York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S35

Laboratory Research Clinical Trial Set Up

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/or Q-Pulse 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Date:	18th January 2023
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	17th January 2023

This SOP will normally be reviewed at least every 3 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	Reviewers	Details of significant changes
1.0	9th November 2017		
2.0	31st August 2020		Stage 1 – Minor updates. Stage 2 – Changed from 'Review & Authorisation' to 'Funding'. There are two versions of Stage 2; commercial and non-commercial. Stage 3 – Changed from 'Readiness Checklist' to 'Review & Authorisation'. Stage 4 – Updated to include a readiness checklist. The following sections have been added; Laboratory Research Clinical Trial Setup Form (R&D/F73) Completion Guidance, Laboratory Site File and MHRA Clinical Trial Analysis Listing guidance added. Change of link to R&D website.
3.0	13th February 2023	Sarah Bell	Change of author. Update to guidance and instructions of clinic trial set-up in line with update of corresponding document R&D/F73. Removal of Questions Raised and Outcomes section, in line with R&D/F73. Removal of tasks no longer relevant. Removal of redundant related documents, no longer in use. Removal of appendixes no longer in use.

Contents

1 Introduction, Background and Purpose

All studies which involve the use of the Research and Development (R&D) Laboratory Service or the Trusts' Laboratory Medicine Services, must be reviewed by the R&D Laboratory Team before commencing to ensure the Laboratory Services can support the study taking into account, but not limited to, the following:

- Available funding
- Staff time (including study specific training)
- Test availability
- Turn-around-times of results
- Retest interval
- Workload
- Practical aspects of processing the samples
- Equipment availability
- Sample storage
- Sample shipping
- Any other resource allocations

The '*green light*' should be given prior to R&D issuing confirmation of capacity and capability (CCaC), However, the '*green light*' may be given after CCaC has been issued if timeframes are tight but should be given before the recruitment of the first patient.

The Laboratory Medicine departments that may be required to support research activities are as follows:

- **Clinical Biochemistry including Point of Care Testing (POCT)**
- **Haematology, Blood Transfusion, and Immunology**
- **Microbiology and Serology**
- **Histology, Cytology, and the Mortuary**

The study set up process, detailed in this SOP, follows a four-step procedure, outlined below:

Stage 1 – Initial Feasibility Assessment

Generally, this is an initial assessment to determine whether there are any major barriers to conducting a study, e.g. equipment or assay availability and laboratory staff capacity. The information and documentation available at this stage is sometimes limited.

A site qualification visit (SQV), site feasibility visit (SFV), site evaluation visit (SEV) or site selection visit (SSV) by the study Sponsor is common at this stage.

These visits offer an opportunity for R&D Laboratory staff to put questions regarding laboratory feasibility directly to the Sponsor.

If after this, there is still information required to fully assess feasibility that is currently missing, e.g. “laboratory testing” listed but no further expansion on specifics, then the Stage 1 is put on hold until this information is available and a full assessment can be carried out – if this occurs, notify the Research Facilitator responsible for the trial.

Stage 2 – Funding & Local Approval

This stage will usually be completed once the Trust has been selected as a site. All study documents must be available to review.

A full assessment of the funding available must be carried out. For commercial studies, this usually means reviewing the Secondary Care Costing Template. For non-commercial, the Schedule of Events Cost Attribution Template (SoECAT) is reviewed. Any other relevant documents are fully assessed here too.

If the Trust’s Laboratory Medicine Service(s) are required for the study, the specific department involved must be identified and permissions must be granted, including laboratory capacity & capability, and funding approvals.

Stage 3 – Review & Final Authorisation

This stage will usually be completed once the Trust has been selected as a site and often in conjunction with stage two.

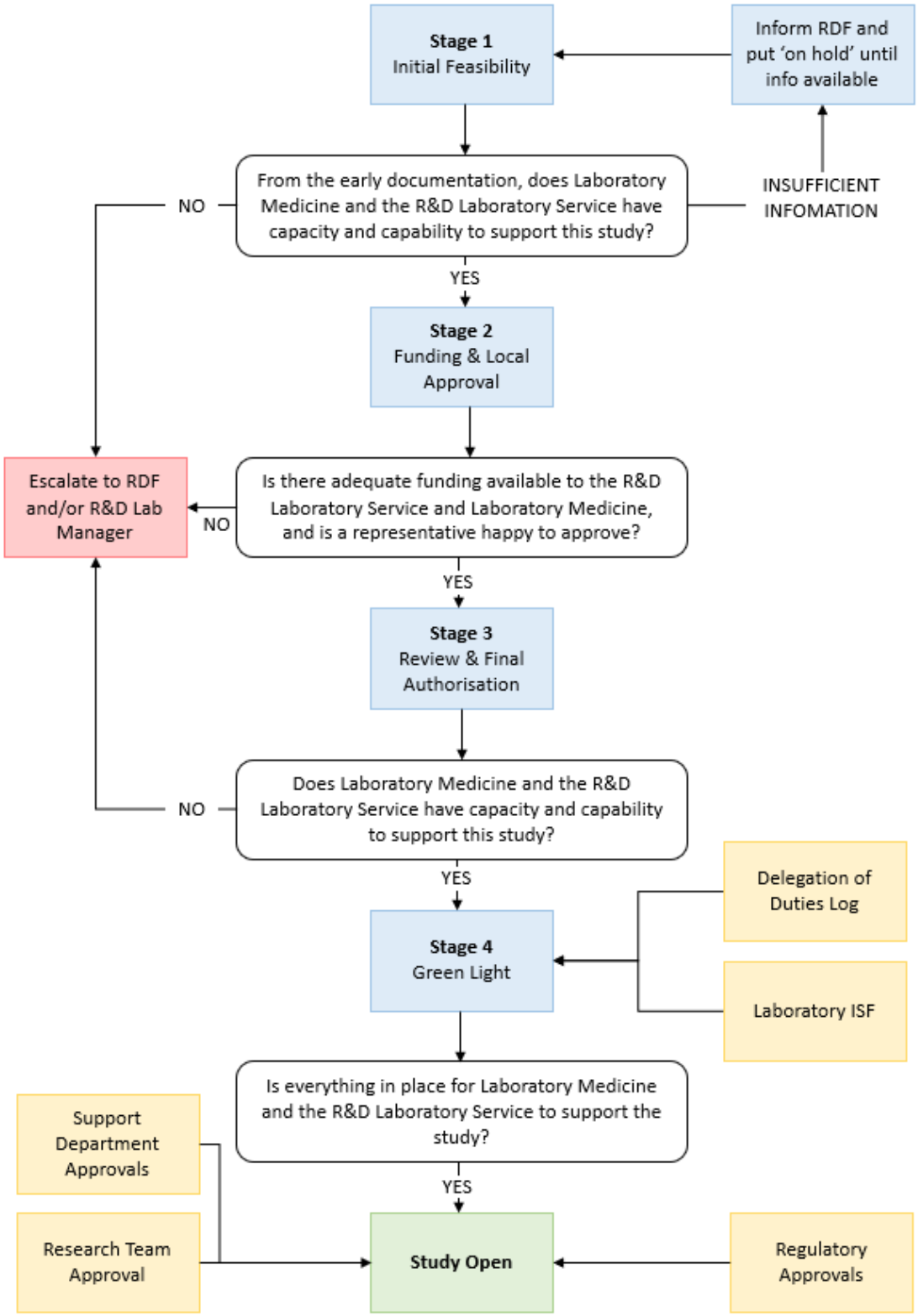
All aspects of the study must be considered. All study documents must be available for review, this must include a study Protocol and will usually be accompanied by a Laboratory Manual. If a study-specific SOP is needed for the trial, this must be identified at this stage (although this does not need to be completed until Stage 4). Any outstanding documents are to be requested as they must be reviewed as part of this stage.

Once this is done, final R&D Laboratory authorisation is given about if the R&D Laboratory and/or Laboratory Medicine has capacity and capability to support the study.

Stage 4 – Green Light

This stage is usually completed following the site initiation visit (SIV) and as soon as possible after ‘Stage 2’ and ‘Stage 3’ have been issued, unless advised otherwise by R&D. Prior to issuing the laboratory ‘green light’ the R&D Laboratory Team is responsible for completing the readiness checklist, setting up a laboratory site file, and ensuring that everything is in place for Laboratory Medicine and the R&D Laboratory Service to support the study.

Overview of the Set-up Process



2 Who Should Use This SOP

This standard operating procedure (SOP) should be used by R&D Laboratory staff, and R&D staff who are involved with setting up studies that require Laboratory Services.

3 When this SOP Should Be Used

This SOP should be used in conjunction with R&D/F73 for setting up a study involving Laboratory Services and as a guide for maintaining Laboratory Site Files.

4 Procedure(s)

Clinical research studies must be setup using a four-stage process in conjunction with the Laboratory Research Clinical Trial Setup Form R&D/F73.

4.1 Stage 1 – Initial Feasibility Assessment

Upon receipt of an email from a Research Delivery Facilitator (RDF) initiating Stage 1 - Initial Feasibility Assessment, the following tasks must be completed in a timely manner:

1. Record the new clinical trial on the '*Clinical Trials Summary Spreadsheet'* and complete as much information as possible at this stage.

\\vsx01\Laboratory M\Biochemistry\01. Trials Info\02. Trials Summary

2. Create a new folder in the shared labresearch@york.nhs.uk inbox in the '*Studies in Setup'* folder and name it as the short study title.

3. Create a new study specific folder in the R&D Laboratory folder using the *'1. TEMPLATE Clinical Trial File'* saved at the top of the list. Name the folder as the short study title and save all study documents in the '*01.Clinical Trial Setup & Key Info*' folder.

\\vsx01\Laboratory M\Biochemistry\01. Trials Info\Studies IN SET UP

4. The Laboratory Research Clinical Trial Set Up Form (R&D/F73) located in the study specific file (*01. Clinical Trial Setup & Key Info > Trial Setup Form*) should be renamed as the short title followed by '*R&D-F73*'.

5. Complete the '*Stage 1 - Initial Feasibility*' section of the Laboratory Research Clinical Trial Set Up Form (R&D/F73). See section 4.6 for guidance. The aim of the assessment it to determine whether Laboratory Medicine and the R&D Laboratory Service has capacity and capability to support the study based on the initial information.

The available documents are reviewed to ascertain if there are any major barriers to supporting the study. The following should be considered:

a. Test availability (including retest intervals) and turn-around-times.

b. Staff time and the required workload for the study.

c. Practical aspects of processing samples and equipment availability.

d. Sample storage, shipping, and any other resource allocations.

Any known or suspected major barrier to supporting the study should be escalated to the RDF or R&D.

If there is insufficient information to determine if the Laboratory Medicine and the R&D Laboratory Services can support the study, or if it isn't clear if there is laboratory involvement from the initial documents, then the review is put 'on hold' until more information is available. If this occurs, contact the RDF who initially requested the review.

Once fully completed, electronically sign the document and save the relevant '*Stage 1 – Initial Feasibility Assessment*' pages as a PDF.

6. Issue Stage 1 by replying to the RDF stage 1 request email using the '*Stage 1 Template Email',* attaching a copy of the PDF.

7. Update the '*Clinical Trial Summary Spreadsheet*' once complete.

4.2 Stage 2 – Funding & Local Approvals

This stage is often completed in conjunction with Stage 3 – Review & Final Authorisation. The R&D Laboratory team should have received all study documents from the RDF, the Research Team and/or the Sponsor. This must include a study Protocol and will usually be accompanied by a Laboratory Manual. If the study is non-commercial a copy of the Schedule of Events Costs Attribution Template (SoECAT) must be made available for review. If the study is commercial, a copy of the Secondary Care Costing Template (CT) must be made available for review.

Note: Outstanding documents are to be requested if not provided, as they must be reviewed as part of this stage.

Upon receipt of an email from an RDF initiating Stage 2 – Funding & Local Approvals, the following tasks must be completed in a timely manner:

1. Save any new documentation in the '*01. Clinical Trial Setup & Key Info'* section of the study specific file in the *'Studies in SET UP'* folder.

2. Update the '*Clinical Trial Summary Spreadsheet*'.

3. Complete the '*Stage 2 – Funding'* section of the Laboratory Research Clinical Trial Set Up Form (R&D/F73). See section 4.6 for guidance. The aim of the assessment it to determine whether **there is adequate**

funding available to Laboratory Medicine and the R&D Laboratory Service to cover the costs of supporting the study, and if Laboratory Medicine are involved to get local laboratory representative approval.

The SoECAT or the CT should be reviewed against the study Protocol schedule of events. Where there are inconsistencies, these should be highlighted to the lead RDF or R&D.

Items or funding may be provided. The following should be considered:

a. Supply of, or funding for, laboratory consumables/equipment, sample collection tubes, compatible needles, laboratory kits, storage containers and all packaging for shipping.

b. Non-standard-of-care testing.

c. Additional (outside of their normal duties) laboratory medicine staff time (including time for any training).

   When Laboratory Medicine staff time is required to support a study, the trials specific activities that laboratory personnel will perform should be confirmed with the relevant department. Laboratory personnel should be fully aware of their roles and responsibilities and consider the appropriate levels of technical training required including GCP. Training records should be retained within the Laboratory Site File.

d. R&D Laboratory staff time (including time for training, setting up the study, processing of amendments, participation in site monitoring visits and archiving of the Laboratory Site File) if the study is **non-portfolio** adopted.

e. Additional shipping costs.

Where there is insufficient funding to cover the costs of all trial activities the following should be considered:

a. Other funding attached to the study could be re-allocated to cover support-department costs.

b. Local agreements with Laboratory Medicine e.g. equipment not owned by R&D could be shared, small quantities of laboratory consumables could be provided or laboratory staff could freeze samples received out-of-hours when R&D Laboratory staff are unavailable.

c. Local agreements with R&D e.g. supply of dry ice for a one-off shipment at the end of a study.

d. Other funding external to the study could be sourced.

Major funding barriers to supporting the study should be escalated to the RDF or R&D.

If the study requires Laboratory Medicine support, written permission must be obtained from each department. Approval or rejection of the funding arrangements and laboratory capacity and capability must be documented: the email correspondence must be saved in the study specific folder *'01. Clinical Trial Setup & Key Info > Permission'*.

4. Once fully completed, electronically sign the document and save the relevant '*Stage 2 – Funding & Local Approvals*' pages as a PDF.

5. Issue Stage 2 by replying to the RDF stage 2 request email using the '*Stage 2 Template Email',* attaching a copy of the PDF.

6. Update the '*Clinical Trial Summary Spreadsheet*' once complete.

4.3 Stage 3 – Review & Final Authorisation

This stage is often completed in conjunction with Stage 2 – Funding & Local Approvals. The R&D Laboratory team should have received all study documents from the RDF, the Research Team and/or the Sponsor. This must include a study Protocol and will usually be accompanied by a Laboratory Manual.

Note: Outstanding documents are to be requested as they must be reviewed as part of this stage.

Upon receipt of an email from an RDF initiating Stage 3 – Review & Final Authorisation, the following tasks must be completed in a timely manner:

1. Update the '*Clinical Trial Summary Spreadsheet*'.

2. Complete the '*Stage 3 – Review & Final Authorisation'* section of the Laboratory Research Clinical Trial Set Up Form (R&D/F73). See section 4.6 for guidance. The aim of the assessment it to determine whether **Laboratory Medicine and the R&D Laboratory Service have capacity and capability to support the study** with the latest information before the opening of the study.

   All study documents are reviewed to ascertain if there are any barriers to supporting the study. **The following should be considered for each Laboratory Medicine department**:

   a. Test availability (including retest intervals), turn-around-times and test frequency. Where the testing regime conflicts with the minimum retest interval specified in CB-INF-RISC, exceptions for the study should be confirmed with Clinical Scientists.

   b. Practical aspects of processing samples and equipment availability. Adequate provisions should be made to ensure that laboratories have sufficient additional capacity for the storage of chilled and frozen samples, should a refrigerator or freezer malfunction.

c. For studies which involve histology: sample storage and shipping to central laboratories, regarding FFPE tissue and slides. All specimen requirements should be considered e.g. it may require a suitably qualified member of staff to assess slides in order to select a suitable FFPE tissue block for submission to the central laboratory. Laboratory personnel should be fully aware of their roles and responsibilities including the anonymisation of specimens and pathology reports. If it is known at the outset that specimens are stored in other Trusts' Histology facilities, consideration should be given as to how they will be accessed.

d. Any other resource allocations specific to the study should be considered.

All study documents are reviewed to ascertain if there are any barriers to supporting the study. **The following should be considered for the R&D Laboratory Service**:

a. Consider the specific sample processing requirements:

   i. Sample type: how will this impact sample handling? Will the samples be high risk? For instance, swabs, fluids, or aspirates may require processing in a category 3 laboratory or within a microbiology safety cabinet (MSC).

   ii. Time frame: if multiple samples are collected at a single visit and they all require different processing conditions can these all be met? Consider clot times, centrifugation settings, aliquoting and storage.

   iii. Other special conditions: does the sample need to be transported to the laboratory on wet ice?

   iv. Sampling frequency: for instance, if PK samples are to be collected at 0, 2, 4, and 8 hours post IMP administration, is there sufficient time to process all samples as per the Laboratory Manual?

   v. Sampling schedule: will samples be collected on specific days or at specific clinics? Will sampling visits fall on weekends or bank holidays?

b. Consider the equipment and consumables required for sample processing and storage. Is there sufficient capacity for long-term storage of samples? Adequate provisions should be made to ensure that laboratories have sufficient additional capacity for the storage of chilled and frozen samples, should a refrigerator or freezer malfunction.

c. Consider the shipping arrangements:

i. Which courier(s) will be used? Is suitable packaging supplied for transport of biological substance category B?

ii. Given the sample processing and storage requirements, is the shipping schedule realistic? e.g. if PK samples are to be collected at 0, 2, 4, and 8 hours post IMP administration, is there sufficient time to ship all samples as per the Laboratory Manual? Can shipping frequency be increased if requested?

d. Consider staff capacity:

i. Will all research activities be carried out during normal working hours? If not, will there be RN support or Laboratory Medicine staff support?

ii. In some cases, study specific sampling is straight forward and it may be appropriate for Research Nurses or Associate Practitioners to collect the samples and ship them e.g. a single whole blood sample for genetic analysis may be collected, packaged, and sent via Royal Mail on the day of collection. If arrangements are made for the Research Team to have sole responsibility of sampling this must be documented.

e. Any other resource allocations specific to the study should be considered.

f. Consideration to overall R&D Laboratory Service capacity must be given. Are there other studies ongoing or in set up that will compete for resource to the extent that the R&D Laboratory Service is unable to support both studies? If insufficient capacity is suspected, it must be escalated to the RDF or R&D.

3. Once fully completed, electronically sign the document and save the relevant '*Stage 3 – Review & Final Authorisation*' pages as a PDF.

4. Issue Stage 3 by replying to the RDF stage 3 request email using the '*Stage 3 Template Email',* attaching a copy of the PDF.

5. Update the '*Clinical Trial Summary Spreadsheet*' once complete.

4.4 Stage 4 – Green Light

This stage is usually completed at the soonest available opportunity after Stage 3 – Review & Authorisation has been sent to the RDF overseeing set-up of the clinical trial, unless advised otherwise by R&D. Prior to issuing the laboratory 'green light' the R&D Laboratory Team is responsible for completing the readiness checklist, setting up a laboratory site file, and ensuring that everything is in place to enable Laboratory Medicine and the R&D Laboratory Service to support the study.

Upon receipt of an email from an RDF initiating Stage 4 – Green Light, the following tasks must be completed in a timely manner:

1. Update the '*Clinical Trial Summary Spreadsheet*'.

2. Complete the '*Stage 4 – Green Light'* section of the Laboratory Research Clinical Trial Set Up Form (R&D/F73). See section 4.6 for guidance. The aim of the assessment it to **confirm when Laboratory Medicine and the R&D Laboratory Service have capacity and capability to support the study.**

    a. Complete the readiness checklist.

    b. Create or confirm receipt of the Laboratory Site File. In some instances, the Sponsor will supply a Laboratory Site File. If it is not supplied, one must be created. This does not need to be done when there is no R&D Laboratory involvement, but this must be recorded on the form. See section 4.7 for more information and instructions.

    c. Required study specific training should be completed and documented.

    d. The '*Delegation of Duties*' log must be signed by R&D Laboratory staff and Laboratory personnel if required to do so by the Sponsor. It may not be possible for all members of the R&D Laboratory team to sign the delegation log prior to the green light being issued (due to absence), however, all members of staff must be appropriately trained and have signed onto the delegation log prior to carrying out research activities. R&D Laboratory staff do not need to sign the *'Delegation of Duties'* log is there is no R&D Laboratory involvement, but this must be recorded on the form.

3. Once fully completed, electronically sign the document and save the relevant '*Stage 4 – Green Light*' pages as a PDF.

4. Issue Stage 4 by replying to the RDF stage 4 request email using the '*Stage 4 Template Email',* attaching a copy of the PDF.

5. Update the '*Clinical Trial Summary Spreadsheet*' once complete.

4.5 Confirmation of Capacity and Capability

Once approvals have been received from relevant departments (including the R&D Laboratory Service) and regulatory authorities the RDF will issue '*Confirmation of Capacity and Capability*' (CCaC). The following must be completed once CCaC has been issued:

1. The CCaC email is to be saved in the study specific folder '*01. Clinical Trial Setup & Key Info > CCaC*' and a paper copy must also be filed in Section 1 of the Laboratory Site File.

2. The clinical trial specific file must be moved from the '*Studies IN SET UP*' folder to the relevant research speciality or the '*Studies STANDARD CARE & LOCAL LABS ONLY*' folder.

3. Update the '*Clinical Trial Summary Spreadsheet*'.

4. Move the study specific folder in the shared labresearch@york.nhs.uk inbox from '*STUDIES IN SET UP*' to the relevant research speciality.

Note: Receipt of any study specific research samples should not be accepted by R&D Laboratory staff until all set up stages are confirmed as completed and CCaC has been issued. R&D Laboratory staff and Laboratory personnel must only perform work that is detailed in the study Protocol/Laboratory Manual. It is equally the responsibility of the Research Team and R&D Laboratory staff to ensure that only appropriate samples are taken to, and processed by, the Trust's Laboratory.

4.6 Laboratory Research Clinical Trial Setup Form (R&D/F73) Completion Guidance

This form is used to document the set up process clearly, aiding capacity and capability decision making, informing R&D of set up progress, and to prevent studies opening that the Laboratory Medicine departments, including the R&D Laboratory Service, are unable to fully support.

General Guidance Notes

Complete the short title of the clinical trial on every page at the outset. Record the date each stage was requested in the relevant section.

Date actions where appropriate and complete all boxes ensuring no blank spaces are left. If the information is not available or not applicable this should be indicated with a '-', '*N/A*' or other appropriate comment.

The form can be adapted to meet the varying requirements of clinical trials, e.g. if there is more than one central laboratory involved additional boxes can be added to include the second central laboratory details.

R&D/F73 Key Information Guidance Notes

Complete the '*Key Information*' as and when the information becomes available during the setup process. Ensure it is fully completed before issuing Stage 4 – Green Light as this will need to be included in the front of the physical laboratory site file (which is created as part of Stage 4).

Key Information

Short Trial Name:	[*state the short study name/acronym – this will be the same as what is used on the lab fie spine*]	R&D Reference:	[*state the reference code - IRAS number followed by site code 'Y' for York, 'S' for Scarborough, or 'YS' for both*]
Research Facilitator:	[*state the lead RDF*]	EudraCT Number (CTIMP only):	[*state the EudraCT number (if applicable)*]

Site(s):	[*state the site the study will take place (York, Scarborough, York & Scarborough*]	Research Type:	[*state the speciality of medicine the study is looking at e.g. cardiology*]
Commercial/Non-commercial:	[*state if the study is commercial or non-commercial*]	Recruitment Target:	[*state the recruitment target – found on stage request emails sent by RDFs*]
Full Trial Name:	[*state the full name of the study, found on the stage request emails sent by RDFs or in the study protocol*]		

Sponsor: [*state the study sponsor*]

Contact Name:	[*state the name of the sponsor representative, CRA or study co-ordinator*]		
Email Address:	[*state the sponsor contact's email*]	Telephone Number:	[*state the sponsor contact's phone number (if applicable)*)]

Research Team: [*state the research team care group working on the study*]

PI:	[*state the name of the principal investigator*]		
Email Address:	[*state the PI's email*]	Telephone Number:	[*state the PI's phone number (if applicable*)]
Lead Research Nurse:	[*state the name of the research nurse leading on this study*]		
Email Address:	[*state the lead nurse's email]*	Telephone Number:	[*state the lead nurse's phone ext.*]

Central Laboratory: [*state the name of the central laboratory used in the study. If there are multiple labs this section must be duplicated and completed for each one*]

Contact Name:	[*state the name of the central laboratory contact (if applicable)]*]		
Email Address:	[*state the lab contact's email (if applicable)*]	Telephone Number:	[*state the lab contact's phone number (if applicable)*]
Additional Information:	[*state any key information, e.g. all samples will be stored until the end of the study at which time shipping will be co-ordinated and arranged by the sponsor*]		

R&D/F73 Stage 1 - Initial Feasibility Assessment Guidance notes

At this stage, the aim is to determine whether Laboratory Medicine and the R&D Laboratory Service has capacity and capability to support the study, based on early information and to determine if there are any major barriers to conducting a study.

Trial Title: [*state the study's short name/acronym*]

Stage 1 – Initial Feasibility Assessment

Date Stage 1 Requested: [*state the date the stage 1 was requested by the RDF team*]

Summary

Planned SSV/SEV/SQV Date:	[*if planned, state the date the site selection visit is arranged for*]	Planned Open Date & Study Duration:	[*state the planned start date of the study in York or general timeframe e.g. spring 2022, and how long the study will be open (either by timeframe or known end date)*]
Local Laboratory Involvement:	[*state if laboratory medicine will be involved in the study*]	Central Laboratory Involvement:	[*state if there will be any central laboratory involvement*]
Notes/Comments:	[*include any additional relevant information, e.g. background information, recruitment or follow up period*]		

Laboratory Medicine

Local Laboratory Department(s) Involved:	[*state the laboratory medicine department(s) involved or N/A if there is no local involvement*]		
State Each Test Required Locally:	[*state the names of each local laboratory testing required for the study, by department if multiple departments*]		
State the Testing Frequency:	[*state the visits this testing is done*]		
Are All Named Tests Available (*see the Lab Medicine page on Staff Room*):	[*state whether the local laboratory medicine has the capability to do this testing*]	Does Testing Conflict with Minimum Retest Intervals (*see CB-INF-RISC for list of applicable tests*):	[*check laboratory medicine document listed to state whether the testing schedule conflicts with minimum retest intervals or not – if it does, approval is needed from clinical biochemists before starting the study*]
Are any of the Tests Referred to an External Site for Analysis (*as above*):	[*state whether any tests are referrals/send-aways*]	If YES, Please Specify (*Site/TAT/Test*):	[*state the test name, where it is referred to, and the turnaround time listed on the Laboratory Medicine page on Staff Room*]

Is BMS/MLA Staff Time Required (*outside of their usual duties*):	[*state if the local laboratory staff will need to perform any extra duties outside of their normal role*]	If YES, Please Specify (*and determine lab C&C, in principle)*:	[*state extra duties and approach laboratory representative to ensure they are happy with their staff taking on extra work*]
Notes/Comments:	[*state any additional relevant information, i.e. any potential barrier with potential solutions, or highlight any essential information that is currently unknown and/or needs clarifying in later stages*]		

R&D Laboratory

Central Laboratory Name:	[*state the name of the central laboratory used or N/A – if multiple central laboratories are used this section can be multiplied for each lab*]	Central Laboratory Location:	[*state the location (town and country) of the central lab*]
Sample Processing Requirements:	[*state the key steps in sample processing and highlight any foreseen issues, e.g. current processing requirements cannot be met as simultaneous access to three centrifuges is required*]		
Equipment Requirements:	[*state the equipment required and highlight any equipment that is unavailable at site, e.g. -40°C freezer*]		
Sample Storage Requirements:	[*state the required short and long-term storage conditions and comment on storage capacity, highlighting any foreseen issues, e.g. liquid nitrogen is not available on site, limited -20°C space*]		
Sample Shipping Requirements:	[*state the shipping requirements and highlight any foreseen issues, e.g. same-day shipping not feasible due to length of sample processing time*]		
Extra Staffing Requirements (*Out of Hours & Training*):	[*state if R&D staff will be needed to carry out trial procedures outside of normal working hours, e.g. weekends, and if this is possible (N/A if out-of-hours is not required)*]		
Notes/Comments:	[*state any additional relevant information, i.e. any potential barrier with potential solutions, or highlight any essential information that is currently unknown and/or needs clarifying in later stages*]		

Based on the information currently available, can the R&D Laboratory Service support this study? Yes/No

X

Healthcare Science Associate Practitioner R&D

R&D/F73 Stage 2 – Funding & Local Approval Guidance Notes

At this stage, the aim is to determine whether there is adequate funding available to Laboratory Medicine (and in some cases the R&D Laboratory Service) to cover the costs of supporting the study, and if Laboratory Medicine approves of the funding provided and local capacity and capability.

It is essential the schedule of events outlined in the study Protocol matches the schedule in the Laboratory Manual or study SOPs, and that all procedures and investigations (i.e. laboratory tests) are included in the costing template.

Trial Title: [*state the study's short name/acronym*]

Stage 2 – Funding & Local Approval

Date Stage 2 Requested: [*state the date the stage 2 was requested by the RDF team*]

Consumables

Sample Collection Tubes Provided:	[*state if specimen tubes are provided by the sponsor, e.g. EDTA tubes for blood samples, test-dependent*]	Compatible Needles Provided:	[*state if matching needles are provided for the blood tubes provided by the sponsor*]
All Laboratory Consumables Provided:	[*state if R&D lab consumables are provided by the sponsor, e.g. aliquot tubes, pipettes*]	Other Equipment Provided:	[*state if any other equipment needed for the study is provided by the sponsor*]
All Storage Containers Provided:	[*state if specimen storage containers are provided*]	All Shipping Provided (Including Packaging):	[*state if shipping packaging and courier is provided by the sponsor*]
Comments/Notes:	[state *any relevant information, e.g. details of items that need to be sourced/provided, and highlight any issues, e.g. BD Vacutainer tubes not available locally*]		

Staff

Laboratory Staff Time Required (*outside of their normal duties*):	[*state if the local laboratory staff will need to perform any extra duties outside of their normal role*]	If YES, Please Specify:	[*state extra duties and approach lab representative to get written approval to show they're happy with their staff taking on extra duties – can be included in the below approvals*]
R&D Laboratory Staff Time Required (*non-portfolio adopted*):	[*state N/A if the study is portfolio-adopted (this will be the majority) and if not, are R&D lab staff required*]	If YES, Please Specify:	[*state how R&D lab staff will be involved in the study and how their time will be funded*]

Funding in the Costing Template to Cover Staff Costs:	[*state if sample processing time and test costs are included in the costing template*]	If NO, Please Give Details:	[*state the additional trial activities not costed for*]
Comments/Notes:	[*state any other relevant information e.g. if funding is not covered in the costing template, can funding be sourced from elsewhere?*]		

Costing Template Review

R&D Laboratory Set Up Fee Included (*commercial only*):	[*state if there is a laboratory set-up fee included and if not, contact RDF and include below (amendment)*]	All Investigations Included:	[*state if all laboratory investigations mentioned in the protocol are on the costing template*]
All Procedures Included:	[*state if all procedures mentioned in the protocol are on the costing template, e.g. shipping*]	Procedures/Investigations on the Correct 'Tab':	[*state if all above investigations and procedures are on the correct study visit tab of the costing template*]
Non-Standard-of-Care Testing Involved:	[*state if any testing needed for the study is not done routinely as part of standard-of-care*]	If YES, State Non-Standard-of-Care Test(s):	[*state the name(s) of the non-standard-of-care testing required*]
Non-Standard-of-Care Testing Included in Costing Template:	[*state if any required non-standard-of-care testing is in the costing template with appropriate funding*]	If NO, Other Funding Cover for Laboratory Costs:	[*state if the costs of the non-standard-of-care testing can be provided from other funding – confirm with the RDF*]
Comments/Notes:	[*state any relevant information and highlight any issues, e.g. if anything is incorrect or missing from the costing template*]		

Costing Template Amendments

Change Request to Costing Template:	[*state if the RDF has been contacted to query or request a change to the costing template*]	Date Request Made:	[*state the date the query/request email was sent to the RDF*]
Details of Requested Change(s):	[*state what was queried/requested on the costing template*]		
Outcome(s) of Request:	[*state if the query/change request was accepted or rejected and any other relevant information*]		
Comments/Notes:	[state *any relevant information and detail any arrangements made with R&D, the Sponsor, Laboratory Medicine, and any other suppliers*]		

Add or delete as many departmental Laboratory Medicine Approvals, as needed. [*fill the below section in for as many departments that will be involved in the study – email the appropriate laboratory representative for each discipline to confirm they are happy with the funding provided for the study, and the local laboratory involved has capacity and capability to support the study. If specialist input is required from Consultant Clinical Scientist their approval must be obtained and documented*]

Laboratory Medicine Approval

Local Laboratory Department:	[*state the name of the department involved in the study*]		
Funding and C&C Approval Date:	[*state the date email approval has been received*]	Approved By:	[*state the name of the laboratory representative*]
Comments/Notes:	[*state any relevant information and details of any agreements with the local laboratory, e.g. Clinical Biochemistry to provide 50 false bottom tubes*]		

Laboratory Medicine Approval

Local Laboratory Department:	[*state the name of the department involved in the study*]		
Funding and C&C Approval Date:	[*state the date email approval has been received*]	Approved By:	[*state the name of the laboratory representative*]
Comments/Notes:	[*state any relevant information and details of any agreements with the local laboratory, e.g. Clinical Biochemistry to provide 50 false bottom tubes*]		

Can the R&D Laboratory Service authorise the funding arrangements for this study, and has the study been approved by a local laboratory representative? Yes/No

X

Healthcare Science Associate Practitioner R&D

R&D/F73 Stage 3 – Review & Authorisation Guidance Notes

At this stage, the aim is to review all documents and information, and from that determine whether Laboratory Medicine and the R&D Laboratory Service has capacity and capability to support the study.

A collaborative approach involving Laboratory Medicine and R&D is needed to ascertain how the research will be delivered and who will be responsible for its delivery (specialist input may be needed e.g. consultant histopathologist).

Additional tasks do not necessarily need to be executed but they must be identified, e.g. SOP to complete.

Trial Title: [*state the study's short name/acronym*]

Stage 3 – Review & Final Authorisation

Date Stage 3 Requested: [*state the date the stage 3 was requested by the RDF team*]

Summary

SSV/SQV/SEV Date/Attendance:	[*state the date of the site selection, qualification, or evaluation visit*]	Planned SIV Date/Attendance:	[*state the planned date for the site initiation visit*]
Comments/Notes from SSV/SQV/SEV:	[*state any key information that was provided at the SSV/SQV/SEV*]		

Laboratory Medicine

Local Laboratory Department(s):	[*state the laboratory medicine department(s) involved or N/A if there is no local involvement*]	Site(s):	[*state which hospital(s) or other site(s) will be involved in this study*]
State Each Test Required Locally:	[*state the names of each local laboratory testing required for the study, by department if multiple departments*]		
State the Testing Frequency:	[*state the visits this testing is done*]		
Are All Named Tests Available:	[*state whether the local laboratory medicine has the capability to do this testing*]	Does Testing Conflict With Minimum Retest Intervals (*see CB-INF-RISC for list of applicable tests*):	[*check laboratory medicine document listed to state whether the testing schedule conflicts with minimum retest intervals or not – if it does, approval is needed from clinical biochemists before starting the study*]
Are any of the Tests Referred to an External Site for Analysis:	[*state whether any tests are referrals/send-aways*]	If YES, Please Specify (*Site/TAT/Test*):	[*state the test name, where it is referred to, and the turnaround time listed on the Laboratory Medicine page on Staff Room*]

Laboratory Staff Time Required (*outside of their normal duties*):	[*state if the local laboratory staff will need to perform any extra duties outside of their normal role*]	If YES, Please Specify:	[*state extra duties and confirm this has been approved in stage 2*]
Comments/Notes:	[*state any relevant information and details of any agreements with the local laboratory*]		

Research and Development Laboratory – Histology Studies Only

Anonymised Pathology Report Required:	[*state if an* anonymised *pathology report is needed for this study*]	Samples Retrieved from Other Trusts (*If Yes, Name Trusts*):	[*state if samples will need to be requested from other Trusts and if yes, detail any requirements or agreements needed to facilitate this*]
Central Laboratory Document Requirements:	[*state any study-specific documentation requirements, e.g. original copy of requisition to be sent with samples*]		
Central Laboratory Sample Requirements:	[*state any study-specific sample requirements, e.g. how many blocks are needed*]		
Central Laboratory Shipping Requirements:	[*state any study-specific shipping requirements, e.g. sponsor provides transport or funding*]		

Research and Development Laboratory – Sample Processing

Central Laboratory Name:	[*state the name of the central laboratory used or N/A – if multiple central laboratories are used this section can be multiplied for each lab*]	Central Laboratory Location:	[*state the location (town and country) of the central laboratory*]
Sample Processing Requirements:	[*state the key steps in sample processing and highlight any foreseen issues, e.g. current processing requirements cannot be met as simultaneous access to three centrifuges is required*]		
Comment/Notes for Sample Processing:	[*state any additional information regarding sample processing, e.g. any solutions for previous issues identified*]		

Research and Development Laboratory – Equipment

Equipment:	Required:	If YES, Please Comment:	Study Specific Temperature Range:
Centrifuge:	[*state if a centrifuge is needed for sample processing*]	[*state the centrifuge settings needed e.g. 2100g*]	**N/A**
Fridge:	[*state if a fridge is needed for sample storage*]	[*state the storage requirements e.g. quantity of samples for what timeframe*]	[*if a study specific temperature range is required, state the range and any reporting requirements*]
-20°C Freezer (*York only*):	[*state if a -20°C freezer is needed for sample storage (York*	[*state the storage requirements e.g. quantity of samples*	[*if a study specific temperature range is required, state the*

	only) lab medicine - 20°C in Scarborough has very limited space]	*for what timeframe*]	*range and any reporting requirements*]
-80°C Freezer:	[*state if a -80°C freezer is needed for sample storage*]	[*state the storage requirements e.g. quantity of samples for what timeframe*]	[*if a study specific temperature range is required, state the range and any reporting requirements*]
Incubator:	[*state if an incubator is needed for sample processing/storage – R&D do not have an incubator, but space can be borrowed from lab med* with approval]	[*state the storage requirements e.g. quantity of samples for what timeframe*]	[*if a study specific temperature range is required, state the range and any reporting requirements*]
Mechanical Pipette:	[*state if a mechanical/precision pipette is needed for sample processing*]	[*state the pipette requirements e.g. 1000µL*]	**N/A**
Comments/Notes for Equipment:	[*state any additional information or agreements in place regarding sample processing and equipment e.g. access to their incubator*]		

Research and Development Laboratory – Storage

Sample Storage Required:	[*state if samples are required to be stored for the study*]	Duration:	[*state how long samples need to be stored for*]
Adequate Storage Capacity:	[*state if there is adequate storage capacity to meet study requirements*]	If NO, Please Comment:	[*state how any capacity issues are to be solved e.g. purchase of a new freezer*]
Special Storage Condition Requirements:	[*state if there are any study-specific storage conditions*]	If YES, Please Comment:	[*state any special requirements e.g. multiple storage units (-20°C for 24 hours then move to -80°C)*]
Comments/Notes for Sample Storage:	[*state any additional information and agreements with laboratory medicine concerning sample storage*]		

Research and Development Laboratory – Shipping

Sample Shipping Condition(s):	[*state the shipping temperature e.g. ambient, frozen (dry ice)*]	Shipping Frequency:	[*state how often samples need to be shipped*]
All Packaging Provided:	[*state is all shipping packaging is provided by the sponsor*]	If NO, Please Comment (c*an it be sourced or funded elsewhere*):	[*state where/how shipping packaging will be sourced*]
Courier(s) Used:	[*state the name of the courier(s) used*]	Shipping Day(s):	[*state days samples can be shipped*]

Increased Shipping Frequency if Storage Capacity is Limited:	[*state if samples can be shipped more regularly if storage capacity is reached*]	If NO, Please Comment:	[*state plan if unable to increase shipping e.g. purchase of a new freezer*]
Sample Shipping Comments/Notes:	[*state any additional information and agreements with laboratory medicine concerning sample shipping*]		

Research and Development Laboratory – Staff

R&D Laboratory Staff Time Required:	[*state if R&D lab staff time is needed*]	If YES, Please Give Details:	[*state the study activities*]
Study Specific Training Provided:	[*state if any extra training is needed for the study*]	If YES, Give Details of Study Specific Training:	[*state any details of training e.g. who will provide it*]
Out-of-Hours Requirement:	[*state is there are any staff out-of-hours requirements*]	If YES, Please Give Details:	[*state any details of our-of-hours e.g. evenings, weekends and how this will be done*]
Comments/Notes:	[*state any additional information and agreements with laboratory medicine concerning R&D laboratory staff*]		

Does R&D Laboratory Service have the capacity and capability to deliver this study? Yes/No

X

Healthcare Science Associate Practitioner R&D

R&D/F73 Stage 4 – Green Light Guidance Notes

At this stage, the aim is to determine when Laboratory Medicine, including the R&D Laboratory Service, will have capacity and capability to support the study. This is the final step to ensure everything is ready before the study opens.

Trial Title: [*state the study's short name/acronym*]

Stage 4 – Green Light

Readiness Checklist

Item/Document/Other	Required	Details	Completed (*If not, state reason and action plan*)
Sample Collection Equipment:	**YES/NO**	[*e.g. blood tubes, needles, etc.*]	**✓/N/A**
Laboratory Consumables:	**YES/NO**	[*e.g. cryovials, pipettes, etc.*]	**✓/N/A**
Other Equipment:	**YES/NO**	[*e.g. new freezer, analyser, etc.*]	**✓/N/A**
Sample Storage Boxes:	**YES/NO**	[*e.g. freezer boxes, etc.*]	**✓/N/A**
Shipping Packaging:	**YES/NO**	[*e.g. padded envelopes, Royal Mail safebox, etc.*]	**✓/N/A**
Shipping Documents:	**YES/NO**	[*e.g. waybills, etc.*]	**✓/N/A**
Study Specific Documents/Forms:	**YES/NO**	[*e.g. study lab documentation, etc.*]	**✓/N/A**
Login(s):	**YES/NO**	[*e.g. study databases, etc.*]	**✓/N/A**
SOP(s) Created Completed:	**YES/NO**	[*e.g. Trust-sponsored study SOPs, etc.*]	**✓/N/A**
Additional Checklist Comments/Notes:	[*state any additional information or study-specific items needed before opening*]		

Go-Live Checklist

Tasks	Required	Details	Completed
Laboratory Site File Created (*N/A for studies with local testing only*):	**YES/NO**	**N/A**	**✓/N/A**
Study-Specific Training:	**YES/NO**	[*state any study-specific training required before opening*]	**✓/N/A**
Delegation of Duties Log Signed (*N/A for studies with local testing only)*:	**YES/NO**	**N/A**	**✓/N/A**
Comments/Notes:	[*state any additional information or study-specific tasks needed before opening*]		

Is the R&D Laboratory Service ready for this study to open and can the Green Light be given? Yes

X

Healthcare Science Associate Practitioner R&D

4.7 Laboratory Site File

To prepare the Laboratory Site File:

1. Place a set of file dividers (1-17) in a folder. Standardly, use a A4 leaver-arch folder, but sometimes a smaller one can be used, e.g. histology studies, or more than one folder might be needed.

2. Label the file using the Spine Template R&D/T09 so that the study information is clearly visible on the file exterior.

3. Place all template documents in the relevant section and clearly write the page number and the name of the clinical trial on every page.

The table below should be used in conjunction with the Laboratory Site File Contents Page (R&D/T07) and Laboratory Site File Audit Checklist (R&D/F13) as a guide:

Section	Document(s) to File
File Exterior	• Spine Template (R&D/T09): the file spine should display the key study information so that it is clearly identifiable.
Front Page	• Laboratory Site File Contents (R&D/T07): additional sections may be added. Alternatively, the sections themselves may be changed depending on the specific study requirements.
1. Key Information & Clinical Trial Setup	• Laboratory Research Clinical Trial Setup Form (R&D/F73): ensure it is fully completed and signed. • File copies of all permissions. • File a copy of the CCaC once it has been issued.
2. Staff Signature &Training Log	• Staff Signature & Training Log (R&D/F72): sign and complete one document per member of staff. • Record all future training in the log, and update with new versions of study documents. • File any evidence of training, e.g. copies of training certificates obtained.
3. Protocol	• File a copy of the Protocol (ensure it is the correct version). • Superseded versions should be removed from the Laboratory Site File.
4. Amendment Log	• Laboratory Amendment Log (R&D/F23): all amendments are to be documented on this form.

5. Correspondence	• All key correspondence should be printed and filed in the relevant section, however, if it is general correspondence (not related to a specific section) it should be filed here.
6. Laboratory Manual & Clinical Trial SOP(s)	• File a copy of the laboratory manual and/or SOPs (ensure it is the correct version). • Superseded versions should be removed and placed in section 17.
7. Specimen Receipt Log	• Specimen Receipt Log (R&D/F51).
8. Requisition Form(s)	• File all requisition forms in this section - if the original is to be sent with the samples/required to be filed in the main site file, ensure a photocopy is made.
9. Specimen Location Log	• Specimen Location Log (R&DF32): complete when a specimen is placed into storage and when moving a specimen. • *Optional* - Storage Box Sample Location Log (R&DT60): complete when specimens are retained in long-term storage boxes or there are complex storage requirements that can't be detailed on Specimen Location Log (R&DF32) alone. When the box is shipped the Box Sample Location Log should be moved to section 10. • *Optional* - Specimen Incubation Log (R&D/F74): only file if applicable to the clinical trial.
10. Specimen Shipping Log	• Specimen Shipping Log (R&D/F62): complete when a sample is shipped. • *Optional* - Storage Box Sample Location Log (R&DT60): complete when a box of specimens is shipped.
11. Shipping Document(s)	• File all receipts from couriers (signed and dated if applicable). • Multiple small tear-off slips can be stuck on an A4 sheet and filed.
12. Specimen Deviation Record	• Specimen Deviation Log (R&D/F31): record any sampling, storage, shipping, or other deviation. Follow R&D/04 for reporting suspected serious breaches of GCP or the study Protocol.
13. Clinical Trial Specific Paperwork	• Ensure all clinical trial study-specific paperwork are filed in this section, e.g. documentation provided and required by the Sponsor of the clinical trial.
14. Specimen Destruction Log	• Specimen Destruction Log (R&D/F28): complete for any samples destroyed. • File the correspondence with the Sponsor requesting sample destruction if applicable.
15. File Note Log & File Note(s)	• File Note Log (R&D/59) • File Note Template (R&D/T20): complete file notes when appropriate and record in the File Note Log (R&D/59). File in appropriate section.
16. Audit Assessment(s)	• Laboratory Audit Checklist (R&D/F13): to be used when auditing the laboratory site file and filed in this section.
17. Superseded Laboratory Manual(s) & Clinical Trial SOP(s)	• File superseded versions of the laboratory manual and/or SOPs. • The current version(s) should be filed in section 6.

5 Related SOPs and Documents

Research and Development

R&D/F13	Laboratory Site File Audit
R&D/F23	Laboratory Amendment Log
R&D/F24	Specimen Checklist
R&D/F28	Specimen Destruction Log
R&D/F31	Specimen Deviation Log
R&D/F32	Specimen Location Log
R&D/F51	Specimen Receipt Log
R&D/F59	File Note Log
R&D/F62	Specimen Shipping Log
R&D/F72	Staff Signature & Training Log
R&D/F73	Laboratory Research Clinical Trial Setup Form
R&D/F74	Specimen Incubation Log
R&D/T07	Laboratory Site File Contents Page
R&D/T09	Spine Template
R&D/T20	File Note Template
R&D/T60	Storage Box Sample Location Log

Laboratory Medicine

CB-INF-RISC

https://www.yorkhospitals.nhs.uk/our-services/a-z-of-services/laboratory-medicine1/