MELBOURNE HEALTH	OFFICE FOR RESEARCH		
	STANDARD OPERATING PROCEDURE: SOP007		
	CRFs, Source Documents, Record Keeping and Archiving		
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1. AIM

To describe the procedures related to the completion of case report forms (CRFs), data collection forms (DCFs), source documents, record keeping and archiving. This includes the requirements around scanning of study documentation into the hospital's electronic medical records system (EPIC-EMR) in accordance with Melbourne Health's (MH) MH05 Documentation and Records Management Policy.

2. SCOPE

Applicable to **all clinical research studies** undertaken at Melbourne Health, including, investigator initiated research, collaborative research, commercially sponsored research and all phases of clinical investigation of medicinal products, devices and diagnostics.

This principle applies to all records created, used, stored or accessed for research at MH including CRFs, DCFs, source documents and/or records referenced in the MH SOPs, irrespective of the type of media used.

3. APPLICABILITY

The Principal Investigator (PI) is responsible for ensuring research study activities are conducted in accordance with this SOP.

The PI may delegate, as appropriate, some or all activities outlined in this SOP to study team members including, Associate Investigators (AI), research coordinators, nurses, and data managers. Delegation of study activities should be recorded on the signature and delegation log.

The PI is responsible for supervising any activities described in this SOP that have been delegated to ensure they are conducted appropriately. The PI remains responsible for any delegated activity.

4. PROCEDURE

All research study information (clinical trial or other) should be recorded, handled and stored/digitised in a way that maintains data integrity and allows its accurate reporting, interpretation and verification. This principle applies to all records referenced in the MH SOPs, irrespective of the type of media used.

4.1 Case Report Forms, Data Collection Forms and Source Documents

The PI or appropriate delegate should:

4.1.1 Establish a source document identification log (SDIL) for each study. The log should identify each document in which any source data is recorded (i.e. progress notes/medical record, Case report form (CRF), data collection form (DCF), X-ray, photographs, electronic data capture systems etc), the names of these source documents, storage locations, and person responsible for access/management for each type of source document used in the study. Refer to Appendix 3 for the template source document identification log

4.1.2 Maintain adequate and accurate source documents and study records that include all pertinent observations on each participant.

4.1.3 Prepare template form(s) to assist source/data collection for the study. The template form(s) should contain content/prompts tailored to the data to be collected for the study including:

- Consent process including confirmation of inclusion/exclusion criteria.
- Study visits.
- CRF/DCF.

4.1.4 Where information including consent information/visit information relevant to clinical care is not recorded directly into the participants EPIC-EMR, the information should be forwarded to HIS for scanning into EPIC-EMR.

4.1.5 The participant's identity should remain confidential. The participant should only be identified on the CRF/DCF by means of the allocated study number and/or initials. The Subject Identification Log (a confidential record of participants with their full name and study number) must be kept separately and securely by the Principal Investigator.

4.1.6 Ensure source data is attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available when needed. Refer to Appendix 2 for descriptions for these terms (Elements of the ALCOA/ extended ALCOACCEA principle for good documentation practice).

4.1.7 CRFs should be completed according to the specifications of each study, prospectively and where possible as close to the study visit as possible. Data from participants' visits should be entered into the CRF within 5 business days from the visit.

4.1.8 For externally sponsored studies:

- Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and data collection forms and in all required reports.
- Obtain further guidance for timeframes of CRF completion from the Sponsor and if required, document in the CTRA.

4.1.9 If data is unavailable an explanation should be written in the CRF. The terms 'not available', 'not done', or 'unknown' are insufficient and should be avoided.

4.1.10 Where the CRF and/or DCF is not the source document, ensure that data reported in the CRF and DCF are derived from, and consistent with the source documents. Any the discrepancies should be explained.

4.1.11 If using paper records, the CRF must be signed by the Principal Investigator or designee to assert that he/she believes the record to be accurate and complete.

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4.2 Documenting information in the participants Medical Record

The PI or appropriate delegate must:

4.2.1 Enter ALL interactions with patient participants into the Health Record in accordance with the MH Health Information Service (HIS) Documentation and Records Management Policy (MH05), including consenting visit, research visits, telephone calls and clinic visits that have a research component into the participants patient medical record with relevant information.

4.2.2 Send all **original** source documents and authorised MH documents to the Health Information Services (HIS) department for scanning in accordance with the MH05 Documentation and Records Management Policy.

4.2.3 Original source documentation which must be scanned by the HIS via ECM to EPIC-EMR includes, but is not limited to, the following:

- Participant Information and consent form (PICF)
- Progress Notes / Correspondence (including on-site and telephone visits) – where these have not been directly entered into EPIC-EMR
- Prescriptions
- Pathology Reports from external sources
- Imaging Reports from external sources
- ECGs
- Photography if not collected by MPS (medical photography)

4.2.4 Document all interactions with participants, including:

- Consenting visit,
- Research visits,
- Telephone calls, and
- Clinic visits

4.2.5 Document the following information for each event:

- Date,
- Identification that the visit was for "Research",
- Research study title and/or HREC number,
- Visit number /identification information,

- Full consent/reconsent process information (for consent visits),
- Purpose for telephone call (if a call),
- Summary of procedures undertaken at visit,
- Information collected/ decisions made at visit, including AEs,
- Name staff member(s) conducting the visit/collecting the information, signature, signature date, contact number (phone/pager).

4.2.6 Place all source data/documents to be sent for digitisation into the medical record in yellow "Research" folders. Place the yellow folders into the nominated ECM collection points within the ward/clinics/Clinical Trail Centre (CTC) for collection.

4.2.7 Ensure that source documentation is submitted to HIS within 24 hours of seeing the patient As per MH05 Documentation and Records Management Policy, scanning occurs on a daily basis, with documentation available for viewing in EPIC-EMR within 24 hours of receipt.

4.2.8 Study teams should request the return of the original PICF which should then be stored in the study file.

Note: Upon being scanned onto EPIC-EMR, the digitised source documentation is thereafter considered to be **original** source. Per Digitisation Plan, paper clinical record documentation is destroyed 6 months after digitisation. There is no requirement or expectation for photocopies to be retained.

Note: As documents need to be submitted for scanning within 24 hours, this means that study coordinators will need to do one of the following with respect to entering this data into the CRF:

- Option 1 – Enter the data into the CRF immediately after the visit (within the first 24 hours) from the original hardcopy notes, prior to these being submitted for scanning.
- Option 2 – Documentation can be photocopied so that these photocopied notes can be used to permit data entry into the CRF, so that the original notes can be submitted within 24 hours as required. If coordinators request your assistance with photocopying, please accommodate them as best as you can, but I would ask that they swipe you onto the photocopier, so that this is charged to their cost centre.
- Option 3 – Data entry into the CRF can be undertaken by referencing the data once it has already been scanned into EPIC-EMR.

4.2.9 Researchers should note that the following organisational and speciality specific systems interface with EPIC-EMR, meaning that patient information is automatically transferred from these systems to EPIC-EMR. Researchers do not need to send information located in these systems to EPIC-EMR.

- Auslab (pathology)

- Karisma (radiology)
- MPS (medical photography)
- CareHR (VIDS documentation system)
- Endobase (scope procedures)
- Nephworks (nephrology)
- Ortho DB (orthopaedics)
- OzeScribe (dictation letters)

4.3 Changes/Corrections to CRFs, DCFs and Source Documents including data stored in the Enterprise Content Management system

The PI or appropriate delegate should:

4.3.1 Ensure that changes are made only by study team members authorised to do so.

4.3.2 Ensure that the original data is not obscured.

4.3.3 Changes/corrections are traceable i.e. auditable.

4.3.4 Retain records of the changes and corrections.

4.3.5 For Paper Documentation:

- Ensure that any change or correction to a CRF, DCF or other source documents is dated, initialled, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections.

4.3.6 For Electronic Records including EPIC-EMR:

- Ensure that changes are made only by study team members/personnel authorised to do so.
- Ensure that the original data is not deleted and can be accessed if required.
- Changes/corrections are traceable i.e. auditable.
- For changes to information scanned into via ECM you will need to log a chart correction in EPIC
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4.3.7 For Sponsor requested changes:

Any change or correction to a CRF, DCF or other source document, including for medical records, requested by the sponsor or sponsor representative, should be:

- Reasonable and substantiated by appropriate evidence,
- Reviewed and approved by the PI or delegated team member,
- Undertaken by the PI or delegated team member,
- Should not obscure the original entry,

- Documented by (i) dated and initialled if paper documents or (ii) audit trail if electronic system,
- Explained (if necessary),
- Auditable.

4.4 Storage of Source Documents - record keeping

The PI or appropriate delegate should:

4.4.1 Ensure that during the active phase of the study (enrolment to data analysis phases) all store all source documents according to the Data Management Plan and SDIL, the HREC, RGO or other approvals and any applicable requirements such as laws, legislations, codes or guidelines.

4.4.2 Keep original source documents (i.e. the document where the individual item of data was first recorded). This includes documents scanned via ECM.

4.4.3 4.4.1 Where copies are generated to replace an original record the copy must meet the requirement of a certified copy. If you do not already have a process for creating certified copies, use Melbourne Health Office for Research SOP – Certification Procedure for Copies of Records or Other Documents.

4.4.4 Take measures to prevent accidental or premature destruction of these documents i.e. send to be scanned via ECM where required/appropriate, processes for maintaining, and restricted access to, offices, paper records, electronic records.

4.4.5 Ensure that study data is maintained in a durable manner and is not lost due to degradation of the document and:

- Send to be scanned into via ECM where required/appropriate.
- Generate certified copies of documents/records that do not meet the requirements of documents to be stored in the medical record e.g. Equipment printouts often use thermal paper that is not stable and may not be legible for the entire period which records must be stored for the specific research study. Attach the thermal paper print out to the back of the certified copy of the document. If you do not already have a process for creating certified copies, Melbourne Health Office for Research SOP – Certification Procedure for Copies of Records or Other Documents.

4.4.6 Restrict access to the study documents including source documents to authorised persons only to maintain data integrity and privacy. These include study personnel as per the study delegations, authorised representatives of the sponsor (if applicable), HREC or RGO, and regulatory bodies.

4.4.7 Ensure that upon request of the monitor (if externally sponsored study), auditor, HREC, or regulatory authority, make available for direct access all requested research/trial related records including access to EPIC-EMR in accordance with MH policy, approval privacy and any other applicable requirement.

4.5 Archiving Source Documents

The PI or appropriate delegate should:

4.5.1 Determine when to archive study documents including essential documents and source data/documents i.e. this is generally after completion of data cleansing, full analysis and/or publication, final report to HREC.

4.5.2 Identify a secure location for archiving study documentation with consideration to the format of the data i.e. paper/electronic. This must be at a MH site or a MH recognised/contracted storage provider.

4.5.3 Electronic data must be stored on the MH server unless otherwise approved by the HREC and RGO.

4.5.4 Maintain an archive log that records where and how study information including source data are archived, minimum archive retention date (i.e. date not to be destroyed before) and method of destruction to be use. The archive log may be incorporated into the SDIL

4.5.5 Maintain archived study information including source data for at least the minimum retention period relevant to the study type requirements.

4.5.6 Refer to the Guidelines for Data Management in Research and/or *Code* for minimum retention periods for research data noting the following for clinical trial data:

- Study documentation for clinical trials should be maintained for a minimum of 15 years for adult studies or 25 years for paediatric or other period approved by the HREC.

- For legal reasons, sites may consider indefinite archiving periods.

- The TGA position on document retention states:

  "The TGA requires records to be retained by the sponsor for 15 years following the completion of a clinical trial. However, in Australia the overriding consideration for sponsors with respect to record retention is the issue of product liability and the potential need for sponsors of products to produce records at any time during, and possibly beyond, the life of a product in the event of a claim against the sponsor as a result of an adverse outcome associated with the use of the product."

- ICH-GCP requirements for record retention state:

  "Ensure that essential documents are retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or 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. These documents should be retained for a

longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor".

4.5.7 Generated certified copies according to ICH-GCP guidelines and with respect to Melbourne Health SOP "*Certification Procedure for Copies of Records or Other Documents*".

5. Dissemination and Implementation

This SOP will be disseminated by the Office for Research. Updates will be made available with details of planned dates of implementation.

6. Monitoring Compliance and Effectiveness

Compliance with this SOP will be monitored as part of the Office for Research monitoring process. Any problems or potential problems concerning the effectiveness of this SOP may be identified during the Office for Research monitoring process or through users informing the Office for Research.

7. Review and Updating

This SOP will be reviewed every three years, or whenever there are changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

8. GLOSSARY

Associate Investigator (or Sub Investigator)

Individual member of the research/clinical trial team designated and supervised by the investigator at a research/trial site to perform critical research/trial-related procedures and/or to make important research/trial-related decisions (e.g., associates, residents, research fellows).

Case Report Form (CRF)

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each research/trial participant.

Certified Copy

A copy (irrespective of the type of media used) of the original record that has been verified (i.e. by a date and 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.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Health Records

Documents held by the Melbourne Health department of Health Information Service that are the record of personal and health information about each patient, including referrals and correspondence, admission notes, treatment, medication and progress notes, theatre sheets, investigation reports, consent forms, Limitation of Medical Treatment forms, powers of attorney (medical), discharge summaries, images/scans, charts, recordings etc (as defined in MH Policy MH05 Documentation and Records Management Policy). This includes electronic "documents" scanned into ECM.

Research visit original clinical notes and copies of the signed PICF form part of the MH Health Record

HIS

MH Health Information Services (department of)

Human Research Ethics Committee (HREC)

A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

The National Statement on Ethical Conduct in Human Research requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

International Conference on Harmonisation (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Principal Investigator

An individual responsible for the conduct of a research studies including clinical trials at a research/trial site and ensures that it complies with GCP guidelines. If a research/trial is conducted by a team of individuals at a research/trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

iPM

MH patient administration system.

Source Data Identification Log

A document that identifies information about source data for a study including; type of source data (i.e. progress notes/medical record, CRF, DCF, X-ray, photographs, electronic data capture systems etc), related source documents, storage location, type of document (paper, electronic, film, recording etc.) and person responsible for document control (i.e. identification, search and retrieval) The Source Data Identification Log helps to ensure that all source data for the study is identified and can be located when required during and after the study.

Source Documents

Original documents (where the data was first recorded), data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, participant files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the research/clinical trial). Please note that once original paper source documentation has been scanned onto ECM, the original documentation is then destroyed, and the digitised record becomes the original source.

9. REFERENCES

1. Research Policy MH18
2. Documentation and Records Management Policy MH05
3. Clinical Documentation MH05.01
4. Melbourne Health Clinical Record Digitisation Plan
5. Privacy and Confidentiality of Patient Information MH03.08
6. ICH Good Clinical Practice E6 R2 2016
7. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, February 2018.
8. MH Guidelines for Data Management in Research
9. MH GCP SOP 002 Study Site Master File and Essential Documents
10. Melbourne Health Office for SOP 001 Data Management Plan
11. Melbourne Health Office for Research SOP – Certification Procedure for Copies of Records or Other Documents
12. Connecting Care Program - Parkville EMR: Appropriate Use for Research
13. Process for Parkville EMR: Access for External Monitors Inspectors & Auditors

7. APPENDICES

Appendix 1: SOP Change Log

Appendix 2: Elements of the ALCOA/ extended ALCOACCEA principle for good documentation practice**)**

Appendix 3: Source Document Identification Log (SDIL)

DOCUMENT END

APPENDIX 1: SOP change log

Version No.	*Reason for Issue*
1	First issue
2	Sarah Rickard 18/10/2013: Review of content
3	Sarah Rickard 28/02/2017: review and minor updates
4	Sarah Rickard 28/6/2018: major review and update throughout • Updates with respect to iPM and ECM • Addition of appendices 2 and 3
5	Sarah Rickard 16/9/2020: revise due to implementation of EPIC-EMR • Delete 4.2: requirement to add information to the research tab of iPM • Delete iPM definition from Glossary • Update throughout re: ECM is the digitisation process for scanning information to EPIC-EMR • Update reference to the medical record throughout to be EPIC-EMR • Update references to include the processes for using EPIC-EMR • Minor formatting updates including numbering subclauses

APPENDIX 2: Elements of the ALCOA/ extended ALCOACCEA principle for good documentation practice)

Attributable	Source documents must be directly attributable to the individual who made the observation; each individual who makes an entry on the source documents must initial/sign and date that entry. For electronic data, the person undertaking the action should be recorded by the system (unique identification is necessary). It is importance that the electronic data are time/date stamped when the data are created/generated.
Legible	Recorded data should d be legible. All source documents must be clear and readable in order to be meaningful to an independent reviewer. An illegible piece of text is equivalent to the information not being documented.
Contemporaneous	The recording of a clinical observation needs to be made at the same time as when the observation occurs. Any latter additions, deletions or corrections should be identified by initialling and dating the changes with the date on which they were made and pervious data must still be legible/ available for audit purposes.
Original	Original data are those values that represent the first recording if study data/observation. Where original documents and the original data recorded on those documents are replaced by certified copies, the certified copies must be identical to the original documents and this must be verified (through a process for creating certified copies.
Accurate	The documented information is a true reflection of the original observation.
Complete	It should be possible to fully reconstruct the activities performed and to get a complete picture of what actually happened, from the source documents.
Consistent	There is only one truth. All pieces of source documentation should match each other. There should only be one source defined ant any time for any data element.
Enduring	Source documentation should be protected from destruction or damage.
Available when needed	Source documents continue to be available, readable and understandable by any individual when required

APPENDIX 3: Source Document Identification Log (SDIL)

MELBOURNE HEALTH

SOURCE DATA IDENTIFICATION LOG

Study Title	
Study Numbers	
Site	
Principal Investigator	
Department	

Steps for Preparing a source data identification log (*delete these instructions on the final log*)

1. Review your protocol for your key data points and work out where you will first record / obtain this data, what is the source data, what is the source document.
2. Determine where source data/documents will be stored.
3. Remember: there should only be one source defined at any time for any data item.
4. Where paper documents are scanned into the ECM, the medical record becomes the source document. Refer to MH05 Documentation and Records Management Policy for further information.
5. Example information is provided in the below table. Complete/customise the below table for your study.
6. PI to sign the source data identification log
7. File the Source Data Identification log in the study folder.
8. Update the table as required to record new/updated information.

Source Data	Source Document	Location within the Organisation	Type of record (Paper, film electronic, etc.)	Person Responsible for document control (id, search and retrieval)

Progress notes of study visits Includes scan of PICF	Participant Medical Record (ECM)	HIS	Electronic	Director HIS
Consent forms (PICF) – Original ink signatures	Participant folder	Level and room numbers -"in locked filling cabinet" or other internal location as applicable	Paper	PI
Documentation of consenting procedure	e.g. Participant Medical Record (ECM), REDCap or paper CRF in participant folder	HIS	Electronic	Director HIS if ECM PI if other departmental records
Inclusion & exclusion criteria	e.g. Participant Medical Record (ECM)	HIS	Electronic	Director HIS
Randomisation Number	e.g. REDCap or other record (in in participant folder?)	HIS, or Level and room numbers -"in locked filling cabinet" or other internal location as applicable	<insert type of record>	PI
Demographics	e.g. Participant Medical Record (ECM), REDCap or other record (in participant folder?)	HIS or Level and room numbers -"in locked filling cabinet" or other internal location as applicable	<insert type of record>	PI
Medical History incl correspondence (GP, family)	Participant Medical Record (ECM)	HIS	Electronic	Director HIS
Physical examination/s	Participant Medical Record (ECM)	HIS	Electronic	Director HIS
Prescribing of study drug, including correct dosage	*e.g. - Pharmacy dispensing records* - Participant Medical Record (ECM) *(prescriptions)*	HIS	Electronic	Director HIS
Prescriptions	e.g. Participant Medical Record (ECM)	HIS	Electronic	Director HIS
Vital signs	Participant Medical Record (ECM)	HIS	Electronic	Director HIS

Height & Weight	Participant Medical Record (ECM)	HIS	Electronic	Director HIS
Questionnaire completion (participant/parent)	*e.g. - Direct entry by participant to REDCap* *- paper questionnaire (in participant folder)*	insert Level/room numbers>, <"in locked filling cabinet" or other internal location as applicable>	<insert type of record>	PI
ECG	e.g. - Participant Medical Record (ECM)	HIS	Electronic	Director HIS
ECG	Participant folder of research only (not used for clinical decisions)	Level and room numbers -"in locked filling cabinet" or other internal location as applicable	<insert type of record>	PI
Pharmacy records	*e.g.* Direct upload to Participant Medical Record (ECM)	HIS	Electronic	Director of HIS
Pathology results	e.g. Direct upload to Participant Medical Record (ECM) (if RMH lab)	HIS	Electronic	Director of HIS
Pathology results (External Source for clinical care uploaded to ECM)	Define document (if from external) source uploaded to ECM	HIS	Electronic	Director of HIS
Pathology results (External Source not for clinical care)	<insert source document>	Level and room numbers -"in locked filling cabinet" or other internal location as applicable	<insert type of record>	<insert applicable person/role>
Radiology records (RMH radiology)	e.g. Direct upload to Participant Medical Record (ECM) (if RMH radiology)	HIS	Electronic	Director of HIS
Radiology results (external source for clinical care uploaded to ECM)	Define document (if from external) source uploaded to ECM	HIS	Electronic	Director of HIS
Radiology results	<insert source document>	Level and room numbers	<insert type of	PI

(External Source not for clinical care)		-"in locked filling cabinet" or other internal location as applicable	record>	
Concomitant medication checks	e.g. Participant Medical Record (ECM) Direct entry to REDCap	HIS or REDCap or _____	<insert type of record>	PI
Adverse Events	e.g. Diary, Direct entry to REDCap, Participant Medical Record (ECM), paper record, laboratory reports etc. *Important Notes:* • SAE records/forms could contain source data (e.g. assessment of relationship to drug, severity of the event), IF the record/form is where the information is initially recorded. • If a paper record/form contains source data, the document must be signed/initialled and dated like other documentation. • For direct recording into electronic systems, the system should be accessed by a unique username and password which act as the signature. • Identify and specify the source document for each data element captured on the SAE record/form.	HIS or REDCap or _____	<insert type of record>	<insert applicable person/role>
Serious Adverse Events	e.g. Participant Medical Record (ECM) (if MH event) or alternative record such as other hospital discharge summary, laboratory reports *Refer to the Important notes section in the AE section*	HIS	Electronic	Director HIS
<insert other study specific procedures/ source data>	<insert source document>	Level and room numbers -"in locked filling cabinet" or other	<insert type of record>	<insert applicable person/role>

		internal location as applicable		

Abbreviations:

CRF – Case Report Form (also called data collection form)

ECM – Electronic Content Management for medical records

REDCap - secure, web-based application designed to support data capture for research studies

Comments:

I acknowledge that the source documentation for this study is as listed in this Source Document Plan.

Principal Investigator: _____ (*signature*) **Date:** _____