Storage & Archival Of Documents & Data



Module 6 Topic 6

"Essential" Documentation

Documentation, Record Keeping, and Retention

- Permits evaluation of the conduct of a study
- Permits evaluation of data collected
- Demonstrates GCP and compliance with applicable regulatory requirements
- Facilitates study management and oversight
- Allows for monitoring and evaluation of practices



"Essential" Documentation

- Essential Documents
 must be organized and
 retained for the
 conduct of clinical
 studies
- These organized documents are referred to as the REGULATORY BINDER
- The binder must be kept at the Investigator's clinical site





**TIP: Synonyms: Investigator Binder = Regulatory
Binder = Investigational Site File (ISF) = Study Binder
= Master Trial File (MTF)

Key Definitions: Documentation

- Source Documents are original records and certified copies of original clinical findings and observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial Section 1.51 ICH E6 GCP
- Case Report Forms (CRF's) A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor for each trial subject (Section 1.11 ICH E6 GCP) to capture essential source data about the subject for analysis to answer the hypothesis of a study

creating the source



Key Definitions: Data Management Plan

- Data Management: Is the responsibility of the research staff and a host of other IT professionals related to collecting, entering, securing, and preserving data as a valuable, and reproducible resources for the outcome of the study.
- Data Integrity: Includes the development of policies and ethical practices for consistent procedures that properly manage the full data lifecycle needs for the outcome of the clinical trial. The principal investigator (PI) is the person responsible for data integrity, but must rely on the team of research professional in IT and the research coordinator to uphold the policies



Key Members for Source Data Lifecycle to Achieve Data Integrity

It involves many different research members!

- Clinicians, Nurses and Clinical Research Coordinators (Site)
- Clinical Research Associates or CRA Monitors (Industry)
- Data Safety Committee (DSC) monitors



Key Members for Source Data Lifecycle to Achieve Data Integrity (contd)

- Data Offices (Industry)
- Database Managers
- Biostatisticians (Site or Industry)
- Nurses, Doctors who manage safety offices for drug manufacturers(Industry)





Essential Documents - Regulatory Binder

 Essential Documents must be organized and retained for the conduct of clinical studies.



- These organized documents are referred to as the REGULATORY BINDER
- The binder must be kept at the Investigator's clinical site



Purpose

- To provide an organizational framework for filing paper versions of essential study documents (or referencing location of an electronically stored file)
- Compliance for Good Clinical Practice
- Core documentation required by Good Clinical Practices (GCP) before a study is initiated
- Additional GCP-required essential documents satisfy NIH grant documentation requirements
- To ensure all GCP-required essential documents are in place and in order for the clinical trial



Organizing Your Regulatory Binder

Location

- Locked office accessible to research study team
- Single or multiple binders stored in the same or different locations



Regulatory Binder (contd)

 List other locations in binders, if other than primary site. Know binder locations!



 Place a note to file in the section of the binder reference location of separate binder or location of Electronic document access



**TIP: The Regulatory Binder is the first document reviewed during audits or inspections

- Organizing Your Regulatory Binder
- Filing
- Use tabs or dividers for each section; place documents in corresponding sections
- Label outside of binder cover and spine (protocol number, PI name, study site)



- Store documents in reverse chronological order with the newest items within a section placed at the front of the section
- Know document placement to pullout in a timely manner
- Group documents as generated before study generation, during the trial conduct and after study completion
- Multi-sites studies: The lead site may choose to customize the checklist for the study and provide to all participating sites



Table of Contents

- Protocol Amendments
- Notes-To-File / Correspondence
- Telephone / Communications Log
- Clinic Staff Roles & Responsibilities / Signatures
- Investigational Product Accountability / Logs
- · Regulatory Documents
- Individual Patient Records / Files and Source Documents
- Enrollment / Recruitment Logs

List of Essential Documents

- Protocol
- Supplemental Protocol instructions (Manuals)
- Case Report Forms (Blank master copies)
- Investigator Brochure (IB)
- Consent Forms / Information for Patients
- Subject Logs
- Serious Adverse Event / Safety reports
- IRB Submission Tracking Log / Approvals / Correspondence
- Site-Sponsor Correspondence



Essential Study Documents Overview

- Study Protocol signed, dated by all entities (PI, sponsor)
- Study Protocol Amendments
- Informed Consent
- IRB Approval(s)
- Delegate of Authority and Log of Responsibilities
- Curriculum Vitae (CV's) current
- Financial Disclosures



Essential Study Documents Overview (contd)

- Protocol Training Documentation
- Training Documentation to conduct research, studyrelated duties or functions
- Adverse Events and/or unanticipated events
- Study Protocol Deviations
- Note to File (NTF)
- Standard Operating Procedures(SOPs); Manual of Procedures (MOPs) and or Appendixes
- All communications between entities (PI, research team, CRO, sponsors, governing boards)



Protocol & Amendments

- IRB-approved Protocol (original and amendments)
- Signed principal investigator (PI) signature pages (PI address/ signature/date)
- IRB-approved Case Report Forms (CRF's)
- IRB-approved advertisements, brochures, letters
- IRB-approved Participant Information Sheets
- IRB-approved Protocol Amendments and (PI) signature page
- Store in reverse chronological order current approved version first
- Log of protocol changes



IRB Documentation & Approvals

- IRB contact information for missing documents
- Updated IRB Membership Rooster
- IRB registration
- IRB approval letters
- Original IRB application/New Project Submission
- IRB correspondence related to contingent approvals or stipulations
- IRB interim/annual review progress reports
- HIPAA authorization, waiver, and or research preparation purposes



Informed Consent Documents

- IRB-approved/stamped consent documents (clean copy)
- IRB-approved/stamped assent documents
- IRB-approved/stamped short form consents for non-English languages include guidance for consent of non-English speaking
- Place most currently approved consent in plastic sleeve
- Store in reverse chronological order with current approved version
- Log of Informed Consent versions



Investigator Qualification Documentation

- Current Updated investigator and sub-investigator curriculum vitae (CVs) with address, signature and date
- CVs address should reflect address on 1572
- Current clinical professional licensure (dental, medical, nursing, pharmacy, etc.) for PI and coinvestigators, if licensed
- Update CV and licensure documents as they expire
- The CV & licensure dates should reflect mirror each other.



Clinical Investigator's Brochure (IB)

- · Clinical investigator's brochure (drug or device) or
- Package insert; include labeling for approved medications
- All amendments to the IB
- Device information sheet/manual



FDA Documents

- FDA Form 1571 (if applicable): Date and sign all versions
- FDA Form 1572 (If applicable): Investigator initiated INDs
- Signed investigator agreement (if applicable)
- Samples of labels attached to investigational product containers
- Regulatory approval or authorization
- FDA Correspondence Log (if applicable)



Example: Form FDA 1572:

	FINENT OF HEALTH MICHARIN SI FOOD AND DRUG ADMINISTRATO TATEMENT OF INVESTIGAT	Switzer Day See CHE that	o OME No. 1010 OT a is frateuply 26, 2015 ament or Revenu.		
(TITE# 24, 00)	DE OF RESERVA, REGULATIONS) (See Instructions on revenue scin.	CFIS PART 312)	P 31Q) So readydo my pelitipal if an medigillor utilizativumida he para; a projektel, agrani flakovsk of medigila (SA 1570) (SR XLSkin).		
1.1486-0101-007691	OF PRIESTIGATOR				
Name of Circles (needings)					
Allfans 1		Address 2			
Personal Control of the Control of t		Marian I			
Ole	Sectionalism	County	JP in Ploate Code		
	E INC EIPERENEE THE GLAUP THE LIE LINCOT MASS FOR THE ST. TH				
	Contolon Vise	() Other National	et of Southwaters		
VIMENE THE ILLANDA	OF ANY MEDICAL BOHOOL HEISFITAL OF MINESFER FIRE STREET, MEDICAL PROPERTY AND ADDRESS OF THE STREET, MEDICAL P	OR ETHER RESENACH I	NOLEY	TOWNSON HOE HOE TO THE PERSON IN	
Norw of Medical School, 6	hopisi a Othe Research Facility				
Althora 1		HATHER 2		7	
Oly	Statific exaffejan	Goothy		29ho Posta Code	
4 MME AIG IGCHESS	OF ANY SLANCE, LINEOUVEDING THOSE	H 10 (38), 90 (7 89)	FIOY	EDATMONTON HOSE Services	
Name of Contact advantage	e Facility			-	
Address 1		Address 2			
Oly	last confeps	Country		29'or Florid Code	
MAKE AND MODIEST	OF THE RESTRICTIONS, REVENUED HE AL OF THE STREYERS	HER THAT IS ASSESSED.	98LE FOR	SOMFMANTON TAKE Service 6	
Nerw FTD					
Attimes 1		dibber 2			
Glp	SeePointe/Age	County		JP-or Florin Code	
		7.77			

Tie Phase 2 or 3 or a bealed with the drug of subjects to age, or	outgets that will be involved. edigitized, ar cultime of the equity protocol including on- and the number to be entployed as contribut. I any, the o to, and condition, the tolocol of dispensions entitle and copies or a literatyleter of case report forms to be used.	Pricel uses to be investigated; characteristics contains bette to be contacted; the estimated
COMPLETE		
	olyjnej in accomiance with the relevant, current protecció opciwinen recionalny is protect the safety, rights, or wells	
Topie troeronally con	(ut ir supervise the described investigation().	
rapes to often any out assure that the requirem and approval in 21 CPR	ents, or any persone coedine controls, that the drugs are arts relating to obtaining informed consent in 21 CVEC for fact IV are med.	teing used for investigational purposes and I will it SI and Institutional review found (FSE) review
	onor almine equitinos fiel ocur in the custe of the unbestigate in information in the insulgator's inschus,	
i agree it-encore that all adligations in meeting to	secclates, colleagues, and employees sections in the creations commitments.	artists of the study (set) are informed about their
lagner ti-maintain abay tepeditin in accordance	alls and according records in accordance with 21 OFR 21 with 21-DFR 242-88.	ESE pricino malaritrosa recordo analistia for
nonless and approval of the practicipated problems of	hal conglies with the requirements of 21 CFR Part SIZ of the obtain investigation. I also agree to promptly report to making date for human subjects or actives, Applicanally in set reconscopy to all nitides appared investigate hazards it	te RD al changes in the research activity and all ellinocrasive any changes in the research without
i agrae iti compti selti ali 21 OFR Red 312.	other requirements regarding the obligations of contacts	realigation, and all other partnerst requirements of
	METRICTIONS FOR COMPLETING FO STATEMENT OF INVESTIGAT	
1. Congress of sections	Provide a separate page l'additionel space in resolut	
2. Provide curriculum vis	se or other statement of qualifications as issurface in Ea	de i
1. Protti protestruti	ne as described in Section S.	
4. Sign and date below.		
incorporate this inform	PLOTED FORMAND CTHER SCIOLARISTS BEING PER ellor strop with other technical state sits on twentypics THIS POPEL SMICE IL Y TO THE FORCO MAD STRUCKE	ol New Drug Application (MCI, MVEST/GWTORE)
C DALE SAMESSING	1. BOWING OF INVESTIGATION Sign	
yearning a willing beau	datement is a criminal offense. U.S.C. Tile 18, Sec. 1	Wr.)
The information before against	only to requirements of the Properties in Reduction Act of	HE.
The budge time for this color expense, including the time to and represely the date resided a convenience expending this busile	tion of information is assimilated to coverage 16th have pain represent influentime, search resting 56th counties, gather of particulation of motion the collection of information. Send restinated in particular appeal of the information activation, by this business in the collection in regist.	Department of Hapith and Humain Bensions Fract and Drog Administration Office of Operations Reported Habitation Ad (MIA) (Ital) PARISHRIGHT Habitation (Ital)
Ne against may not contact or calculate of information units of	gonesic, and o juminor is very regulated to respected to, as alligation as controlly vallet CRRS represent	SCHOT SERO YOUR COMPLETED FORM TO THE PIOLETAP COME, ACCRESS.

IS PROVIDE THE FOLLOWING CLANCE, PROTOCOL INFORMATION, SURVIVING HTM Mining.



Financial Disclosure Forms (FDF)

- Signed Financial Disclosure Forms for PI, sub-PIs, coinvestigators, and applicable research team members
- Update if disclosure changes

Delegation of Authority (DoR) or Responsibilities Log

- Delegation of authority log with role descriptions;
- Involvement start and stop dates; PRINTED name, initials, and original signatures



Example: Delegation of Authority (DoR)

vestigator Name:		Protocol:		Site Numb	Site Number:		
staff to whom the Prin	cipal Investigator (PI) has deleg	ated signific	ant study-related duties.				
lame Responsibiliti		Initials	Signature	Start Date	End Date	PI Initials/Date	
		_			-	_	
		-					
initialing above, I, the P	I, declare that during the cond	act of the ab	ove study, I have delegated the	e following study-relat	ed activities:		
		uct of the ab	ove study, I have delegated the	e following study-relat	ed activities:		
			ove study, I have delegated the		ed activities:	15	
Responsibilities Legend		6. Randor		11. Comp			
Responsibilities Legend 1. Administer Conse	nt	6. Randor 7. Dispen	mize Subjects	11. Comp 12. Provid	lete Study Form	tructions	
Responsibilities Legend 1. Administer Conse 2. Screen Subjects	istory	6. Randor 7. Dispen 8. Drug A	mize Subjects se Study Drug	11. Comp 12. Provid 13. Make	lete Study Form de Discharge Ins	tructions	
Administer Conse Screen Subjects Obtain Medical H	nt istory Exam	6. Randor 7. Dispen 8. Drug A 9. Assess	mize Subjects se Study Drug ccountability	11. Comp 12. Provid 13. Make	lete Study Form de Discharge Ins Follow-up Phor	tructions	
Administer Conse Screen Subjects Obtain Medical H Perform Physical	istory Exam	6. Randor 7. Dispen 8. Drug A 9. Assess	mize Subjects se Study Drug ccountability Adverse Events ete Source Documents	11. Comp 12. Provid 13. Make 14. Query	lete Study Form de Discharge Ins Follow-up Phor Management	tructions	

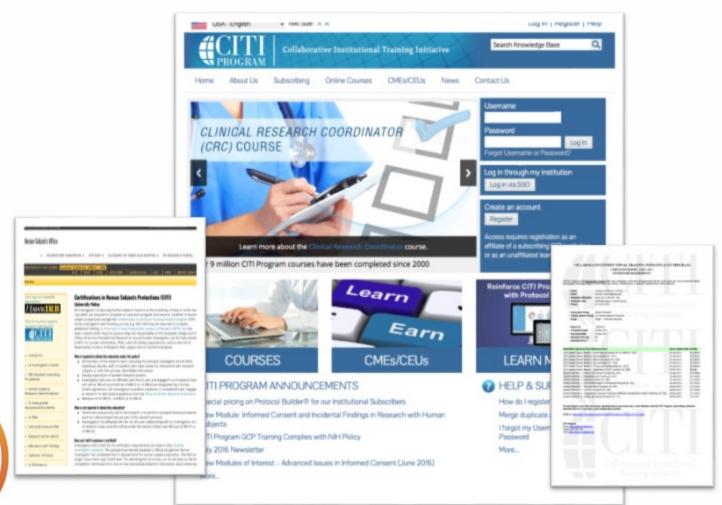
Clinical Research & Study Training

- Documentation of educational completion certificates for Human Subject Protections and Good Clinical Practice training for all staff members (CITI)
- Documentation of study-related training
- Dangerous Goods training (if applicable)
- Documentation of shipping biologics (IATA)
- Procedure training log



**TIPS: Current certifications based on institutional, GCP, & ICH guidelines

Research Educational Training HSP & GCP





Screening/Enrollment

- Subjects who were screened; reasons for screen failure
- Enrollment log
- Site screening plan

investigator Name:			di .	Site Number:			
Subject ID Date of Consent Con		Version of Consent	Date Screened	Eligible for Enrollment? Irofig		glicity Reason (Fapplicable)	
1							

Signed Consent Documents

 All original signed IRB approved and stamped versions consent documents



Subject Visit Tracking Log

- Log all enrolled subject visits
- Reasons for Early Termination (ET)
- Tracks/keeps scheduled visits as per protocol

Subject Identification Code List

- Confidential list of subject names
- Link between identity and study code to allow only the
- Investigator to reveal identity of any subject

Investigator Name:				Proteool: Site Nu			umber		
Visit	Specimen Name/Type	Specimen ID (Accession #)	Date Collected	Date Shipped	Tracking #	Receiving Lab	Dute Received	Comments	



Study Product Records

- Documentation of study product disposition
- Investigational Product Accountability Log: Stock Record
- Investigational Product Accountability Log: Subject
- Dispense Record





Local Clinical Lab Certificates/ Reference Ranges

- Laboratory reference ranges
- Copy of laboratory certification and accreditations

Lab Specimen Tracking Log

- Specimen sample log
- Shipping documentation
- Storage temperature logs



Local Clinical Lab Certificates







Serious Adverse Events (SAEs)

- SAE forms or memos
- Correspondence, copies and acknowledgement of reports of internal AEs
- External reports to IRB, Sponsor, regulatory authorities

Unanticipated Problems

Unanticipated Problems reports to IRB, Sponsor and regulatory authorities



Clinical Site Monitoring Visits

- Monitoring Visit Signature Log
- Each Visit's correspondence
- Post visit follow up letters



Study Communication

- Letter of Understanding/Confidentiality Agreement
- Data Sharing Agreement
- Material transfer Agreement
- Signed agreements between parties (i.e. sponsor/investigators)
- Important decisions regarding study conduct, such as notes to the Study File - Notes to File (NTF)



Guideline for Writing Notes to File (NTF)

Written to identify a discrepancy or problem in the conduct of the clinical research study to note:

- Root cause of the identified problem
- Identify the corrective action taken to prevent recurrence of the problem
- Document that the corrective action has resolved the problem
- The note should be forward-looking and not seek to explain an error discovered
- Print on institution letterhead initiated and authored by an individual responsible for its content



Guideline for Writing Notes to File (contd)

Retention and Distribution:

NTF should be kept on site in the site regulatory file,

Made available to the clinical site monitors reviewing the site's documents and procedures.

If the issue relates to PI responsibilities (e.g., human subject protection, data integrity at the site), the PI should write and sign the note to file.

If the issue relates to actions taken by the sponsor or monitor (e.g., clarification of a protocol section), an appropriate credentialed individual from the sponsor should write and sign the note to file.



Key Definitions: Documentation

 Source Documents are original records and certified copies of original clinical findings and observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial (Section 1.51 ICH E6 GCP)



Key Definitions: Documentation (contd)

 Case Report Forms (CRF's) A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor for each trial subject (Section 1.11 ICH E6 GCP) to capture essential source data about the subject for analysis to answer the hypothesis of a study



**TIP: All Source must have a signature and date, original or electronic, by the person creating the source

Key Definitions: Documentation (contd)

 Case Report Forms (CRF's) A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor for each trial subject (Section 1.11 ICH E6 GCP) to capture essential source data about the subject for analysis to answer the hypothesis of a study



Key Definitions: Data Management Plan

- Data Management: Is the responsibility of the research staff and a host of other IT professionals related to collecting, entering, securing, and preserving data as a valuable, and reproducible resources for the outcome of the study
- Data Integrity: Includes the development of policies and ethical practices for consistent procedures that properly manage the full data lifecycle needs for the outcome of the clinical trial. The principal investigator (PI) is the person responsible for data integrity, but must rely on the team of research professional in IT and the research coordinator to uphold the policies



Key Members for Source Data Lifecycle to Achieve Data Integrity

It involves many different research members!

- Clinicians, Nurses and Clinical Research Coordinators (Site)
- Clinical Research Associates or CRA Monitors (Industry)
- Data Safety Committee (DSC) monitors





Key Members for Source Data Lifecycle to Achieve Data Integrity

It involves many different research members! (contd)

- Data Offices (Industry)
- Database Managers
- Biostatisticians (Site or Industry)
- Nurses, Doctors who manage safety offices for drug manufacturers(Industry)



What Does Data Integrity Look Like?





Data Management Plan Best Practice: Let the protocol Begin!

- Protocol is approved
- CRFs are created based on the protocol
- Source Data is collected; entered, and reviewed for accuracy in the CRF electronic system
- Principal Investigator reviews, signs off
- Statistical Analysis data is pulled for analysis & interpretation
- Write manuscript and submit for publication



Good Documentation Practice (GDP)

Documentation

- Standards by which accurate and complete study
- Documents are created and maintained
- Study documents and data collection forms record the details of the study for that participant
- "Tells the story" of the participant in the study
- Complete and accurate study documentation supports the fundamental principle of protection of study participant's safety, rights, and well-being



Source Documentation

- Original paper clinical visit note by a clinical licensed professional (i.e., nurse, physician, ARNP)
- Electronic Medical Record (EMR) notes or reports scanned into the EMR from outside medical offices.
- Test results printed from an institutional EMR
- Pathology reports and/or procedure(s) results
- Specific form created by the CRU for the study to record a mandatory process required by the protocol (i.e. PK sample statement log, patient drug diary, procedure orders)



Study Documentation

- Documentation should follow the course of the participant in the study: from consent process → through all study visits → to completion or discontinuation and why.
- Examples of source documents can include:
 - tracking database
 - clinic and research charts
 - lab and radiography reports
 - consent documents and process documentation
 - visit checklists
 - participant questionnaires, participant diaries
 - medication lists, pharmacy records



Good Documentation Practice (GDP)

Attributes of GDP: "ALCOA"

- Attributable it should be clear who has documented the data
- Legible readable and signatures identifiable.
- Contemporaneous the information should be documented in the correct time frame along with the flow of events



Good Documentation Practice (GDP)

Attributes of GDP: "ALCOA" (contd)

- Original original or exact copy (photocopy preferred over 2nd original); the first record made by the appropriate person. Originals maintained at satellite locations during the study with copy to PI.
 Originals filed with PI at conclusion of study for records retention
- Accurate accurate, consistent and real representation of facts







Capturing Study Information

- Document what is and what is not done, including reasons for any missed information
- Use of indelible blue or black ink on paper forms
 - Reduces fading over time or smudging
 - No pencils, felt-tipped markers or white-out
- No back or future dating use of current date when entries are made



Capturing Study Information

- Discourage use of ditto marks for repetitive data.
- For any instrument printouts, adhere printout to chart with clear adhesive tape and include initials and date where the printout is attached



Correcting Study Information

- Corrections are expected!
- Single line through incorrect information, making sure not to obscure the original data
- No white out or writing over data (e.g. turning a 0 into a 9) because it hides the original data
- Enter the correct information
- Initial and date when the corrections were made
- Entries on study documents and changes to those entries should be made by study team members with the authority to do so as delegated by the PI.



Source Documentation

- If it is not documented it did not happen!
- ALCOA =

Attributable-Legible-Contemporaneous-Original-Accurate

- No white out if paper
- Single Line through incorrect data, must be legible
- Date and initial changes any additions by appropriate research staff person
- Electronic Medical Records present security, and other legal challenges; know your institutional regulations at UIHC



Optimize Documents

- Minimize impact by collecting only essential data
- Relevant and critical to safety and effectiveness endpoints
- Meet all guidance recommendations, where applicable
- Capture via checklist, limit to numbers, and or to a few descriptive words
- "Less can be more" avoid duplicate copies
 Errors happen!



- Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product
- It is the responsibility of the Sponsor to inform the investigator/institution as to when these documents no longer need to be retained



- The sponsor and the chief investigator shall ensure that the documents contained, or which have been contained, in the TMF are retained for at least 5 years after the conclusion of the trial and that during that period are—
 - readily available to the licensing authority on request; and
 - complete and legible



Confidentiality & Security

- Filing space should be available for the storage of TMF and local ISF during the conduct of the clinical trial. ISFs will normally be stored in an investigator's office or local filing area
- At the end of the trial the files must be transferred to a suitable archiving facility



Record Keeping

Investigators must ensure that data are recorded and stored correctly and accurately. This not only includes data recorded on Case Report Forms (CRFs) but also all original source data(patient medical notes for example), laboratory test results, radiological images and pharmacy data (drug dispensing records and drug accountability records for example)



Environmental Conditions

- The minimum requirement is for documentation to be stored in conditions that minimize the risk of damage or loss of information
- The risk of damage from water should be reduced by storing documentation above floor level and away from overhead water pipes
- Documentation should be located in areas with minimal variation in temperature and humidity if stored long periods of time



Research Team Responsibilities:

- All documents for hosted or Trust Sponsored studies which are to be archived must be presented to the R&D unit in a state ready for archiving
- The site file should be organised in a suitable lever arch file, and be labelled with the name of the Investigator, Acronym/Short Study Title, REC reference, R&D Reference and Sponsor



- All CRF's should be labeled with the patients Study ID, Acronym/Short Study Title, REC Reference & R&D Reference; or included in a file labeled with these details
- All other essential documents should be filed in a lever arch file which should be labeled with the name of the Investigator, Acronym/Short Study Title, REC reference, R&D Reference and Sponsor



For CTIMPs only original copies of pharmacy prescriptions are to be included as part of the archived pharmacy file. Duplicate copies do not require archiving with site file essential documents and can be confidentially destroyed at the time of preparing documents for archiving.



Source Data that forms part of current patient medical records (such as clinical observations, test results etc.) should remain within the patient's medical files and a note detailing the location of these source documents should be included in the archived documents.

The Investigator is responsible for ensuring that medical notes of participants are appropriately labelled to prevent premature destruction.



R&D Responsibilities

Once the documents have been received in R&D, the Named Archivist will ensure that all trial related documentation is placed into a suitable archive box (boxes). Depending on the number of documents to be archived it is permissible to archive more than one study in one archive box.



R&D Responsibilities

- Prior to transferring the documents to secure storage for archiving, the Named Archivist will complete the R&D archiving log with details of the study(ies) archived, including the following information:
- Archive Box Number
- Short Title of Study
- R&D Reference
- REC Reference



R&D Responsibilities (contd)

- Description of documents archived (i.e. site file, pharmacy file, CRF's for patients.)
- Name and Contact Details of Sponsor
- Name and Contact Details of Chief Investigator/ Principal Investigator
- Date of transfer for archiving
- Retention Period and expected destruction date

