STANDARD OPERATING PROCEDURE FOR MANAGEMENT OF A CHAIN OF CUSTODY FOR SAMPLES IN CLINICAL RESEARCH

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1. PURPOSE

This Standard Operating Procedure (SOP) describes the Chain of Custody process that is required for samples obtained from clinical research studies to ensure the purpose and objectives of the Good Clinical Practice (GCP) principles are satisfied.

2. SCOPE

This SOP applies to members of staff who handle clinical research samples from studies that are sponsored or co-sponsored by the University of Dundee (UoD) and/or NHS Tayside.

3. RESPONSIBILITIES

Clinical research staff will practice a Chain of Custody procedure whereby documentary evidence for the tracking of all samples obtained for clinical research purposes will be maintained from receipt to disposal.

4. PROCEDURE

4.1 The Chief Investigator or delegate should at all times be responsible for custody of the sample(s) and their security and preservation.

4.2 All samples must be uniquely identified with a number/code which remains with them all the way through storage, analysis, reporting, depletion to nil or disposal. Participants' names, dates of birth or any other means of identification must not be used.

4.3 Samples may be stored in the areas where they are collected until they are sent to the analysing laboratory. Samples should be stored as per Protocol, Laboratory Manual or equivalent and a Sample Log maintained. All samples should be labelled with sample identification number/study code and the date taken. Their storage location should be recorded in the Trial Master File (TMF)/Investigator Site File (ISF). Fridge and freezer temperatures should be recorded regularly to ensure that they are within the required ranges and a log maintained.

4.4 When transferring samples to the analysing laboratory the date of transfer and destination should be recorded. A copy of the samples log should accompany the samples.

4.5 For samples that need to be transferred internally between departments, a standard safety carrier bag (e.g. Versapak) should be used.

4.6 If a sample is to be sent for analysis to an external centre, the sample details and destination must be recorded. The courier's name and accompanying paperwork should be kept. **Confirmation of receipt from the receiving laboratory should be recorded/filed by the sender.**

4.7 Sample transport arrangements must conform to relevant national/international transport regulations. Account must be taken of the potential infectious nature of samples and any other hazards such as dry ice usage (see Control Of Substances Hazardous to Health website).

4.8 Samples that come into a laboratory should be logged, either manually or electronically (barcodes), before storage at the correct temperature. Fridge and freezer temperatures should be recorded regularly to ensure that they are within the required ranges. If samples are poorly labelled, missing or unexpectedly received, the research team should be contacted in order to investigate and resolve such issues. It is imperative that samples are not analysed until their identity is confirmed. It should always be possible to cross reference a sample with the documentation held by the study team.

4.9 **Disposal** - sample disposal (which is mandatory if stated in the study protocol) must be recorded, signed and dated by the laboratory manager or other responsible person. For a batch destruction, TASC template Doc Ref 123 may be used to record the destruction. A copy of the record of disposal or depletion should be given to the study team.

4.10 **Long Term Storage** - if the study protocol and participants' consents allow it, samples may be retained at the end of a study. Tissue samples (i.e. any sample containing cellular material) should be stored securely in a temperature-controlled environment and anonymised (i.e. labelled without any participant identifiable information). Where long term storage is to be within UoD, the collection of samples must be registered online with Tayside Biorepository and only used for further research (over and above that permitted in the original study) after seeking authorisation from the Tayside Biorepository Access Committee. Where long term storage will be outside the Tayside Biorepository remit, the collection of samples should be registered with the appropriate licenced storage facility.

5. ABBREVIATIONS & DEFINITIONS

COSHH	Control of Substances Hazardous to Health
GCP	Good Clinical Practice
ISF	Investigator Site File
NHST	NHS Tayside
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

TMF Trial Master File
UoD University of Dundee

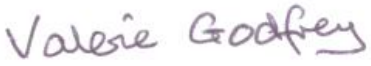
6. ASSOCIATED DOCUMENTS & REFERENCES

TASC Doc Ref 123: Certificate of Sample Batch Destruction

7. DOCUMENT HISTORY

Version Number:	Reviewed By (Job Title)	Effective Date:	Details of editions made:
History of reviewers prior to 2019 is detailed in the archived SOPs			
6	Valerie Godfrey (TASC QA Manager)	26/03/2019	Refresh of text throughout. New TASC SOP format implemented. Addition of Doc ref 123: Certificate of Sample Batch Destruction.
7	Valerie Godfrey (TASC QA Manager)	29/01/2021	Biennial review, no update required. Date brought forward from March to January to allow upload to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
8	Valerie Godfrey (TASC QA Manager)	03/02/2023	Abbreviations list amended.

8. APPROVALS

Sign		Date
APPROVED BY:	Professor Russell Petty, R&D Director, NHS Tayside	
Signature		31st Jan 2023
APPROVED BY:	Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee	
Signature		26 Jan 2023