The NHG Research Ethics Committee deliberated over this case and concluded that biological sample(s) collected for research are deemed to be gifted to the study team for the research study. Therefore, the biological sample(s) should not be returned to subjects and subjects should be made aware of this during the consent process. However, subjects should be allowed to request that the investigators discard or destroy the biological sample(s) (e.g. upon withdrawal) if it has not already been anonymised (i.e. the sample can still be traced) and their wishes must be respected.

In order to avoid potential disputes between the subjects and the investigators regarding the return of biological sample(s), the DSRB has revised the ICF requirements for studies involving prospective collection of biological sample(s).

With effect from 01 April 2014, studies that involve the prospective collection of biological materials must include a statement in the ICF to seek consent from subjects that all biological samples collected for the study will be gifted to the institution/sponsor for the purposes as described in the ICF and will not be returned to them, and to inform subjects that they retain their rights to ask the Principal Investigator to discard or destroy any remaining sample(s) if it has not been anonymised.

## Re-consenting Subjects for Ongoing Studies that Involve the Prospective Collection of Biological Sample(s)

As this change is being implemented to protect the interest of both the subjects and study teams, investigators of ongoing studies where the subjects will be returning for study visits are also required to make the same changes to the ICF over a one year period.

The Principal Investigator must submit a study amendment to DSRB to update the ICF(s) and re-consent returning subjects BEFORE **01 April 2015**. A tracked change copy and a clean copy of the amended ICF(s) will have to be uploaded for the acknowledgement from DSRB prior to its use.

Please refer to Section 11 "Voluntary Participation" in the updated DSRB Informed Consent Form Template (Document No. 207-001, Version 5, dated 3 Mar 14).

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# GCP FAQ: Guidelines on Source Documentation of Subjects' Study Progress

Inadequate documentation of subjects' study involvement and progress in the source documents and/or medical case notes is a common issue noted during study reviews. Documentation is important as it allows reconstruction of study events, which in turn helps to support the evaluation and validation of research findings.

The following are some tips on how you can improve the source documentation practice at your site and ensure that sufficient information is captured to substantiate the integrity of your study data.

## Source documents to be used for the study should be pre-determined

Source documents are all documents that contain original records and certified copies of original records of clinical findings, observations, or other activities in a study that is necessary for the reconstruction of the research.

Prior to study initiation, the Principal Investigator (PI) should clearly identify the types of source documents required in the research and ensure that they are accessible by the study team.

Examples of source documents: Hospital records, clinical and office charts, laboratory notes, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, microfilm or magnetic media, x rays, subject files, and records kept at the pharmacy and laboratories.

## Develop appropriate templates and/or tools to capture pertinent study information

The study team may also develop and utilise source document templates or stamps for the study, to ensure that all study-related procedures are carried out and appropriately documented.

Study templates developed for the study should also include:

i. A document version control (e.g. version number and/or date)
ii. Page numbering (e.g. page 1 of 2)
iii. Space/line for the person performing the data entry to initial and date to document that he/she was responsible for completing the information.

**Examples of templates / tools:** Subject eligibility assessment checklist, source document templates to record specific study assessments, stamps to capture information on informed consent process and adverse event reviews.

## Ensure study documentation is maintained by an appropriate personnel

Only personnel who has been adequately trained on the protocol (i.e. training recorded in a training log / record form) and delegated by the PI (i.e. delegated tasks specified in the study responsibility / delegation log) should perform study related activities and maintain documentation at site.

**Guidance Table on Documentation in Source Documents / Subject Medical Records:**
The table on the next page aims to provide guidance on the study documentation required when recording a subject's study involvement and progress in source documents and / or medical case notes.

**References**

1. Singapore Guideline for Good Clinical Practice (SG GCP)
2. NHG Proper Conduct of Research Standard Operating Procedures (PCR SOP) 501-B05- Documentation available at: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+sops
3. NHG Proper Conduct of Research Standard Operating Procedures (PCR SOP) 501-C01 - Informed Consent Form and Process available at: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+sops

**Ms Maggie Lee**
*Senior Executive*
*Research Quality Management*
*Office of Human Research Protection Programme (OHRPP)*
*Research & Development Office*
*National Healthcare Group*

| Item | Requirements | Reference |
|---|---|---|
| **Eligibility Assessment** | (1) The eligibility assessment of each subject should be documented and information should include:<br>▪ Who conducted the eligibility assessment<br>▪ When the eligibility assessment was completed<br>▪ Whether the subject met all the eligibility criteria<br>▪ The diagnostic test(s) (type / date of tests / results) used to assess the subject's eligibility – if any<br>▪ Diagnostic reports used to assess eligibility should be filed and made available for review – if any.<br>(2) An eligibility criteria checklist may be developed to facilitate the eligibility assessment. The person(s) completing the assessment should initial and date on the checklist. | NHG PCR SOP 501-B05 |
| **Informed Consent Process** | The study team member who conducted the informed consent discussion should record:<br>▪ Protocol reference, e.g. protocol title or number<br>▪ Date the informed consent was obtained<br>▪ The informed consent process, e.g. any impartial witness and/or translator used, and the reason for these)<br>▪ Language used to conduct the informed consent process<br>▪ How the subject was given adequate time to consider participation<br>▪ That a signed copy of the informed consent form (ICF) was given to the subject. | NHG PCR SOP 501-C01 |
| **Study Progress** | The following items should be included when documenting the subject's progress in the study. | NHG PCR SOP 501-B05 |
| **Study Visits** | Each study visit completed by the subject should be recorded in the source documents. Documentation should include:<br>▪ Date of study visit<br>▪ Name of study team members who conducted the visit<br>▪ Procedures completed, e.g. blood draw timings, physical examination, vital sign measurements, investigational products (IP) dispensed to and/or collected from subject (where applicable)<br>▪ Instructions provided to subjects, e.g. handling of IP, completion of subject dosing diary, etc.<br>▪ Other relevant information, e.g. reasons for deviations from study schedule or procedures, discrepancies noted in IP accountability, etc. | NHG PCR SOP 501-B05 |
| **Serious Adverse Events (SAE), Adverse Events (AE) and Safety Monitoring Assessments** | (1) Assessment of subjects for AEs should be performed at every study visit and recorded in source documents.<br>(2) Investigators should review all study-related laboratory / diagnostic test results to assess the clinical significance of any abnormal findings. This review should be documented.<br>(3) SAE and AE documentation should include:<br>▪ Protocol number or title<br>▪ Description of AE, e.g. fever, rash<br>▪ Onset date<br>▪ Severity, e.g. mild, moderate, severe<br>▪ Expectedness of event<br>▪ Relatedness to the study drug and/or study procedures<br>▪ Action taken, e.g. treatment provided, study drug / procedures interrupted / altered / stopped<br>▪ Outcome of event<br>▪ Date or resolution or death | NHG PCR SOP 501-B05 |
| **Study Completion / Termination / Withdrawal** | At the last study visit, in addition to documenting the activities completed during the visit, the site should also record:<br>▪ Subject's status / condition<br>▪ Date of last study visit / end of study participation<br>▪ If subject was prematurely withdrawn from the study, the reason for withdrawal and need for further follow up (where necessary) should be documented. | NHG PCR SOP 501-B05 |