinical-Practice--Integrated-Addendum-to-ICH-E6%28R1%29.pdf

- ICH GCP E6 (R2): https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf

- FDA BIMO (Bioresearch Monitoring) Manual: https://www.fda.gov/media/75927/download

Thank You!