York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S94

Laboratory Procedures for Research Studies

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 Unit's website and R&D Newsletter 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.northyorksresearch.nhs.uk/sops.html

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	Date:	11th January 2016
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	Signature:	Signed copy held by R&D Unit
	Date:	11th January 2016

This SOP will normally be reviewed every 2 years unless changes to the legislation require otherwise

Version History Log

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
1.0	17th October 2014	
2.0	8th February 2016	Change of author. Only laboratory procedures for research studies relevant to research teams and R&D staff were outlined in this SOP. Any clinical trials procedures specific only to Laboratory staff were outlined in the Trust Laboratory SOPs and are managed via Labs section of Q-Pulse.

Contents

1 Introduction, Background and Purpose

York Teaching Hospital NHS Foundation Trust has Standard Operating Procedures for research activities taking place within the organisation. This SOP covers procedures within the Trust's Laboratories when they are involved in the processing or storage of research samples.

These laboratory procedures for research studies are relevant to research teams and R&D staff. All research studies procedures specific only to Laboratory staff are kept within the Trust Laboratories SOPs.

2 Who Should Use This SOP

Trust Laboratory staff involved in receiving, processing, storing and/or shipping research samples.

Research teams involved in studies where samples are sent to the Trust's laboratories.

All R&D Unit staff.

3 When this SOP Should be Used

This SOP applies at any time when the Trust's laboratories are involved in receiving, processing, storing and/or shipping research samples.

4 Procedure(s)

4.1 Study review and Setup

Where a research study involves samples being sent to the Trust Laboratory then it is a requirement that the study is reviewed by the Trial Co-ordinator for Laboratory Medicine (TCLM) or delegated individual. The R&D Unit will co-ordinate this review as part of the local approvals process. No research study involving the laboratory can receive NHS Permission from the Trust without laboratory approval confirmed. Refer to R&D/S14 for more information.

A member of Laboratory staff should be invited to attend site initiation meetings for research studies involving the Trust's Laboratory.

Where research samples require specific handling by the research team or laboratory staff then this should be agreed in advance and documented in a study specific SOP prior to NHS Permission being granted.

4.2 Documentation held by laboratory

For each study involving the Trust Laboratory there should be a suitable laboratory research study file. This will be a paper file and an electronic file. The paper file will be accessible to all laboratory and research staff and will contain a minimum of: Laboratory Protocol/Manual (if provided by the sponsor) or Laboratory Specific Instructions written by the TCLM or delegated individual

(specifying sample processing and storage requirements, courier information and any additional trial specific details), Sample Receipt Log (specifying storage location) (*RD-TEM-SAMPLE*), Sample Shipping Log (*RD-TEM-SHIPPING*) and Sample Deviations Log (*RD-TEM-EQUIP/TEMP DEVIAT*, *RD-TEM-SAMPLE DEVIAT*). The electronic file will contain any other trial specific information such as current trial protocol and confirmation of local approvals. In addition, front page of Lab Protocol/or Lab Specific Instructions (stating location of complete documents) will be published on Q-Pulse.

When an amendment is made to a study protocol or study processes then it is the responsibility of individual research teams to ensure that the laboratory receives updated study documentation and a date on which the amendment is to be implemented locally. All received amendments will be recorded (*RD-TEM-AMEND*) and filed within the relevant laboratory research file. The laboratory should be in receipt of up to date versions of the study documentation at all times.

Staff training records should be up to date and compliant with R&D/S25. Training records should be retained and available for review upon request.

4.3 Sample Receipt and Processing

All clinical trials samples that pass through the Trust's Laboratories should have a complete chain of custody clearly documented.

Samples are manually logged by a member of the laboratory research team upon receipt in the laboratory. Trial sample logs to track the receipt, storage (*RD-TEM-SA*), and shipment (*RD-TEM-SH*) of research samples through the laboratory must be completed.

All aspects of sample processing should be documented where this is specifically requested by a study Sponsor (e.g. time sample taken, time received by laboratory, time to freeze). In most circumstances samples will require specific handling by the research team and/or laboratory staff and this requirement should be made clear to staff in advance of the study commencing. These requirements should be clearly detailed in Labs Protocol/Manual or Lab Specific Instructions, and where necessary, a study specific SOP should be in place. In these cases all research samples must be clearly identifiable to laboratory staff by either placing a 'Research Sample Sticker' on the samples and request form, or by the Research Nurses delivering sample to the laboratory research team by hand.

Where specific requirements exist (such as expedited processing, freeze times) the laboratory research team must take immediate and appropriate action where such requirements have not been able to be met.

See section 4.6 for documenting and reporting deviations.

4.4 Sample Storage and Shipment

TCLM (or delegated individual) should record at the outset of the study where research samples will be stored (*RD-TEM-SAMPLE*). Samples should be stored in this location and every attempt made to retain samples in this location for the duration of their storage. If samples are moved from their storage location for any reason then this must be documented (*RD-TEM-LOCATION*).

Storage temperatures (ambient/fridge/freezer) must be recorded daily by a nominated member of laboratory staff and any deviations escalated appropriately (refer to RD –SOP-EQUIP).

Sample shipment must be fully documented following any Sponsor instructions. As a minimum the TCLM (or delegate) must ensure that they document:

- the research samples that have been shipped;
- the shipment conditions (e.g. temperature, whether a logger was included);
- the date of the shipment;
- the name of the person packaging the samples for shipment;
- the name of the courier company or other delivery method;
- the reference number from the airway bill.

Shipping records must be retained within the relevant research laboratory file (*RD-TEM-SHIPPING*).

4.5 Assessing, documenting and reporting deviations and/or excursions

All deviations (including temperature excursions/equipment failures, sample receipt, processing and shipping deviations) that occur on research studies must be documented and assessed (*RD-TEM-EQUIP/TEMP DEVIAT for equipment/temperature deviations and RD-TEM-SAMPLE DEVIAT for sample receipt/processing/shipping deviations*).

The TCLM has initial responsibility for assessing the impact of any deviation or temperature excursion. This assessment must be documented and should detail as a minimum:

1. the appliance/location where the deviation/temperature excursion took place
2. the extent and/or duration of the deviation/excursion the research samples subjected to the deviation/excursion
3. assessment of the impact of the deviation/excursion on the samples

This will involve checking any instructions from the Sponsor (Labs Protocol/Lab Specific Instructions) and it must include an assessment as to whether the breach is deemed to be 'serious' or not (as defined in R&D/S04) and should be signed by the TCLM or delegate. In cases of any doubt or where no specific Sponsor instructions exist then the TCLM must notify the Sponsor, contact and copy to the R&D Unit via research.governance@york.nhs.uk and also to the research team. This, and any subsequent resulting correspondence, must be retained in the laboratory electronic research file and a copy placed in the relevant study file and archived at the end of the study.

For breaches that are not suspected to be serious the TCLM should check the sponsor instructions to see whether any additional action is required. If additional actions are required and if the breach/excursion is assessed as notifiable to the sponsor, as a minimum, the R&D Unit and the relevant

research team should be notified in writing and a copy of the written breach assessment provided to the team.

All other deviations (not-serious, not-notifable) must be documented. These must be monitored for any patterns of repetition as they may amount to a quality control failure which is reportable as a serious breach (refer to R&D/S04).

Where the TCLM, considers that the breach/deviation may be 'serious' (as defined in R&D/S04) then the Sponsor, R&D Unit and research team should be notified within 24 hours following the procedure outlined in R&D/S04. In the event of a suspected serious breach the R&D Unit will liaise with the TCLM to ensure that all necessary actions are taken.

The TCLM is ultimately responsible for retaining oversight of the extent and frequency of all deviations and temperature excursions for research samples and for escalating issues (e.g. quality control issues) to R&D as necessary. All recorded sample receipt, storage and shipment deviation (*RD-TEM-SAMPLE DEVIAT*) will be filed within the relevant laboratory research files; all recorded deviations related to equipment and temperature monitoring (*RD-TEM-EQUIP/TEMP DEVIAT)* will be kept in the Laboratory Equipment File for clear oversight of their extent/frequency.

In addition, all labs research files will be regularly checked for completeness by TCLM or delegated individual (*RD TEM AUDIT, RD TEM CHECKLIST*).

The Trust Laboratories also appear on the Research Quality Assurance Officer's audit schedule and deviations and breaches will be reviewed upon audit.

At the end of each research study the TCLM should ensure that all laboratory breaches and/or deviations that may have impacted on the study samples are notified to the Sponsor for consideration and inclusion in the end of study report. This may be direct from the TCLM or via the research team.

4.7 Adverse Incidents

It is a requirement that all Adverse Incidents (AI) within the Trust are reported via the DATIX online system and this includes adverse incidents that occur in the laboratory.

Where an adverse incident involves any aspect of a research study (this includes research processes, equipment and samples) the reporting individual should check the 'research' box on DATIX to ensure that the R&D Unit is appropriately notified.

Where a research-related adverse incident is reported that involves or affects the Trust Laboratory but where the TCLM has not been involved in submitting that report (e.g. where an AI is reported by a member of a research team) then the R&D Unit will ensure that the TCLM (or delegate) is notified and involved in any investigation or necessary resulting remedial action.

4.8 Archiving

It is the responsibility of the TCLM to ensure that all laboratory research study documentation is archived following the processes described in R&D/S11.

Where documentation is provided from the laboratory to either the research team or Sponsor for archiving a receipt should be requested and securely retained within the laboratory as evidence.

4.9 Research Misconduct/Fraud

All staff involved in research studies across the Trust are required to abide by R&D/S16.

5 Related R&D SOPs and Documents

R&D/F18 Amendment Checklist (Research Teams)

R&D/S04 Serious Breach of GCP or the Study Protocol

R&D/S11 Archiving of Research Study Documents

R&D/S16 Research Misconduct and Fraud

R&D/S25 Providing and Documenting Training for Researchers

R&D/S28 Quality Assurance

6 Related Labs specific SOPs and templates (relevant to laboratory staff only and available via Labs Research section of Q-Pulse):

RD –SOP-EQUIP Research Equipment: Temperature Monitoring & Deviations

RDTEM-AMEND Amendments Log

RD-TEM-FPAGE Laboratory Research Study File- Front Page

RD-TEM-SAMPLE Sample Storage Location

RD-TEM-SHIPPING Sample Shipping

RD-TEM-EQUIP/TEMP DEVIAT Equipment/temperature Deviations Log

RD-TEM-SAMPLE DEVIAT Sample Deviation Log

RD-TEM-LOCATION Change to Sample Storage Location

RD-TEM-AUDIT Laboratory Research Files – Audit Log

RD-TEM- CHECK Trial Checklist

RD-TRM-PROTOCOL Trial Protocol Details/Location