

# Facing the Challenge of Preparing Site Documentation to Meet the ICH GCP Standards

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Sometimes  
Stuff  
Happens!

What to do  
when  
stuff happens...

# Document Checklist General Issues

- Lost, misplaced, or damaged
- Copies versus originals
- Expiration of initial approval periods
- Language barriers
- No document at all

# 1. Investigator's Brochure/Package Insert

- Updates to brochure

## 2. Signed Protocol/Amendments, and Sample Case Report Forms (CRFs)

- Amendment implementation dates, IRB approval vs. implementation, site to site
- Update to CRF based on protocol change or error at study start up

### 3. Information Given to Trial Subject

- Revisions to protocol or consent require updates to subject information
- Consent amendment for protocol amendments, or change in risk, new information about product under study
- HIPAA concerns

## 4. Financial Aspects of the Trial

- Updates to financial disclosure information
- Changes in contract, scope of the study
- Changes in compensation to PI
- Sponsor funding

## 5. Insurance Statement

- Change in insurance requirements, change in the amount of insurance coverage if specified, based on protocol changes or other change in risk

## 6. Signed Agreement Between Involved Parties

- Changes to contract terms for any relationship – driven by protocol or capacity changes, or business/financial decisions
- Mergers

# 7. Dated, Documented Approval/Favorable Opinion of IRB/IEC on Documents

- Updates, amendments
- Continuing review
- Advertising scripts for different media – radio vs. print
- Information provided to prospective subjects vs. health care providers for subject referral
- Investigator membership on IRB, independence, non-voting

# 8. Institutional Review Board/Independent Ethics Committee Composition

- Changes in membership
  - Membership must comply with regulations
  - IRB statement of compliance
  - Differing compliance rules from country to country
  - Assurance numbers (e.g., FWA)

# 9. Regulatory Authority Authorization/Approval/ Notification of Protocol

- Monitor for an update, if required

## 10. Curriculum Vitae and/or Other Relevant Documents Evidencing Qualifications of Investigator and Subinvestigators

- Medical licensure validation of PI and all subinvestigators
- Updated CV – signed/dated

# 11. Normal Value/Range for Medical/Laboratory/Technical Procedure and/or Test

- Adjustments in normal ranges by laboratory, based on population

## 12. Medical/Laboratory/ Technical Procedures/Tests

- Ongoing accreditation/validity documentation
- Expiration of accreditation
- Other country documentation

# 13. Sample of Label Attached to Investigational Product Container

- Blinding Integrity
- Glue

# 14. Instructions for Handling of Investigational Product and Trial-Related Materials

- Availability for emergency situations

# 15. Shipping Records for Investigational Product and Trial-Related Materials

- Compliance
- Disposition
- Accountability

# 16. Certificate of Analysis of Investigational Product Shipped

- Stability
- Breakdown
- Expiration dates

# 17. Decoding Procedures for Blinded Trials

- Availability
- Security

# 18. Master Randomization List

- Security
- Consistency with protocol

# 19. Pretrial Monitoring Report

- When to do this?
- Sponsor waiver

# 20. Trial Initiation Monitoring Report

- Follow up concerns, if any

## 21. Relevant Communications – Letters, Meeting Notes, Telephone Calls

- “Living” master list of all communications for end-study archival
- E-mails

## 22. Signed Informed Consent Forms

- Lost
- Replacement
- Storage location on-site
- Appropriate use of witness
- Personally sign and date
- Person obtaining consent
- Legally authorized representative

## 23. Source Documents

- Accuracy
- Completeness
- Accessibility

## 24. Signed, Dated, and Completed Case Report Forms

- Accuracy
- Completeness
- Accessibility

## 25. Documentation of CRF corrections

- Documented endorsement by PI
- Delegation by PI

## 26. Sponsor Notification of Serious Adverse Events by Originating Investigator

- Date and event description accuracy
- Reporting timelines – other countries

## 27. Sponsor/Investigator Notification to Regulatory Authority and IRB/IEC of Unexpected Serious Adverse Drug Reactions/Other Safety Information

### *Investigator to IRB*

- Timing is dependent upon local IRB SOP
- Check investigator's compliance

### *Sponsor to Regulatory authority*

- By local law

## 28. Sponsor Notification to Investigators of Safety Information

- Within allotted regulatory time period
- Accessibility at site

## 29. Interim or Annual Reports to IRB/IEC and Authority

- Available and retrievable for long term studies

## 30. Subject Screening Log

- Confidentiality
- Maintenance
- Inclusion of screen failures
- Comparison to signed consents

# 31. Subject Enrollment Log

- Confidentiality
- Maintenance
- Inclusion of screen failures
- Comparison to signed consents

## 32. Investigational Product Accountability at the Site

- Disaster management
- Return to sponsor or disposal

## 33. Signature Sheet

- Comparison with all study documents

## 34. Record of Retained Body Fluids/Tissue Samples

- Informed consent, if required
- Storage

# 35. Trial Monitoring Visit Reports

- Action items?
- Where's the action?

# 36. Completed Subject Identification Code List

- Confidentiality

## 37. Audit Certificate

- From local authorities or others
- Observe and compare findings, if available

## 38. Final Trial Close-Out Monitoring Report

- Supplies returned at the time of final visit
- Follow up may be required

# 39. Treatment Allocation and Decoding Documentation

- Confidentiality
- When to unblind?

## 40. Final Report by Investigator/Institution to IRB/IEC and Regulatory Authority

- Availability
- Notification

# 41. Clinical Study Report

- Interim vs. final reports

*Slides available at*

*[www.raninstitute.com](http://www.raninstitute.com)*

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*Thank You!*