Standard Operating Procedure RD SOP04: Pathology Sampling and Specimen Handling

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Department website for information relating to the implementation of new or revised versions.
Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use.

Author:	John Hiley & Deepa George
Version:	4.2
Date implemented:	30/01/2019
Review Date:	Annually

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
4.2		i. Changed new BDCFT logo where appropriate. ii. Changed FAO Clinical studies assistant to Lead CSO/ study team. iii. Procedural updates to reflect changes in service collaboration between ANHST and BDCFT iv. 4.3 Clarification of labelling of samples/request forms v. 4.8 Clarification of invoicing as a result of 4.3 changes vi. Appendix 3 added for CSO reference

This SoP agreement was made on …….

Parties:

1) Airedale NHS Foundation Trust
Skipton Road, Steeton
Keighley BD20 6TD

2) Bradford District Care Foundation Trust
New Mill, Victoria Road
Saltaire BD18 3LD

Signed on behalf of the participating Trusts:

Airedale NHS Foundation Trust

Name: …… Signature ……

Position: …….. Date: …….

Bradford District Care Foundation Trust

Name: …… Signature ……

Position: …….. Date: …….

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1 Introduction, Background and Purpose

This SOP is intended to facilitate clarity and understanding of the mechanism for handling of biological pathology samples for studies within BDCFT.

Research pathology is contracted to Airedale General Hospital Pathology Dept, and that department should be consulted in the set up of any study in which sampling is required.

All communications should be sent to:

Dr Afruj Ruf
Head of Pathology
Consultant Healthcare Scientist
Airedale NHS Foundation Trust
Airedale General Hospital,
Skipton Road,
Steeton,
Keighley,
West Yorkshire,
BD20 6TD

Tel: 01535 293476 (direct)
e-mail: afruj.ruf@anhst.nhs.uk

This is an internal guidance document only and therefore, not associated with any specific study documentation.

This guidance is written with due consideration to the Human Tissue Act (HTA) 2004, with the receipt of consent before any sampling is undertaken as a key aspect in the procedure for obtaining pathological samples.

2. Who Should Use This SOP

All those involved in the collection of samples for pathological investigation/storage for research purposes

- **2.1. Senior Clinical Staff/Principal Investigators**
- **2.2. Members of those Investigator's teams**
- **2.3. Clinical Studies Officers/ Research Nurses/Clinical Research Assistants**
- **2.4. Other members of the study research teams.**

3. When this SOP should be used

This procedure will apply when considering enrolment into an approved study that involves the collection of pathological samples, either for local analysis, or storage at local facilities **FOR RESEARCH PURPOSES ONLY**.

Samples for other purposes, eg clinical work, should be processed in line with the usual Trust arrangements.

4. Procedure(s)

4.1. Study set-up:

4.1.1. When setting up studies involving pathological sampling for local analysis or storage, a review of laboratory requirements must be undertaken by AGH pathology

4.1.2. Such requirements may include:

- Samples for local analysis
- Samples for storage
- Arrangements for transfer of samples e.g. Frozen samples, need for dry ice etc.
- Notice arrangements for the delivery and collection of samples as required by the protocol

4.1.3. A study requirement form (see appendix 1) should be completed and forwarded with a copy of the protocol to Dr Afruj Ruf.

4.1.4. The study sponsor shall be made aware of the off-site provision of laboratory facilities.

This procedure must be undertaken as part of the feasibility assessment for the study

4.2. Booking specimen receipt:

4.2.1. Patients for entry into research studies will be identified according to the study protocol and associated recruitment SOP (where applicable).

4.2.2. When a patient is identified and an appointment booked that will involve sampling for pathology, the AGH Pathology labs should be notified of this date at the same time. This will allow them to be aware of the arrival of BDCFT samples for the relevant research project.

4.2.3. Information supplied should be:

4.2.3.1. Study title (short title from IRAS form)

4.2.3.2. Participant identifier (e.g. Randomisation Number or NHS number)

4.2.3.3. Tests to be performed

4.2.3.4. Date of sampling appointment

4.2.3.5. Date/time of transfer to AGH Pathology reception (note: in most cases this will be on the day of sampling)

This information should be recorded in the patient documentation file (i.e. SystmOne) <u>not</u> in the participant CRF

4.3. Labelling of samples/request form:

4.3.1. Samples should be labelled with regard to the MOST COMPREHENSIVE information requirements from:

- the study protocol or
- AGH Pathology minimum requirements as the detail to be added to specimens and request forms ie:
  - Participant Identifier (e.g. Randomisation Number or NHS number)
  - Study Name
  - Date of Birth

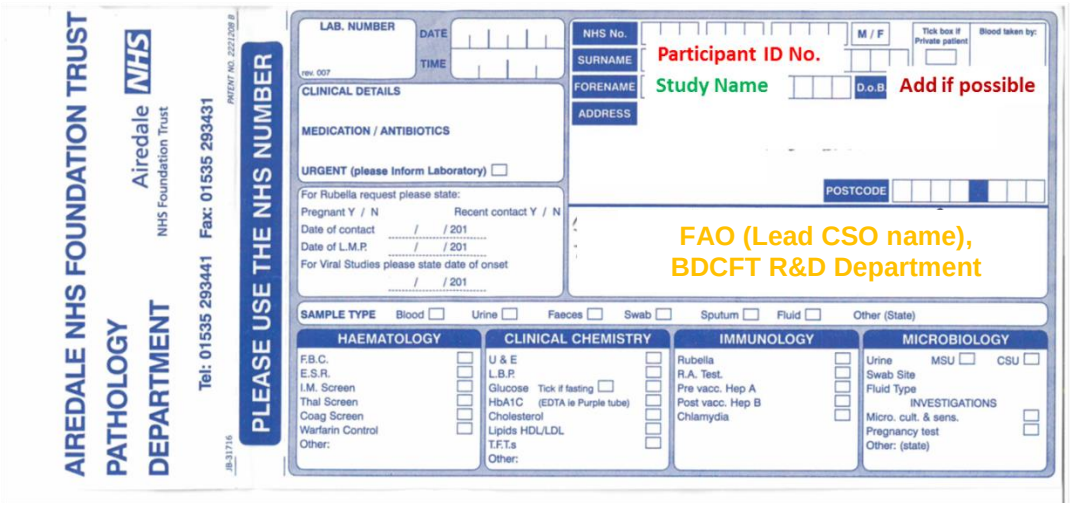
4.3.2. Request forms

4.3.2.1. A fully completed ANHSFT pathology request from must accompany any sample sent to the laboratory. These are available from the BDCFT R&D Department, or the AGH Laboratory.

4.3.2.2. It should be completed in line with the requirements described in the Pathology Handbook (see Section 6 for link, or contact AGH Pathology))

4.3.2.3. It should be appropriately identified as:

- Participant identifier
- The name of the trial/study
- Name of the lead CSO who will be coordinating the test results
- See example below:



4.4. Activity Record:

4.4.1. For each study the study Lead CSO responsible shall set up and maintain a pathology activity record (Appendix 3)

4.4.2. This shall record, for each participant, each sample and test sent to AGH, and the date these samples were sent

4.4.3. This shall be kept in the site file and be available for audit at any time

4.5. Transporting samples to AGH:

<u>Not using BRI Transport</u>

4.5.1. Samples should be transported to the AGH Pathology Reception on the day of collection (unless specifically otherwise specified in a study protocol or related SOP).

4.5.2. Study Clinical Studies Officers or other members of the research team should transport the samples personally, or arrange secure transport (eg. by taxi) should the relevant study budget allow.

4.5.3. Designated CSO to inform AGH about the delivery of sample either previous day or morning of delivery.
Contact Adam at AGH 01535 292910 or another designated person.

4.5.4. In regards to the transportation of blood sampling specifically in the transportation of carrying sampling in your own vehicle use a red box with a yellow label which states pathological samples in transit (See Appendix 4)

BRI blood transport van

4.5.5. Samples should be transported to the AGH Pathology Reception on the day of collection (unless specifically otherwise specified in a study protocol or related SOP).Samples to AGH leave BRI at 9.30 and additionally between 13.30 -15:30

4.5.6. BDCFT Lead CSO / Research Nurse should ensure transport log is completed by themselves and also signed and dated by member of staff receiving sample in BRI

4.5.7. BDCFT Lead CSO / Research Nurse should notify AGH Path lab via email or fax that sample has been dropped off at BRI
Contact Adam at AGH 01535 292910 or any other designated person. (see Appendix 5 for more details)

4.6. Collecting stored samples for later transport:

4.6.1. Samples stored at AGH Pathology may need to be transported for further work, in accordance with the specific study protocol. All such transport arrangements should be undertaken and supervised by BDCFT staff working on the study in question.

4.6.2. BDCFT Lead CSO/PI should carefully note the conditions required for the transport of samples e.g. refrigeration requirements, temperatures, time scales for transport etc.

4.6.3. Careful discussion with AGH Pathology and destination location for samples should ensure that all appropriate requirements are identified and arrangements made to fulfil these requirements.

4.6.4. When the time of collection is known, AGH pathology should be contacted to arrange the preparation of those samples

4.6.5. It is important that sufficient notice is given to AGH Pathology to enable appropriate preparation. This should be discussed as part of the feasibility assessment (see section 4.1 above)

4.7. Reporting of results[1]:

4.7.1. Results will be reported to the nominated BDCFT R&D Study Lead CSO/ study team.

4.7.2. Contact: t: 01274 363258, f: 01274 228621
email: research@bdct.nhs.uk

4.7.3. BDCFT R&D will be able to audit trail records with prior arrangement with AGH laboratories

4.8. Invoicing for services

4.8.1. AGH Pathology shall, on a quarterly basis, report their BDCFT related activity.

4.8.2. Breakdown of monthly charges by study/participant will be possible assuming conditions in 4.3 are met

4.8.3. Invoices will be sent directly to the BDCFT R&D Manager, reflecting that quarter's activity, for processing and payment

4.8.4. A tariff of charges for commonly used tests appears in Appendix 2

4.9. HTA Licensing requirements

4.9.1. The nature of the studies undertaken by the Trust, and the processes undertaken by Trust staff (Clinical Studies Officers/Research

[1] Access to ICE to be reviewed

Nurses/Research Assistants) mean that a separate licence is not required for R&D activity.

4.9.2. All material obtained will be in relation to NHS Research Ethics Committee approved studies

4.9.3. No material will be stored for a period longer than the minimum required to transfer the material to another establishment (AGH or other as per study protocol) as soon as possible.

4.9.4. No processing of samples will be undertaken by BDCFT R&D staff on site or outside the regulations of a licence holding establishment.

4.10. Support for Inspections/Audit/Monitoring:

4.10.1. On request from the relevant body undertaking monitoring activities, AGH laboratory will be able to supply:

4.10.1.1. Equipment calibration logs

4.10.1.2. All appropriate accreditation as required by the study sponsor

4.10.1.3. Staff training records as appropriate

4.10.1.4. Evidence of Good Laboratory Practice compliance as required.

5. Contacts:

BDCFT Senior CSO/Research Nurse	Deepa George	deepa.george@bdct.nhs.uk	01274 363149
BDCFT Head of Research	John Hiley	john.hiley@bdct.nhs.uk	01274 363149
AGH Head of Pathology	Dr Afruj Ruf	afruj.ruf@anhst.nhs.uk	01535 293476

Pathology Helpline: **01535 293441**

Monday - Friday 0830 - 1700 (outside these hours please contact the relevant Department)

6. Related Documents

- Airedale NHS Foundation Trust Pathology Dept Handbook Z:\R&D\SOPS\Approved\Pathology Sampling
- Human Tissue Act 2004 http://www.legislation.gov.uk/ukpga/2004/30/contents
- RDSOP02 BDCFT R&D: Guidance on Research Finance
- RDSOP06 BDCFT R&D: Resording Research Information in Patient Medical Records
- RDSOP08 BDCFT R&D: Obtaining Informed Consent for Research

Appendix 1 – Study Set Up Form

Form available at: Z:\R&D\Research Dept Management\SOPS policies and strategies\SOPs\SOP 4 Pathology Sampling\Current approved version

Bradford District NHS Care Trust

Airedale NHS NHS Foundation Trust

RESEARCH & DEVELOPMENT DEPARTMENT

SERVICE REQUIREMENTS FOR STUDY FEASIBILITY
WITHIN BRADFORD DISTRICT NHS CARE TRUST
TO BE PROVIDED BY AIREDALE NHSFT DPEARTMENTS

This form has been produced in order to help you decide whether there are implications for your study over and above standard routine patient care, and to clarify these requirements to service providers.

This Study has been proposed by the Lead Research Investigator at BDCT and is being assessed for feasibility within the Trust. This form should note all specific assessments for which extra services are required, and **should accompany copies of the protocol sent to ANHSFT departments**, as appropriate, for their approval as part of the feasibility assessment.

BDCT CSO/RA:		
Study Name:		
Type of Trial: Non-Commercial Portfolio; Commercial Portfolio; Non-Portfolio Commercial Study		
BDCT Lead Investigator		
Anticipated Number of BDCT Recruits:		
Study Duration (Months/Years):		
Recruitment Period:		
Department:		
Dept Signature		

Please see below for a list of extra interventions required for your department:

	Tick if study involves these depts	Tick if protocol sent to dept	Give details of extra to standard care
Pharmacy			
Radiology			
Histo-Pathology			-
Immunology, Haematology, Biochemistry			
Other Cardiology			
Impact on CSO/RA time e.g. drawing or spinning bloods			

Please note that this form is adopted from a standard ANHSFT form, and certain sections MAY NOT APPLY to BDCT studies.

Version 2 29.06.2011 - BDCT

Appendix 2 – Tariff of Charges for Commonly Used Pathology Tests

U&E	£3.50
TFT	£6.50
LFT	£6.50
Cortisol	£6.50
FBC	£3.50
Gamma GT	£3.50
Prolactin	£6.50
Pregnancy test	£9.00

Pathology Helpline: **01535 293441**

Monday - Friday 0830 - 1700 (outside these hours please contact the relevant Department)

Appendix 3 - BDCFT RESEARCH BLOOD SAMPLE DISPATCH RECORD (Z:\R&D\Research Dept Management\SOPS policies and strategies\SOPs\SOP 4 Pathology Sampling\Current approved version)

Name of blood tests required	Date/time blood sample taken		Study	Participant study ID	Dispatch Centre (Airedale / Bradford)	Delivered to dispatch point by (initials)	Name of person receiving sample	Receiving staff signature	Date	Time	Alert fax /email sent to Airedale time & initials	Comments
	Date	Time										

Page no ……

Appendix 4 : Transporting Biological specimens (e.g. Blood samples).

- Compliance with the ***Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009***
- Compliance with the ***Packing Instruction 650*** for the Transportation of Biological Specimens

Must have the **Yellow** **UN3373 Diagnostic Specimen labelled Transportation box**.

Never the Green Clinical Waste Label on standard Waste Transport Boxes

Compliance with *Packing Instruction 650*

(1) The Diagnostic specimen must be held in an original leak proof container [for blood the plastic sample tube]
(2) This must be placed into a sealable plastic bag. Sufficient additional absorbent material must be added to the bag to absorb all fluid in case of breakage. This can be an absorbent pad or cotton wool wad or vermiculite.
(3) Bag and contents then go into the above Yellow Labelled Transport Box.

You are now compliant

These Diagnostic Specimen Transport Safety bins look very similar to Waste Transport bin Transport Boxes. These are also obtained from Daniels.

NHS Supply Chain Code: KCP139

Appendix 5 : Guide to the Packaging & Transportation of Biological Specimens by Road

Guide to the Packaging & Transportation of Biological Specimens by Road

P650 PACKAGING INSTRUCTION P650

This packing instruction applies to Un No. 3373 (Diagnostic Specimens)

1. The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during carriage, including transhipment between vehicles or containers and between vehicles or containers and warehouse as any removal from a pallet or over pack for subsequent manual or mechanical handling. Packaging shall be constructed and closed to prevent any loss if contents that might be caused under normal conditions of carriage by vibration or by changes in temperature, humidity or pressure.

2. The packaging shall consist of three components

a) a primary receptacle;
b) a secondary packaging; and
c) an outer packing.

3. Primary receptacles shall be packed in secondary packaging in such a way that, under normal conditions of carriage, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging shall be secured in outer packaging with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.

4. For carriage, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The width of the line shall be at least 2mm; the letters and numbers shall be at least 6mm high.

5. The completed package shall be capable of successfully passing the drop test in 6.3.2.5. as specified in 6.3.2.3. and 6.3.2.4. except that the height of the drop shall not be less that 1.2m. The smallest external dimension of outer packaging shall be not less than 100mm.

6. For liquid substance:
a) The primary receptacle(s) shall be leak proof;
b) The secondary packaging shall be leak proof;
c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;
d) Absorbent material shall be placed between the primary receptacles(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;
e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa

(0.95 bar).
7. For solid substances:
a) The primary receptacle(s) shall be sift proof;
b) The secondary packaging shall be sift proof;
c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.

8. Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen
a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of ADR shall be met. When used, ice or dry ice shall be placed outside the secondary packaging or in the outer packaging or an over pack. Interior supports shall be provided to secure the secondary packaging in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or over pack shall be leak proof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build up of pressure that could rupture the packaging and the package (the outer packaging or the over pack) shall be marked “Carbon dioxide, solid” or “Dry ice”.
b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were lost.

9. Infectious substances assigned to UN No. 3373 which are packed and packages which are marked in accordance with this packing instruction are not subject to any other requirement in ADR.

10. Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distribution to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for carriage.

11. If any substance has leaked and has been spilled in a vehicle or container, it may not be reused until after it has been thoroughly cleaned and, if necessary, disinfected or decontaminated. Any other goods and articles carried in the same vehicle or container shall be examined for possible contamination.

Royal Mail requirements

Royal Mail will only carry UN3373 Diagnostic Specimens if they are packed following Packaging Instruction P650, and:

- Are sent by first class post or Special Delivery and to inland addresses only
- The packet is marked with the sender's name, telephone number and address

TNT (Courier) requirements

- The "Nature and Quantity of Goods" box must contain the text "Biological Substance, Category B" and "UN3373" on the Consignment note/Air Waybill.
- The Dangerous Goods "YES" box must be ticked.
- The name and telephone number of a "responsible person" must be written on the consignment note or on the package.
- The package must carry the warning symbol bearing the text UN3373, and the words "Biological Substance, Category B".