Essential Documents – It's Not Just a Binder!

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SCORE – June 5, 2014

But…
What percentage of 2014 (to date) OHSP QI Reports have had essential documentation findings?

82%

BIMO Inspection Metrics (2013): Most Common Site Deficiencies

- Failure to follow the investigational plan and/or regulations
- Protocol deviations
- Inadequate recordkeeping
- Inadequate accountability for the investigational product
- Inadequate communication with the IRB
- Inadequate subject protection – failure to report AEs and informed consent issues

FDA Bioresearch Monitoring Program (BIMO) Annual Inspection Metrics 2013

Essential Documents

- Essential Documents Basics
- Categories of Essential Study Documentation
- Best Practices
- Resources
- Scenario/Case Study Presentations

Before I Dive Into Details…

- Remember:
  - Essential Documentation will vary from study to study
    - Federal oversight (HHS vs. FDA)
    - Industry vs. PI-initiated
    - Use of investigational product
    - Funding source
    - Nature of the study
  - Required documents vs. good practice

Essential Documents

"Essential Documents are those that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to *demonstrate the compliance* of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements."

ICH GCP Guidelines

Essential Documents

Essential Documents: Federal Regulations

- Non-FDA Regulated (No Drugs/Devices/Biologics)
  - IRB Review, Informed Consent, Event Reporting, Continuing Review, Record Retention

- FDA-Regulated (IND/IDE & IND/IDE Exempt)
  - IRB Review, Informed Consent, Event Reporting, Continuing Review, Record Retention
  - Financial Disclosures
  - IND/IDE Submission & Reporting
  - "Case histories" & "Relevant observations"
  - Control of Investigational Product

45 CFR 46; 21 CFR 50; 21 CFR 56; 21 CFR 312; & 21 CFR 812

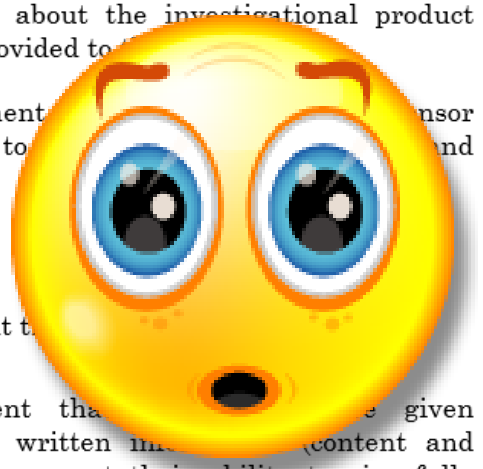
Essential Documents: ICH GCP

8.2 Before the Clinical Phase of the Trial Commences

During this planning stage the following documents should be generated and should be on file before the trial formally starts

	Title of Document	Purpose	Located in Files of Investigator/ Institution	Located in Files of Sponsor
8.2.1	**INVESTIGATOR'S BROCHURE**	To document that relevant and current scientific information about the investigational product has been provided to	X	X
8.2.2	**SIGNED PROTOCOL IF ANY, AND SAMP FORM (CRF)**	document ement to nsor nd	X	X
8.2.3	**INFORMATION G SUBJECT**		X	X
	- INFORMED CONS (including all applica	ocument t		
	- ANY OTHER WRITTEN	To document tha given appropriate written in (content and wording) to support their ability to give fully informed consent	X	X
	- ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used)	To document that recruitment measures are appropriate and not coercive	X	
8.2.4	**FINANCIAL ASPECTS OF THE TRIAL**	To document the financial agreement between the investigator/institution and the sponsor for the trial	X	X

53!



ICH GCP Guidelines

Essential Documents: UR

RSRB Approval Letters

This approval is contingent upon the investigation being conducted in compliance with the approved study protocol including all requirements and/or determinations of the RSRB. Unless a Waiver of Consent is specified above, consent must be obtained and documented in the manner approved by the RSRB. Please note all remarks and/or attachments. Only consent forms and recruitment materials bearing a current RSRB Approved watermark may be used. Only the most recently approved version of any consent or recruitment document may be used when obtaining consent. **Consent forms/recruitment letters must be printed on department letterhead.**

As the Principal Investigator, you are responsible for the following activities:

- Timely submission of continuing review progress reports apply to RSRB at least 8 weeks before expiration. Federal Regulations require that the RSRB conduct continuing review of research. You will receive an email notification when the expiration date is approaching.
- Requesting any proposed changes in the above research activity. All subject recruitment materials must be approved prior to use. Changes may not be initiated without RSRB approval except when necessary to eliminate apparent immediate hazards to the subject(s) and then a report must be submitted along with the amendment request
- Maintaining all approved study documents in your study file
- Maintaining all approved pages of the signed consent form for at least three years after the research is completed (six years if protected health information was collected as part of the research) or for a longer term if required by FDA regulations or other contractual agreements.
- Reporting any unexpected serious problems involving risks to subjects or others (including unexpected deaths, hospitalizations or serious injuries) in accordance with the Guidance for Reporting Reportable Events to the RSRB
- Submitting a final progress report to the RSRB upon completion of this study

Essential Documents

- Essential Documents Basics
- Categories of Essential Study Documentation
  - Investigator Responsibilities
  - Phase of the Research
- Best Practices
- Resources
- Scenario/Case Study Presentations

Investigator Responsibilities

1) Protect the rights, safety & welfare of the subjects
   - Adhere to regulatory, institutional requirements
   - Adhere to the protocol
   - Control the investigational product
   - Event monitoring & reporting

2) Supervise the conduct of the investigation

FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Subjects

Essential Documents: Investigator Responsibilities

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2) Supervise the conduct of the investigation

Reg/Institutional Requirements
- IRB Approval Letters
- IRB Approved Docs
- IRB Comm, Reports

Overall Conduct/ Supervision
- Delegation Logs
- Training Logs
- CVs, Licenses, etc.
- Team Mtg Minutes

Protocol Compliance
- Informed Consent
- Source Docs, CRFs
- Event Reporting
- Inv Product Acct

Regulatory/Institutional Requirements

- All IRB Approval Letters
  - Initial approval, amendments, re-approvals
- All IRB Approved Documents
  - Protocols, informed consent forms, recruitment materials → anything you upload to application
- IRB Communications
  - Reportable events, stipulations memos, QI follow-up memos, etc.

Regulatory/Institutional Requirements

- Additional IND/IDE Documentation
  - IND/IDE submissions, annual reports, amendments, safety reports
  - FDA communications
  - Investigator's Brochure
  - 1571/1572; Investigator Agreement
  - Financial disclosures

- Additional Institutional Requirements
  - COI management plans
  - Ancillary committee approvals

Essential Documents: Investigator Responsibilities

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Overall Study Conduct/Supervision

- Document:
  - ➢Delegated Tasks:
    - Delegation of Authority Log
  - ➢Training:
    - CVs, Medical Licenses, Human Subjects/GCP Training, etc.
    - Study Team Training & Communications
    - Study Team Meeting Minutes
  - ➢Supervision:
    - PI Review of Documentation (with initial/date) – eligibility checklists, investigational products logs, adverse events, lab reports, etc.

FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Subjects

Essential Documents: Investigator Responsibilities

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- Informed Consent
- Source Docs, CRFs
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Protocol Compliance

Let's Brainstorm!

Using the brainstorming worksheet provided at registration, try to come up with a protocol-defined activity that would require documentation for each letter of the alphabet.

A		N	
B		O	
C		P	Payment (Subject Payment)
D		Q	
E		R	
F		S	
G		T	
H		U	
I		V	
J		W	
K		X	
L		Y	
M	Medical Monitor Report	Z	

Protocol Compliance

- Documentation should…
  - ➢Align with the day-to-day procedures described in the study protocol
  - ➢"Tell the story of your study"
    - Could an uninvolved party reconstruct your study long after the study was completed?

- *"If it's not documented, it didn't happen!"*
- *"Document what happened AND what didn't happen."*

Protocol Compliance

- Subject Identification, Recruitment & Consent
  - Screening/Enrollment Log, Signed Informed Consent, Description of Consent Process, etc.
- Study Population
  - Eligibility Checklist & Screening Visit Documentation
- Methods & Procedures
  - Study Visit CRFs, Surveys, Lab Tests, Inv Product Accountability, etc.
- Event Reporting & Monitoring
  - Protocol Deviation Log, Adverse Event Logs, DMSB minutes, etc.

Documentation by Phase

Before

- Protocol (& Amendments, if any)
- Study Documentation/Data Collections Tools/Case Report Forms (CRFs)
- Informed Consent, Recruitment Material, Supplemental Info
- Confidentiality Agreement, Clinical Trial Agreement
- Investigator's Brochure
- Form FDA 1571 / Investigator's Agreement
- Financial Disclosures
- IRB Approvals
- Investigator, Study Team Qualifications
- Pre-Trial Monitoring Reports & Training
- Normal Lab Values & Lab Certifications
- Inv Product – Handling Instructions, Shipping Records, Unblinding Procedures, Sample Label, Cert of Analysis

During

- Revisions to: Protocol, Investigator's Brochure, CRFs, Informed Consent, Recruitment Material, Clinical Trial Agreement, Form FDA 1572, Study Team Qualifications, etc.
- IRB Reports & Approvals (Amendments, Continuing Reviews, Safety, Progress, Non-Compliance)
- Sponsor/Monitoring Reports (Visit Logs/ Reports, Safety-Related Notifications, Communications)
- Delegation Log, Site Signature Sheet
- Signed Informed Consent Documents, Screening/Enrollment Logs, Signed/Dated CRFs, Investigational Product Accountability Docs
- Records of Retained Biological Samples
- Relevant Communications

After

- Completed Enrollment/Subject Identification Logs
- Completed Sets of All Subject Data Forms (CRFs, Query Forms, Event Reporting)
- Final Investigational Product Accountability (including documentation of destruction of unused product)
- Final IRB Report & Close-Out
- Final Sponsor/Monitoring Close-Out
- Final Result/Interpretation Report

ICH Guidelines – Section 8
Liu, 2009
Maddock & York, 2012
OHSP Study Documentation Toolbox – Regulatory File Contents Description

Essential Documents

- Essential Documents Basics
- Categories of Essential Study Documentation
- Best Practices
  - Documentation Plan
  - Good Documentation Practices
- Resources
- Scenario/Case Study Presentations

Best Practices: Documentation Plan

- Hit the pause button
- Have a plan
- Don’t shoot yourself in the foot

Best Practices: Documentation Plan

- How will you document…
  - Regulatory/Institutional requirements?
  - Protocol compliance?
  - Overall conduct & supervision?
  - Study team training?

- How will you organize & maintain that documentation?
  - Accessible to study team?
  - Be consistent!
  - Don't rely on ROSS!

Documentation Tool Development

- Ask yourself…
  - ➢Does the data recorded in the form align with the procedures described in the protocol and the regulatory requirements?
    - Are ALL protocol-defined procedures addressed?
      - Information sent for analysis
      - Information reported to IRB/DSMB/Sponsor
      - If you're not analyzing or reporting: Why collecting? Do you need to revise the protocol/consent?
    - Have you considered regulatory requirements? E.g., informed consent, event reporting, investigational product accountability

Jackson & Pepe, 2014

Documentation Tool Development

- Ask yourself…
  - ➢Am I utilizing the form to demonstrate *and promote* protocol compliance?
    - Consider details that might not be captured otherwise
      - E.g., checklist for subject instructions
    - Include protocol details as reminders
      - E.g., vitals completed after subject has been resting in sitting position for at least 5 minutes
  - ➢Have I demonstrated PI oversight?
  - ➢Am I duplicating information unnecessarily?

Jackson & Pepe, 2014

Documentation Tool Development

- Ask yourself…
  - Have I included all the necessary parties in the development process?
    - PI, Study Coordinator, Statistician
  - Have I provided clear instructions and units of measure?
  - Am I confusing source documentation and data collection tools?
    - Source = Original document, data & records
    - If the EDC or your data collection tool is your source, identify this in your study protocol

Jackson & Pepe, 2014

Documentation Tool Development

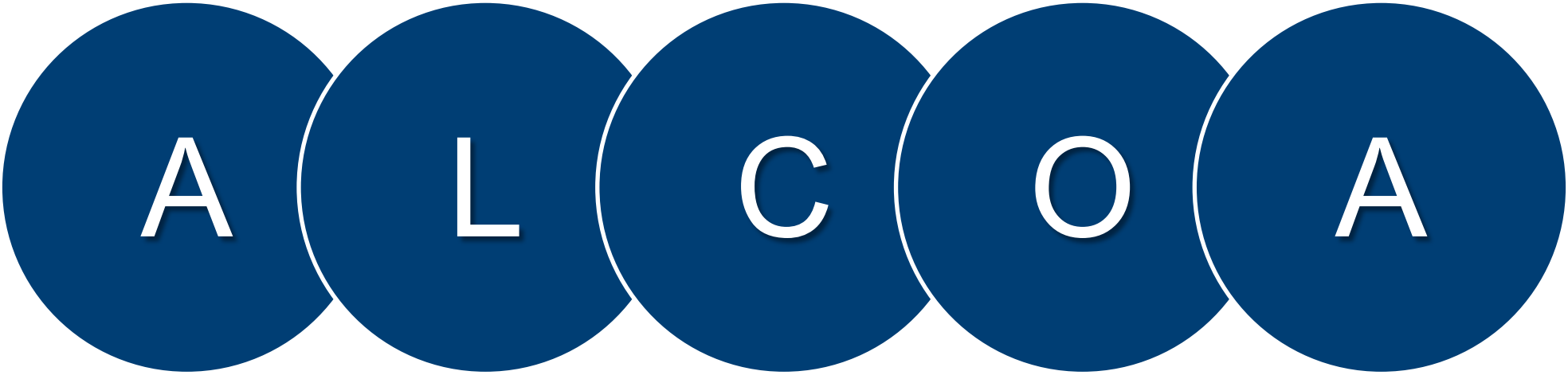
- Ask yourself…
  - ➢Have I included document headers/footers?
    - Subject IDs, study protocol #, date, visit, signature/date of person recording the data, version # & date?
  - ➢Have I left any questions unanswered?
    - Put your 3rd party hat on…
      - Are there blanks? Was the procedure not completed or was the information not recorded?
      - Were there adverse events reported? Did you ask?
      - Did the subject finish the study?
      - Was the blind maintained?
      - Comments/Notes section?

Jackson & Pepe, 2014

Best Practices: Documentation Plan

- How long will you retain your documentation?
  - RSRB: 3 years following completion (6 years if consent includes HIPAA)
  - IND/IDE: 2 years following approval of New Drug Application or Premarket Approval *(21 CFR 312 & 21 CFR 812)*
  - Longer per sponsor or contract?
- Will you put an internal audit process into place? How?
- Remember: KISS!

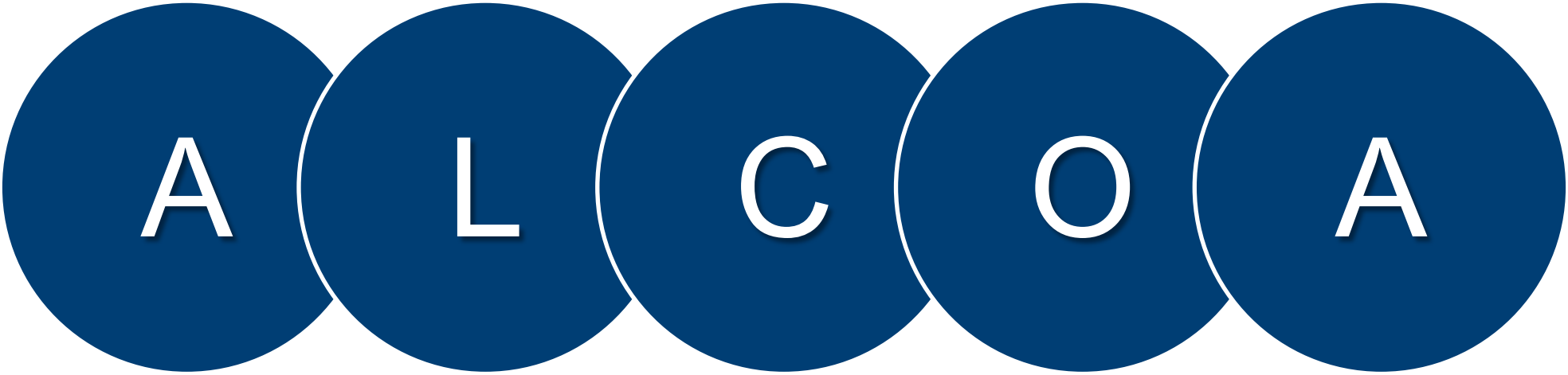
Good Documentation Practices



Attributable
Legible
Contemporaneous
Original
Accurate

Bargaje, 2011

Good Documentation Practices



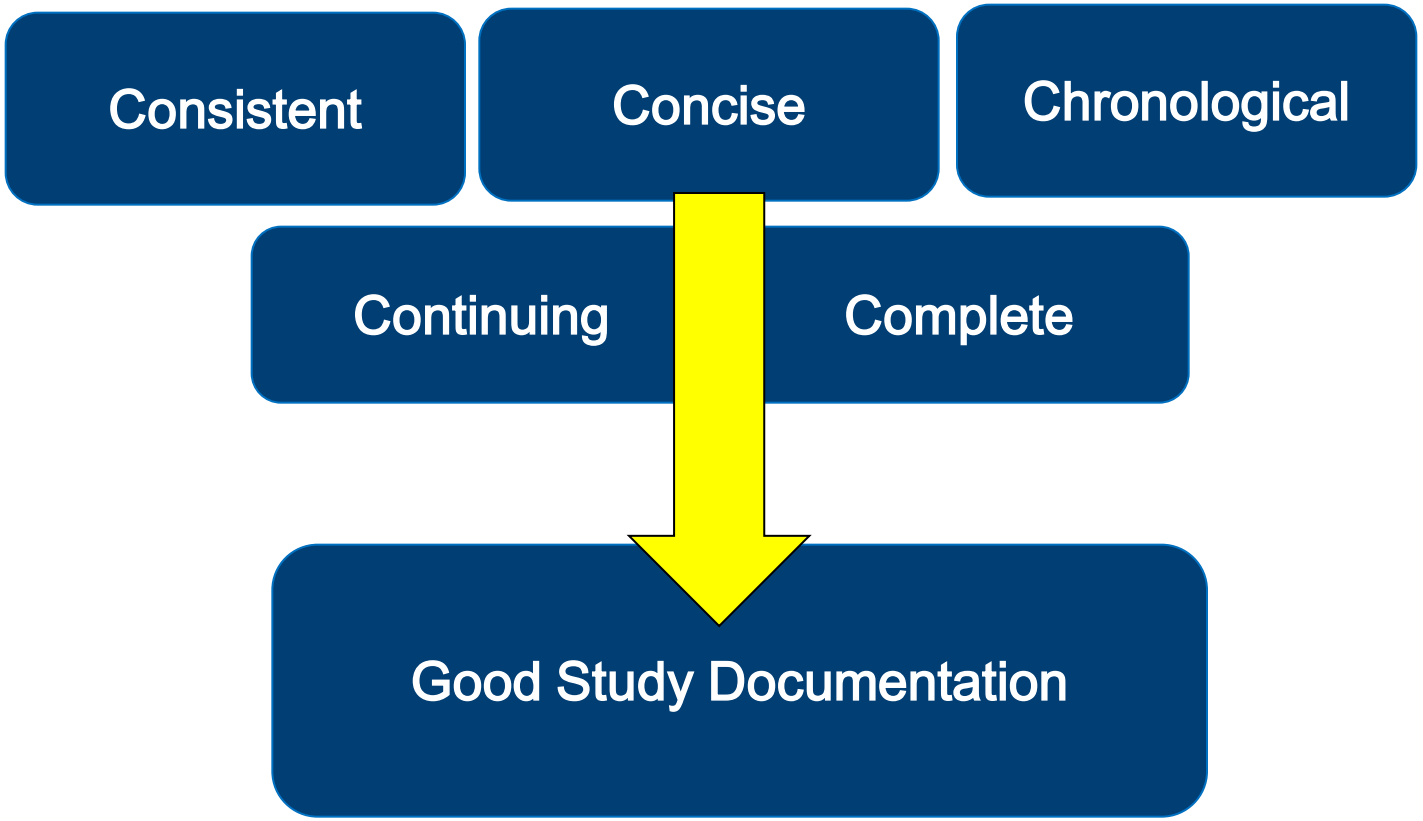
Attributable
Legible
Contemporaneous
Original
Accurate

Enduring
Available & Accessible
Complete, Consistent
Credible & Corroborated

Bargaje, 2011

Good Documentation Practices

The 5C's



Essential Documents

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Resources:
OHSP Documentation Toolbox

Research Study Regulatory File

File(s) can be in a binder or a folder. Much can be stored electronically – but we highly suggest a systematic system as it can become convoluted if your site has many changes over time. Also, if electronic, it needs to be accessible by many in case of emergency.

The following MUST be in your **Regulatory File**.

Protocol

- all approved versions (clean copy, not tracked)
- when an amended version is approved, cross off front page of previous version noting 'superseded by version #2, approved 01JAN13'

Informed Consent forms

- All *watermarked* versions: Original plus any further approved

IRB Approval Documents

- Original Approval Letter
- Amendment Approval(s) Letter
- Annual Re-Approval(s) (Continuing Reviews) Letter

Any other IRB Approved (*watermarked*) Documents (ex.: recruitment flyers, release forms)

Other IRB Communication (ex.: Reportable Events, Stipulation documents):
http://www.rochester.edu/ohsp/documents/rsrb/pdf/ReportableEventDefinitions.pdf

Data Safety Management Plan/Board, and applicable reports as defined by protocol.

Subject-Specific Research File(s)

- Signed Informed Consent form(s), as applicable
- Document Inclusion/Exclusion criteria and PI (or Sub-I) confirmation of eligibility
- Adverse Event assessment (especially if a greater than minimal risk study)
- Data Collection sheets, labeled with study identifier
- Email consent form (if emailing PHI)

Good Clinical Practice Research Studies (mandatory for drug and/or device trials) must have the above, plus the following. These are Good Practice but not mandated for non-drug, non-device trials.

- PI and Co-/Sub-I Curriculum Vitaes
- 1572, if applicable
- 1571, if applicable
- Financial Disclosure form, if applicable. (If a 1572 is required, a Financial disclosure form is required for each person listed)
- Investigator's Brochure, if applicable
- IND/IDE application, approval (safe-to-proceed letter), annual reports, amendment(s), FDA communications, and associated documents, if applicable (UR-PI held IND only)
- Data Safety Management Plan or Board and applicable reports as defined by protocol
- If conducting studies obtaining lab samples (i.e. blood specimens): lab certifications & licenses, normal lab ranges.
  (http://www.urmc.rochester.edu/pathology_lab_medicine/clinical_labs/service_offerings/researchers_services.cfm)
- Certificate of Confidentiality, if applicable (ex.: forced disclosure situations: prisoners)
- Staff Signature Log
- Delegation of Authority Log
- Comprehensive Subject Log (including all subjects screened, screen-failed, withdrawals, and enrolled).
- Identification Code list
- Randomization log, as applicable
- Drug Dispensing Log (tracking expiration dates, subject given to, shipping, proper storage, and destruction of)
- Temperature Log (for IP storage location)
- Sample of Investigational Product label, as applicable.
- Subject-specific drug accountability information.
- Grant documents should be maintained, do not need to be in the study-specific regulatory file
- Conflict of Interest Management Plans, if applicable (should be maintained, do not need to be in the study-specific regulatory file).
- Record of Subject Payments (should be accessible, not in subject files)

OHSP Study Documentation Tool Box

Rule of Thumb

- Non-FDA Regulated
  - ➢Minimum
- FDA Regulated
  - ➢IND/IDE Exempt
    - Minimum + applicable ICH GCP
  - ➢IND/IDE
    - Minimum + all ICH GCP

Minimum

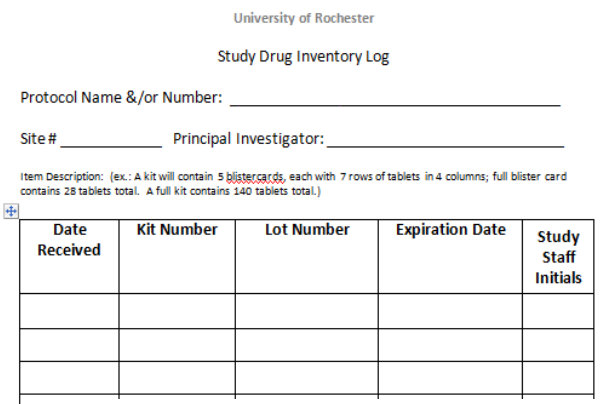
- Regulatory
  - Approved Protocol, Consents, etc.
  - Approval Letters
  - IRB Communications
- Protocol Compliance
  - Informed Consent
  - Email Consent
  - Eligibility
  - AE Assessment
  - Data Collection Sheets/CRFs
  - DSMB/Safety Monitoring

Resources:
OHSP Documentation Toolbox

Study Documentation Tool Box

These templates were created for individuals to use to meet the standards required for conducting research studies with Human Subjects. For those experienced with conducting studies for the pharmaceutical industry or for the NIH, variations of these forms may be familiar to you. They are in Microsoft document format and may be customized to meet protocol-specific requirements.

Templates	Sample
Regulatory File	
Regulatory File Contents Description	---
Logs	
Signature and Delegation of Authority Log 1	pdf
Signature and Delegation of Authority Log 2	pdf
Signature and Delegation of Authority Log 3	pdf
Signature and Delegation of Authority Log 4	pdf
Signature Log 1	pdf
Signature Log 2	pdf
Training Log 1	pdf
Training Log 2	pdf
Consent Log	pdf
Enrollment Log 1	pdf
Enrollment Log 2	pdf
Adverse Event Log 1	pdf
Adverse Event Log 2	pdf
Adverse Event Log 3	pdf
Concomitant Medication Log 1	pdf
Concomitant Medication Log 2	pdf
Subject Investigational Product (IP) Accountability Log	pdf
Investigational Product (IP) Inventory Log 1	pdf



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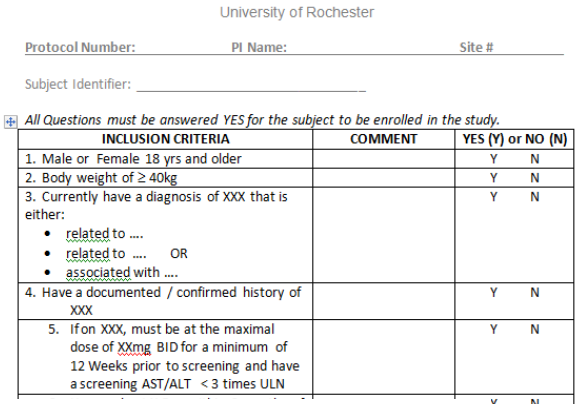
Study Drug Inventory Log

Protocol Name &/or Number: _____

Site # _____ Principal Investigator: _____

Item Description: (ex.: A kit will contain 5 blistercards, each with 7 rows of tablets in 4 columns; full blister card contains 28 tablets total. A full kit contains 140 tablets total.)

Date Received	Kit Number	Lot Number	Expiration Date	Study Staff Initials



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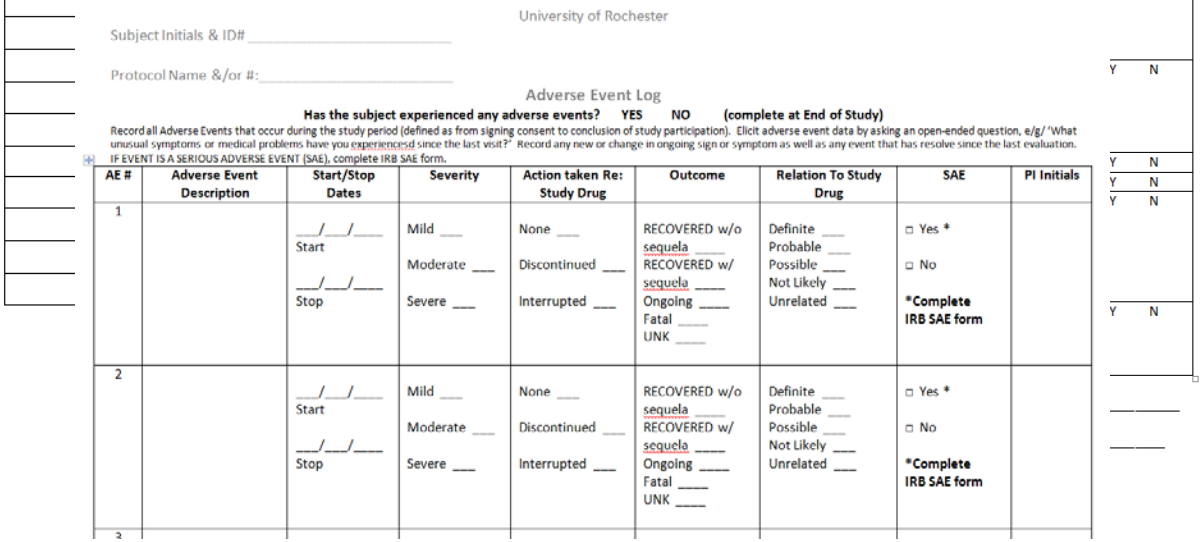
Protocol Number: PI Name: Site #

Subject Identifier: _____

All Questions must be answered YES for the subject to be enrolled in the study.

INCLUSION CRITERIA	COMMENT	YES (Y) or NO (N)
1. Male or Female 18 yrs and older		Y N
2. Body weight of ≥ 40kg		Y N
3. Currently have a diagnosis of XXX that is either: • related to …. • related to …. OR • associated with ….		Y N
4. Have a documented / confirmed history of XXX		Y N
5. If on XXX, must be at the maximal dose of XXmg BID for a minimum of 12 Weeks prior to screening and have a screening AST/ALT < 3 times ULN		Y N



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Subject Initials & ID# _____

Protocol Name &/or #: _____

Adverse Event Log

Has the subject experienced any adverse events? YES NO (complete at End of Study)

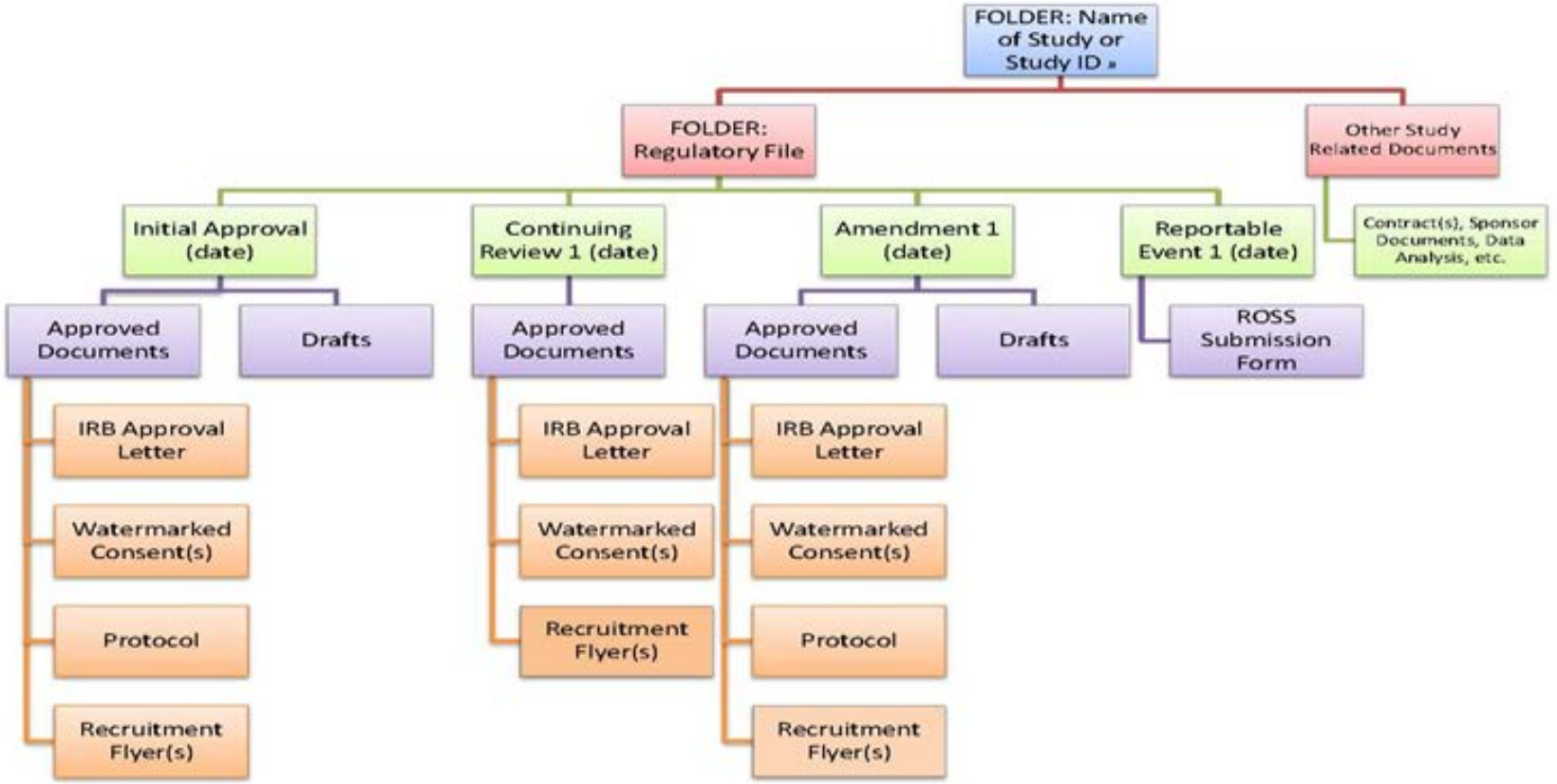
Record all Adverse Events that occur during the study period (defined as from signing consent to conclusion of study participation). Elicit adverse event data by asking an open-ended question, e/g/ 'What unusual symptoms or medical problems have you experiencesd since the last visit?' Record any new or change in ongoing sign or symptom as well as any event that has resolve since the last evaluation. IF EVENT IS A SERIOUS ADVERSE EVENT (SAE), complete IRB SAE form.

AE #	Adverse Event Description	Start/Stop Dates	Severity	Action taken Re: Study Drug	Outcome	Relation To Study Drug	SAE	PI Initials
1		___/___/___ Start ___/___/___ Stop	Mild ___ Moderate ___ Severe ___	None ___ Discontinued ___ Interrupted ___	RECOVERED w/o sequela ___ RECOVERED w/ sequela ___ Ongoing ___ Fatal ___ UNK ___	Definite ___ Probable ___ Possible ___ Not Likely ___ Unrelated ___	□ Yes * □ No ***Complete IRB SAE form**	
2		___/___/___ Start ___/___/___ Stop	Mild ___ Moderate ___ Severe ___	None ___ Discontinued ___ Interrupted ___	RECOVERED w/o sequela ___ RECOVERED w/ sequela ___ Ongoing ___ Fatal ___ UNK ___	Definite ___ Probable ___ Possible ___ Not Likely ___ Unrelated ___	□ Yes * □ No ***Complete IRB SAE form**	
3								

[OHSP Study Documentation Toolbox]

Resources

How to Build an Electronic Regulatory File



[OHSP Newsletter – Q1 2014]

Resources

- National Institute of Dental and Craniofacial Research Toolkit for Researchers
- ICH GCP – Section 8
- Google!

Don’t forget to make the documents work for you! Modify/Delete fields as appropriate.

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Final Words…

"…it is important to understand that proper documentation of a clinical research trial is not just a means of organized filing for a multiplying mound of paperwork. It is a tangible trail that *tells the story of the trial* from conception to completion, *reflecting adherence* to applicable regulations and *demonstrating trial integrity* through transparency."

Maddock & York, 2012

Remember…

- Essential Documentation will vary from study to study
  - ➢Bottom Line:
    - Maintain all documents relevant to each specific trial & maintain all versions of those applicable documents
    - Demonstrate compliance
    - Demonstrate oversight

- When your not sure, ASK QUESTIONS!

Questions?

References & Resources

45 CFR 46; 21 CFR 50; 21 CFR 56; 21 CFR 312; 21 CFR 812

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FDA Bioresearch Monitoring Program Inspection Metrics 2013. Available at: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm261409.htm

FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects. Available at: http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf

References & Resources

International Conference on Harmonization E6 Good Clinical Practice Guideline. Available at: http://ichgcp.net/

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References & Resources

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https://www.nidcr.nih.gov/nidcr2.nih.gov/Templates/Toolkit.aspx?NRMODE=Published&NRNODEGUID={09426ABC-1182-4433-9A7D-A57674A5334F}&NRORIGINALURL=%2fResearch%2ftoolkit%2f&NRCACHEHINT=Guest#startup6

OHSP Newsletter – Q1, 2014:
http://www.rochester.edu/ohsp/documents/ohsp/pdf/newsletters/Q1_OHSP_Newsletter_2014.pdf

OHSP Study Documentation Toolbox:
http://www.rochester.edu/ohsp/quality/studyDocumentationToolBox.html