York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S86

Training Manual & Competencies for Research HSAP*

(*Healthcare Science Associate Practitioner R&D)

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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	Signature:	
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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	Details of significant changes
1.0	15th October 2019	
2.0	16th August 2022	Changes to key personnel, as well as minor language changes to improve clarity. Change of Trust name.

Contents

1. Introduction, Background and Purpose

This Training Manual describes the required training and Standard Operating Procedures in use for Healthcare Science Associate Practitioners (HSAP) working for the Research and Development Unit at York and Scarborough Teaching Hospitals NHS Foundation Trust's Laboratory Medicine Departments.

The role of HSAP for research spans several pathology disciplines and various clinical specialities. Under supervision of the Head Biomedical Scientist and direct line management of the R&D Research Quality Assurance Manager, the R&D HSAPs provide laboratory assistance to a range of clinical research studies across York and Scarborough Hospitals.

The laboratory work involved in supporting delivery of research studies requires scientific and technical support with strict adherence to research protocols and study specific laboratory instructions/manuals and standard operating procedures. The R&D HSAPs get involved in a wide range of support activities, starting from submitting Expressions of Interests (EOIs) to external study sponsors, through assessment of capacity and capability to deliver a research study locally, establishing local arrangements, agreements and quality systems, to facilitating sample processing and analysis/ or sample processing, storage and shipping to central Laboratories for analysis. This wide range of activities performed by Laboratory staff provides data that is used to monitor research participants' safety, assess pharmacokinetic parameters and to measure study end points. The analysis of samples collected from patients participating in clinical research studies form key part of the clinical research process. Consequently, it is essential that research samples are handled (including preparation, processing, shipping & storage) and analysed to standards which will ensure that patient safety is not compromised and that data is reliable and accurately reported.

2. Who Should Use This SOP

This SOP should be used by Healthcare Science Associate Practitioners (HSAP) working for Research and Development Unit to facilitate and support delivery of clinical research studies at York NHS Foundation Trust Hospitals.

3. When this SOP Should be Used

This Training Manual is designed to complement the existing quality systems within the Laboratory Medicine and the R&D Unit. It is intended to cover the conduct of Laboratory support for clinical research studies involving processing and analysis of human samples collected as part of a study protocol. It is applicable to delivery of all clinical studies: interventional studies, including clinical trials of investigational medicinal product (CTIMP), and non- interventional and observational studies.

This SOP should be used for reference and training purposes. The completed workbook will be filed in the trainee's Research Training File for evidence of the role specific competencies.

4. Procedures

The procedures below have been put in place to ensure a warm welcome to the Trust and to support the evidence of training towards becoming a competent member of the Laboratory Research Team who feels confident in their role and able to work as an independent member of the team without direct supervision on day to day basis.

The Laboratory Medicine, the Laboratory Research Team, and the R&D Unit have written standard operating procedures (SOPs) in place that are designed to underpin the quality and

integrity of their work. These procedures are periodically reviewed and authorised by an appropriately qualified personnel. Revisions to procedures are controlled, documented and authorised. When any procedures are issued, or existing procedures reviewed, there is a requirement for staff to carry out a self-directed training in the departmental SOPs and to document this training via the Q-Pulse document management system.

4.1 Welcome

On behalf of the Research & Development Unit and Laboratory Medicine we would like to welcome you to the York and Scarborough Teaching Hospitals NHS Foundation Trust.

The Research & Development Laboratory posts are operated within the department of Laboratory Medicine. Laboratory Medicine is an amalgamation of various pathology disciplines and services operating chiefly from York Teaching Hospital and Scarborough Hospital sites.

This document is a brief guide to the Research & Development Unit and Laboratory Medicine. It provides the information that you will require to settle into your new working environment. The purpose of this training document is to provide the R&D Healthcare Science Associate Practitioners (HSAP) (responsible for handling, processing, shipping and storage of human samples collected as part of various clinical research studies) with information that will help them understand, maintain and work to quality systems which will comply with Good Clinical Practice for research (including Clinical Trials Regulations and associated guidance documents).

4.2 Staff Induction

Induction is recognised as a vital part of employment best practice and is intended to:

- Help you feel settled more quickly in your job
- Lead to a greater understanding of the purpose of your job
- Help you to develop effective working relationships
- Give you enhanced confidence to carry out your duties

4.2.1 Corporate Induction & Statutory Mandatory Training

Shortly after arrival you will be booked onto a corporate induction session and statutory mandatory training sessions relevant to your post. Corporate induction and role specific training courses are mandatory for all new starters and will cover topics such as:

- Trust Values and Objectives
- Health & Safety Risk Management / Fire Safety
- Personal Safety & Security
- Hand Hygiene & Principles of Infection Control
- Information Governance
- Child Protection and Vulnerable Adult training
- Equality & Diversity

- Waste Management
- Manual Handling theory and practice
- IT induction and access to the Trust network systems

4.2.2 Local Induction - Clinical Biochemistry and Research & Development Unit

The local induction process is designed to ensure you are:

- Aware of key contacts and introduced to your new colleagues
- Familiarised with the working environment and working practices
- Aware of important Health & Safety information
- Given the necessary level of support and guidance
- Clear about the purpose of your role and how it contributes to patient care

Details of the general procedures for induction can be found on the Trust Intranet: *'Staff Room'.* Attendance at the Trust statutory mandatory induction courses is recorded on the *Learning Hub/ My Learning*. The standard local induction will be recorded by completing *Local Induction Checklist* on *Learning Hub*.

An induction plan will be presented to you on your first day from the Research & Development Unit. This document will highlight any appointments and courses that have been made on your behalf and aims to settle you into post by allocating time in specific areas across the research specialities, R&D core team, and research support departments. Completion of the induction plan will include familiarising with this Training Manual and completion of evidence for competencies listed within the enclosed Training Booklet.

All new HSAPs will also have an induction specific to Clinical Biochemistry. Documentation is given to all new starters for completion (CB-INF-INDUCT). The attendance at the Laboratory induction courses and training sessions is recorded in Laboratory Q-Pulse. All new staff members within Laboratory Medicine must sign the staff induction form once they have received induction specific to Clinical Biochemistry. This form must then be kept in the individuals training record (LM-TEM-INDUCT). This is also recorded and scanned into Q Pulse.

4.3 Trust Values

Our work is guided by a set of values, drivers and motivators. These are not just phrases. They are a critical element of our organisational strategy. Our ultimate objective is to be trusted to deliver safe, effective healthcare to our community.

Our values, drivers and motivators are:

- Caring about what we do
- Respecting and valuing each other
- Listening in order to improve
- Always doing what we can to be helpful

Supporting each other by:

- Working in partnership and responding to local needs
- Respecting differences and building on similarities
- Empowering people to be involved in decisions about how we provide care
- Encouraging others to behave respectfully in line with our values

Our values and the behavioural framework

NHS
York and Scarborough Teaching Hospitals
NHS Foundation Trust

Organisational Values	Organisational Behaviours	Behaviours we **LOVE**	Behaviours we **EXPECT**	Behaviours we **DON'T WANT**
KINDNESS	We are Respectful	• I understand and champion diversity in patients and colleagues. • I support others to be themselves and respect and value them for who they are.	• I treat everyone as a valued individual and am aware that the things I say and do may upset others. • I always protect people's dignity and feelings.	• I ignore people's feelings or pain. • I make people feel bullied, belittled or judged.
	We are Fair	• I understand how my actions and behaviour affect others and I always treat others fairly. • I am impartial, unbiased and act without prejudice.	• I always treat others fairly. • I have an awareness of how my actions and behaviours can affect others.	• I make others feel uncomfortable. • I don't consider the opinions of others.
	We are Helpful	• I am attentive and compassionate and think about what others need. • I go the 'extra mile' for patients and colleagues.	• I help those who need it or I will find someone who can. I will never walk by.	• I make people feel that they are interrupting, are unimportant or a burden: "it's not my patient/job/problem."
OPENNESS	We Listen	• I take time, even when busy, to truly understand the point of view of others.	• I listen attentively to others and respond.	• I appear disinterested, dismissive or talk over people.
	We Collaborate	• I help others understand how services and teams connect to deliver the best possible outcomes. • I create an environment where help is happily offered, asked for and provided.	• I work as part of a team, value the opinion of others and will communicate and cooperate.	• I focus on one department's needs to the detriment of other services. • I exclude others and work in isolation.
	We are Inclusive	• I empower everyone's voice to be heard and included in decision making.	• I treat people fairly and without favouritism or discrimination.	• I deliberately exclude some people and favour others.
EXCELLENCE	We are Professional	• I lead by example demonstrating awareness of the impact of my behaviours and support others to do the same.	• I am calm, patient and put people at ease. I provide constructive feedback. • I take pride in my appearance, the environment in which I work and our organisation as a whole.	• I am critical. • I pass on stress and negativity to others. • I display an unprofessional appearance.
	We demonstrate Integrity	• I have a positive attitude and take responsibility for my actions. • I will speak up, and support others to speak up, if something isn't right.	• I always seek to do the right thing.	• I do not take responsibility. • I blame or criticise others. • I do not speak up when something isn't right.
	We are Ambitious	• I create an environment where feedback is encouraged and new ideas are taken forward and celebrated. • I empower individuals to do what they know is right for staff and patients.	• I always aim to achieve the best results. • I suggest new ideas and find ways to take them forward.	• I accept average standards. • I complain without searching for solutions.

https://www.yorkhospitals.nhs.uk/about-us/our-values

4.4 Job Description

All staff are given a personal job description outlining their duties and responsibilities. These are reviewed as part of the annual appraisal process. Your job description should also be signed, dated and filed in your Research Training File.

4.5 Dress Code

The purpose of the Trust Dress Code and Uniform Policy is to:

- Provide a standard for our professional appearance and reinforce its importance.
- Send a message to the patients we care for and to the public in general in terms of professionalism
- Allow identification for security and communication purposes
- Comply with infection prevention and health and safety legislation
- Provide managers with specific guidance on what is appropriate for their staff to wear at work

- Empower employees to inform their Supervisors or Human Resources (HR) when they feel other employees are dressed inappropriately and be confident it will be acted upon
- Promote comfort, safety, and mobility for all employees

This policy applies to all staff who work for the organisation, and the full version can be viewed on *Staff Room*.

4.6 Probationary Period

The Trust recognises that to enable individuals to carry out their duties effectively in line with our values, it is imperative that all new starters have a dedicated period of support as part of their induction to the Trust.

In order to ensure consistency across the Trust, a period of 6 months is recommended as the standard length of the Probationary Period for all employees.

The purpose of the Probationary Period is:

- Provide appropriate support, development, and training to help the individual perform the duties of their role and provide/contribute to an effective level of patient care

- To provide a robust induction period for the individual to enable them to become familiar with local and Trust-wide practices and procedures

- To set out clear expectations of performance, conduct, attendance, and behaviours

During your probationary period a number of review meetings will be scheduled with your line manager. For further details please refer to the Probationary Periods Policy on (electronic copy on *Staff Room*).

4.7 Working Hours

The normal working hours are between 9.00am until 5.00pm Monday to Friday, although these hours will vary according to your shift pattern. This will be explained in more detail by your line manager.

Coffee breaks are taken in the morning at your convenience and a 15-minute break is permitted. A rest room is provided on the first floor for this purpose in Laboratory Medicine.

Lunch break is generally half an hour; this is coordinated within the department to provide continuous cover to our service users.

4.8 Annual Leave

Annual leave entitlement is related to length of service: i.e. 27 days per year initially rising to 29 days after 5 years' service and 33 days after 10 years' service (excludes Bank Holidays).

Annual leave requests must be made to your line manager via email and on the *eRostering* System which will be shown to you during your induction.

There are limits to the numbers of research laboratory staff that can take annual leave on any one day.

As annual leave is considered essential in helping staff balance their work and home lives, all staff are encouraged to take their full entitlement of annual leave within each 12-month period.

Annual leave may be bought or sold in accordance with Trust policy – further details are available from your manager or the Trust Intranet site (*Staff Room*).

The Trust has policies and procedures for granting leave which falls outside annual leave arrangements (Special leave and Family leave).

4.9 Trust Sickness/Absence Policy

The Trust policy for managing sickness absence aims to promote and support the health and wellbeing of staff. Health Indicators for alerting managers to higher than expected sickness absence rates are monitored as follows:

- Sickness rate exceeds 3.1% (pro-rata for part time staff) during a rolling 12-month period (i.e. approx. 8 days absence for full time staff)
- Three absences of one or more days / shifts within three months
- Continuous absence of four or more calendar weeks

If one or more of these indicators apply you will be invited to attend an informal meeting with your line manager. Trust policy will be explained and a period of informal monitoring (usually 12 weeks) will commence in the first instance.

A referral to Occupational Health Dept. may be recommended in some circumstances.

If you are unable to attend work due to illness please abide by the following local procedure:

- If you are due to work a normal day shift, please telephone your line manager or allocated member of management at the start of the working day- before 09.30am.

- You are required to state the reason for your absence and, wherever possible, when you expect to be well enough to return (you may give the reason for your absence to a member of Occupational Health or Human Resources if you feel unable to divulge this to your manager).

- Unless you have agreed a specific date/time with your line manager you must make contact on a daily basis to confirm you are still unfit for work.

  Phone Numbers:
  - Cate Laven (Line Manager) 01904 724641
  - Lydia Harris (Head of R&D) 01904 726606
  - Senior Research Nurses 01904 721733
  - R&D Laboratory Team 01904 725887/ 07789 174492

Failure to report your sickness or make contact when agreed may result in pay being withheld and/or disciplinary action as this will be regarded as unauthorised absence.

On your return to work, you will need to fill in a sickness report form with your line manager.

Periods of sickness > 7 calendar days require a Doctors certificate.

4.10 Staff Benefits

The staff benefits page can be found on *Staff Room* on the quick links at the bottom of the page. This is accessed by opening a windows explorer page from any trust computer logged in as yourself.

There is a Staff Shop at both York & Scarborough Hospital. The shops cater for a busy workforce, stocking a range of products at competitive prices. Everyday items such as milk, tea and coffee can be purchased with a varied selection of consumable goods, confectionary and soft drinks.

Reduced tickets can also be purchased for the following: Vue Cinema, City Screen, Theatre Royal, First York Bus, Flamingo Land and many special events arranged throughout the year. Staff who are in the Staff Lottery get a further 10% discount on consumable items.

5. Training & Development while in post

A number of IT training sessions will be arranged for you so that you can access the Trust's network systems and the laboratory computer system (Telepath). You will also be trained to use the Q-Pulse document management system and given a number of key documents to read and acknowledge.

Ongoing mandatory training is managed and delivered via the Trust's Learning Hub on which you will automatically be enrolled.

Laboratory competency training records are held by the Laboratory and Research & Development department and recorded in Q-Pulse. As part of the Research & Development training you will require full GCP Training. This will be facilitated as part of your induction.

Training Co-Coordinators for research Healthcare Science Associate Practitioners:

- Cate Laven, Head of Research Delivery (Clinical)
- Alan Shepherd, Training Officer

The training co-ordinators have overall authority for the training strategy. The main responsibilities are:

- Co-ordinating training between all disciplines
- Ensuring that those who have the delegated responsibility for training are qualified in the relevant discipline
- Ensuring that the day to day training activities are carried out & documented
- Dealing with any inadequacies and responding to any complaint or concern that the trainee may have
- Ensuring that the trainees Competencies Booklet is reviewed at least weekly during the induction period and that the delegated training has been carried out in accordance with the Trust policies & procedures
- Ensuring that training records are maintained for all staff members of the Labs Research Team
- Ensuring that regular 1 to 1 meetings are arranged, and Personal Development Plan agreed (PDR)
- Ensuring that the trainee attends research specific training sessions to ensure they meet standards required for clinical research.

Training Mentors:

- Healthcare Science Associate Practitioners currently in post within the Laboratory Research Team

The role of the Training Mentor is:

- to be responsible for the day to day training of the new R&D HSAP
- to facilitate the training of new R&D HSAP staff
- to be responsible for assessing the assigned competencies (as appropriate)
- to liaise with R&D unit staff, research staff & Head Biomedical Scientists as required

Assessors:
Appointed by the Head Biomedical Scientist to undertake the role of assessor and verifier for Laboratory specific tasks when required and appropriate.

Appointed by the R&D Unit to undertake the role of assessor and verifier for tasks specific to clinical research when required and appropriate.

Both Assessor & Mentoring roles involve reviewing the Training Booklet to verify appropriate training has been undertaken and completed, assessing the candidate through either:

A: Written Assessment (questions and answers)
B: Observation
C: Verbal Assessment
D: Assessment of Problem-Solving Skills

The range of competence and assessment methods will vary depending on the individual and the portfolio requirements. The evidence of achievement in individual sections of the Training Booklet should be signed off by an appropriately qualified member of staff.
The Local Competencies section indicates appropriate in-house competences which are expected to be initiated within the core training period of the first month within post and should be completed by 3 months in post for full time employees (longer period of time should be considered for part time employees).

For new members of staff, prior to starting the training there will be a period of 2 weeks induction plan which will be documented in a separate Induction Plan.

Each HSAP R&D is expected to follow the training booklet through each section. The R&D Unit and Laboratory Medicine will endeavour to follow the listed training as closely as possible but, due to leave and sickness, amendments may have to be made.

Cross Discipline Training:
After completing the core training, R&D HSAPs may request to spend half day/ a day in each discipline (Haematology, Histology, Microbiology, Immunology and Blood Transfusion) in order to provide a more complete experience of Laboratory Medicine and to allow better understanding of roles and time associated with particular tasks.

Rationale:
Research studies cover a range of clinical areas spanning over various disciplines.

Use:
Assessment of feasibility, capacity and capability when setting up new research studies, including initial review of costing and planning logistical arrangements to deliver a research project. For example, research projects that require tissue sample retrieval and support from Histopathology Department.

The R&D Unit will endeavour to provide study time for completion of the cross-discipline training depending on research workload and available staff cover.

Appraisals:
Annually, each member of staff will have an appraisal. This is an opportunity for all members of staff to discuss their training needs. The objectives from the Personal Development Reports (PDR) will form the basis of the 'Training Needs Analysis' and Personal Development Plan (PDP) for every member of staff.

This will be conducted by your line manager. Your performance will be reviewed against your job description.

This is related to pay progression and if targets are not met at certain gateways then pay progression may be halted. The date at which you will have a gateway meeting depends on the circumstances of you obtaining the new role as R&D HSAP, details of which can be found on the "Learning Hub", your manager will help you to prepare for the process.

All new members of staff will have an initial review at the end of their first month to check on progress and to discuss any problems. This is an opportunity to ensure any 'gaps' in their induction programme are addressed and initial training needs can be discussed and agreed.

Training File:
Each member of Laboratory Research should have a training file containing:

- Current and past GCP Certificates (to be refreshed every 3 years as a minimum)
- Current and past Research CV (to be updated every 3 years as a minimum)
- Job Description (to be reviewed at annual appraisals)
- Competencies
- Training Log
- Record of Induction

This folder will be complied with the help of your line manager and laboratory colleagues. Please refer to R&D SOP/S25 for complete information.

6. Introduction to Clinical Research, including Clinical Trials of Investigational Medicinal Product (CTIMPs)

This section is intended to give you a greater understanding of the background of clinical trial conduct and to provide hints and tips to allow a smoother execution of clinical trial support by the laboratory service. It is not intended to be a comprehensive guide to the regulations relating to clinical trials but rather a practical guide.

What are clinical trials?

Clinical trials are a process in medical research and pharmaceutical drug development that are conducted to allow safety and efficacy data to be collected for health interventions (e.g. drugs, diagnostics, devices, therapy protocols). Clinical trials are an essential part of

advancing healthcare and developing new treatments. They provide the basis of evidence-based medicine as well as the information needed by the regulatory authorities to allow drugs to become licensed for use. Clinical trials can only take place after satisfactory information has been gathered and the Medicine and Healthcare Regulatory Agency (MHRA)/Health Research Authority (HRA)/ Research Ethics Committee (REC) approval is granted.

Examples of what a clinical trial may be designed to do:

- Assess the safety and effectiveness of a new medication or device on a specific demographic of patient (e.g., patients who have been diagnosed with a specific disease)
- Assess the safety and effectiveness of a different dose of a medication than is commonly used (e.g. 10mg dose instead of 5mg dose)
- Assess the safety and effectiveness of an already marketed medication or device for a new indication, i.e. a disease for which the drug is not specifically approved for use
- Assess whether a new alternative medication is more effective for the patient's condition compared to the existing medication.
- Compare the effectiveness in patients with a specific disease with two or more approved treatment (e.g. Treatment A vs. Treatment B)

Good Clinical Practice (GCP)

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) is globally applicable guidance that sets the foundations for the conduct of all clinical research. All clinical trials (CTIMP trials) conducted in the UK should follow GCP as this is a legal requirement under the UK Medicines for Human Use (Clinical Trials) regulations.

The cornerstones of GCP are the protection of the rights, safety and wellbeing of human subjects, and the provision of accurate and credible clinical trial data. In any clinical trial, the interests of an individual subject should always be considered more important than the interests of society.

GCP arose in response to various widely publicised drug disasters as well as unethical conduct in a number of clinical trials.

The Tuskegee study was an investigation into syphilis carried out from the 1930s until the 1970s. Although when the study initially started it gathered useful information on syphilis, the people in whom the study was conducted were poor and uneducated African American men in Tuskegee, Alabama who were given inducements to participate. This was the initial unethical side to the study: in addition to this, during the course of the study the effectiveness of penicillin in treating syphilis was discovered but this information was kept from the study participants, who were not offered penicillin treatment for many years. Lessons learned from this study were included in the section in the GCP regulations that state if any new information becomes available about their disease or the drug during the course of a study, then the study participants must be informed of this.

Perhaps the most infamous instances of unethical clinical research were the experiments carried out by the Nazi concentration camps on prisoners of war. This led to the Nuremberg

code, which was formed to ensure that never again would anyone be forced to participate in a clinical trial. The main part of this is 'informed consent', which should be given by a study participant freely without coercion.

These principles were taken further by the World Medical Association in 1964 in the Declaration of Helsinki, which lays out the Ethical Principles for Medical Research involving Human Subjects. This document has been revised many times, most recently in October 2013.

Key Elements of GCP

HIGH LEVEL GCP CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS:

1. The rights, safety and well-being of the trial subjects shall prevail over the interests of science and society.

2. Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.

3. Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.

4. The necessary procedures to secure the quality of every aspect of the trial shall be complied with.

5. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.

6. Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki.

7. The protocol shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.

8. The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.

9. All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.

10. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.

11. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.

12. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

13. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded.

14. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial

Informed Consent

Everyone who participates in a clinical trial should give written, informed consent prior to any study specific procedure being carried out; this should be documented on a signed consent form. To be 'informed', a patient should be given written information and be able to ask the doctor in charge of the clinical trial – the Principal Investigator (PI) - questions.

Qualifications & Training

Everybody who does any work in a clinical trial must be suitably qualified and trained to undertake that task. This suitability is documented in the person's curriculum vitae (CV) and training record.

The Clinical Trial Regulations require that each individual involved in conducting a clinical trial of an investigational medicinal product (CTIMP) should be qualified by education, training and experience to perform his/her respective task.

GCP Training is mandatory for all research staff involved with clinical trials using investigational medicinal product (CTIMPs). Both the HRA and the MHRA advocate a proportionate approach to the application of GCP to the conduct of clinical trials and the appropriate training of staff involved. However, for ALL CTIMPs it is the high level "conditions and principles" of GCP (as listed above) set out in the UK Clinical Trials Regulations that must be complied with and interpreted in proportion to the risks posed to the participants and to the integrity of the results.

It is a requirement set by the York Trust R&D Unit that research staff who are new to clinical research, or who have not been actively involved in clinical research for a period of time, must undertake the face-to-face Introduction to GCP training course provided by the NIHR. Subsequently, GCP refresher training should be undertaken at least every three years - this is the minimum requirement for our organisation. However, GCP training might be required to be updated at more frequent intervals if deemed appropriate and proportionate to the complexity of the CTIMP study/or activities undertaken for the trial by the study Sponsor and/or the Trust R&D Unit. This may also depend on any changes in regulations at the time. Therefore, sometime research staff may be requested by the study Sponsors and /or the R&D Unit to provide evidence of GCP refresher more often than every 3 years.

If a trial related activity is part of a person's normal clinical role and all other protocol activities are undertaken by a member of the research team, then no GCP training may be required for that person (e.g. staff involved in supporting activities such as phlebotomist, chemotherapy nurses or radiology staff where no trial related activities are undertaken outside of their usual role and competencies); however this should be reviewed as part of the risk assessment for a trial and confirmed with the study Sponsor, or R&D Unit contacted for advice. The MHRA strongly recommends training in relevant aspects of GCP for anyone involved in conducting CTIMPs, even if the activities are part of an individual's routine job. In such cases GCP training can be provided in a range of formats, including web-based or as self-directed reading. On inspection, MHRA GCP inspectors will look for evidence that individuals involved in the conduct of CTIMPs have received adequate training in GCP and appropriate legislative requirements commensurate with their roles and responsibilities.

GCP Training is not legally required for other types of research (i.e. studies which are not clinical trials of investigational medicinal products). Such research should be conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected, and that research data are reliable. Members of the research team in such studies are expected to be qualified by education, training or experience but should not be required or expected to undertake GCP training.

A current signed and dated research CV demonstrates education, training, and prior experience. Research CVs must include evidence of ICH GCP training (when provided for CTIMP trials) and current medical practitioner registration details (where applicable). The relevant education & training should also be referenced in the CV. Research CVs must be updated at least every three years to reflect updates to GCP and other research relevant training & experience - this is the minimum requirement for our organisation. However, CVs might be required to be updated at more frequent intervals if deemed appropriate and proportionate to any updates in training, education and experience at the time. Therefore, sometime research staff may be requested by the study Sponsors and /or R&D Unit to provide updated research CV more often than every 3 years.

All staff with research duties and responsibilities delegated to them should undertake the appropriate training (GCP and/or study specific) and provide current research CV before commencing any work on a research project.

Template for a research CV can be downloaded via the following link:
https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/

A scanned copy of the current research CV and GCP certificate should be sent to the R&D Unit (via research.governace@york.nhs.uk) to be uploaded to the EDGE *General Documents* central repository.

Documentation

As with many walks of life, the ethos of clinical trials is "*if it isn't documented, then it didn't happen*". Anything related to a clinical trial should be written down. The first place that anything is noted down is called source data. On no account should any source data be destroyed. This would be an extremely serious breach of GCP.

There are rules on how corrections are made; any changes to data should be made by crossing out the original data with a single line so that it is still legible, writing the new data next to the old data, and verifying the changes by initialling and dating them.

Ethical and Regulatory Approval

Before a clinical trial can take place, it must have received approval from an ethical committee and also the country's regulatory authority, if applicable. The laboratory department running the clinical trial would not normally be involved in getting these approvals, but a copy of the relevant approval letters should be obtained and filed in the Laboratory Site File. The UK competent authority for authorising clinical trials is the Medicines and Healthcare Regulatory Agency (MHRA). Conduct of clinical trials must follow the UK Medicines for Human Use (Clinical Trials) Regulations.

Multinational studies will need to comply with the relevant regulations for each country. In the USA, for example, this is the Food and Drug Administration (FDA) regulations. In March 2016 changes were made regarding ethical and local NHS approvals, the new HRA (Health Research Authority) approval has replaced these. All new studies obtaining approval from this date will have HRA approval, this process is expected to reduce the amount of time required to set-up studies at individual sites.

Confidentiality

Any volunteers participating in a clinical trial should have their personal data protected and stored confidentially. To ensure this, each volunteer is assigned one or more unique identifying numbers. Depending on the study, these may be referred to the screening number, screening ID, enrolment number, randomisation number, patient number, randomisation code or other similar words.

The only time a patient name should be used in correspondence is within the study investigator site (e.g. York Hospital); that is, between the study nurse, the patient's consultant and the pharmacy/labs/radiology.

In correspondence with any external bodies e.g. the sponsor, the patient should be referred to by their unique number, which should also be written on the study specific samples received by laboratory research.

Inspections/ Monitoring and Audits

To ensure the quality of the data as well as the safety of the volunteers, a study site is usually monitored by the study sponsor representative (remotely or via on-site visits). Study sites and teams may also be audited by the R&D Unit or inspected by the Regulatory Authority (MHRA). Reasons for an audit, monitoring or inspection visit can be varied (routine or for cause). If a study site is suspected of a breach of the regulations or fraud, the site would be inspected as part of a full investigation. Even if laboratory research wasn't suspected of being involved in the possible fraud or breach, the Laboratory is still likely to be inspected as a supporting department. This could be during the study or when the study is closed.

Laboratory Research will usually be visited in the course of a monitoring visit simply because of the importance of processing samples in the study, and the laboratory data & results having crucial impact on participants' safety and /or quality of the study data.

Clinical Trial Design Guidance

Blinding

Blinding means that the participant, the investigator, or both, are unaware of which drug the patient is taking. A clinical trial is single blinded if either the patient or the investigator (but not both) is unaware of what they are taking; it is double blinded when neither the patient nor the investigator are aware of the patient's allocated treatment. When a clinical trial is double blinded, it is usual for the sponsor to be blinded also.

The purpose of blinding is to reduce observation bias. If a patient doesn't know what they are taking, it can't influence their reporting of symptoms. Likewise, if the investigator doesn't know what the patient is taking, it can't influence their assessment of the patient. This means that any apparent effectiveness of treatment can be attributed to the treatment rather than expectations that a treatment will be effective.

Randomisation

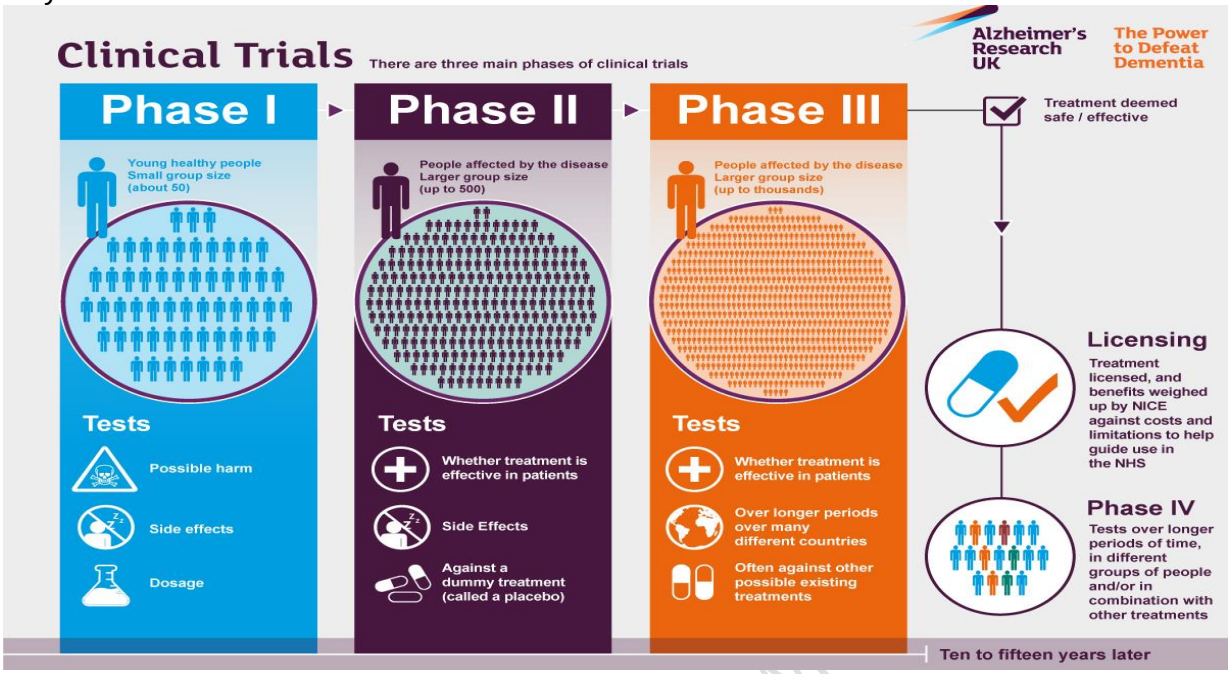
Most clinical trials are randomised. This means each patient enrolled into the clinical trial has a random chance of being assigned to any treatment group.

Randomisation is done for 2 reasons. Firstly, it means patients are not assigned to a given group- either consciously or subconsciously- for a particular reason, such as their health status. This eliminates selection bias. Secondly, each individual will have a number of characteristics that will influence the outcomes of a treatment. Randomly assigning patients to a clinical trial arm means that (providing the clinical trial is sufficiently large) these characteristics are evenly spread between the groups and therefore will not impact on the results. This eliminates confounding.

The actual process of randomisation is described in the clinical trial protocol. The usual method is that when a patient is ready to be randomised, the next unused sequential number is assigned to that patient.

Phases of Clinical Research

The below diagram demonstrates the different phases of clinical trials, which can span up to 15 years.



TRIAL PHASES:

Phase I trials — An experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and determine whether it's possible that the treatment could be effective.

Phase II trials — The experimental drug or treatment is administered to a larger group of people (100–300) to further evaluate its safety/effectiveness.

Phase III trials — The experimental drug or treatment is administered to large groups of people (1,000–3,000) and the data is analysed to establish exactly how effective the investigational treatment is, compare it with standard or equivalent treatments, and monitor any side effects.

Phase IV trials — After a drug is licensed and approved researchers track its safety, seeking more information about its risks, benefits, and optimal use.

Documents used in Clinical Trials:

Protocol

The protocol is a document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial. It must receive ethical and regulatory approval prior to implementation, and this is usually done before laboratory medicine is involved. Once the protocol is approved, any substantial changes planned in the conduct of the clinical trial must be documented in a protocol amendment, which must also be approved prior to these changes being implemented. Some sections of the protocol are of particular importance to lab, these relate to the sample processing and storage, shipping requirements & intervals and scheduling of events.

Laboratory Manual

The Laboratory Manual outlines exactly how samples should be processed and shipped in accordance to the Protocol. However, sometimes these manuals can be quite vague; and so sponsors should be contacted to ensure complete understanding of the processing in the set-up stages of a new trial.

When Laboratory Research is asked to be involved in a clinical trial, it is important that the protocol is reviewed at an early stage to identify any potential problems with the organisation of the clinical trial at the site or with the drug. The Labs Research staff should consider the logistics of participating early on.

When considering the practicalities of being involved in a clinical trial, some common considerations for the set-up process are:

- What is the estimated recruitment target?
- How long is the follow-up period?
- How often are samples received?
- What are the sample processing requirements?
- What conditions should samples be stored in?
- How long will the samples be stored for?
- Will all consumables be provided?
- How much storage space will be required?
- Do we have capacity for the trial?

Key documents for a Laboratory Site File (see R&D SOP/T07 & T63):

1. Current Protocol
2. Current Lab Manual (and superseded versions)
3. CCaC email (Confirmation of Capacity and Capability)
4. Key Information & Set Up Stages
5. Laboratory Senior Approval
6. Staff Signature & Training Log
7. Site File Amendment Log
8. Site File Document Reference Log
9. Sample Receipt Log
10. Specimen Location Log
11. Specimen Shipping Log
12. Specimen Deviation Log

Patient Eligibility Criteria

The protocol will list the criteria that a patient must meet to be eligible to participate in the clinical trial. This is in the form of inclusion / exclusion criteria.

When processing samples, the Laboratory would not be expected to check whether the patient meets eligibility criteria, or whether they have given informed consent – this is a responsibility of the Research Teams and study Principal Investigators. However, if a discrepancy is spotted then this should be reported to the study team.

Study Initiation Visit (SIV)

This should take place prior to the start of the study and the Laboratory Department must be involved to discuss sample processing and shipping. If possible, questions from the laboratory department should be raised with the study sponsor prior to study initiation visit so as to allow an answer to be provided during the initiation meeting. If this is not possible, then all study documentation should be reviewed prior to the initiation meeting to allow any questions to be raised at the meeting.

Fraud

Fraud can sometimes occur in clinical trials and can take many forms. Data may be fabricated or altered for financial, prestige, or other motivations. Whatever the reason, if fraud is suspected it must be investigated. Please refer to R&D SOP/S16.

What is a file note?

A file note is completed for any discrepancy that occurs relating to documentation contained within the site file. This could just be to explain the correct location of paperwork, where any temperature logs are stored, or any documentation errors. File notes may also be required for documenting and reporting deviations and breaches to study protocols, laboratory manuals or GCP requirements. Please refer to R&D SOP/S04.

A file note will need to be completed by a member of staff that is documenting the discrepancy or error that occurred, then signed by either another HSAP, the Research Quality Assurance Manager or the study Principal Investigator. Depending upon the trial we may have to send an electronic copy to the Clinical Trial Monitor or the study Sponsor representative - their details will be found in the Laboratory Site File.

7. Clinical Trial Terminology

Below are a few terms and phrases used commonly when discussing trials. This guide is intended to be a quick reference.

ADVERSE EVENT

An untoward medical occurrence in the health of a participant, including abnormal laboratory findings, that happens during a clinical study or within a certain amount of time after the study has ended. This change may or may not be caused by the intervention/treatment being studied.

ARCHIVIST

The person responsible for the management of the archived research study documents. The York Trust Named Archivist is based within the R&D Unit and can be contacted via: research.governance@york.nhs.uk

ARM

A group or a subgroup of participants in a clinical trial that receives specific interventions, or no intervention, according to the study protocol. This is decided before the trial begins.

BASELINE

Baseline information is gathered at the beginning of a study from which variations found in the study are measured. Baseline can also be described as a known value or quantity with which an unknown is compared when measured or assessed. Safety and efficacy of a drug are often determined by monitoring changes from the baseline values.

CROSSOVER TRIAL

A clinical trial in which all participants receive both treatments, but at different times. At a predetermined point in the study, one group is switched from the experimental treatment to the control treatment (standard treatment), and the other group is switched from the control to the experimental treatment.

EFFICACY

(Of a drug or treatment) the ability of a drug or treatment to produce a beneficial result. A drug demonstrates efficacy if it is effective at the dose tested against the illness for which it is prescribed.

INTENTION TO TREAT

Analysis of clinical trial results that includes all data from participants in the groups to which they were randomized even if they never received the treatment.

INTERVENTION
A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include non-invasive approaches, such as surveys, education, and interviews.

LABORATORY MANUAL
A written plan which will include, but is not limited to, the sample taking, handling, processing and purpose of the analysis and the methodology that will be used to perform the analysis.

OPEN LABEL
Describes a clinical trial in which masking is not used. This means that all parties involved in the trial know which participants have been assigned which interventions.

PARALLEL STUDY
A parallel designed clinical trial compares the results of a treatment on two separate groups of patients. The sample size calculated for a parallel design can be used for any study where two groups are being compared**.**

PLACEBO
A substance that does not contain active ingredients and is made to be physically indistinguishable (that is, it looks and tastes identical) from the actual drug being studied.

PLACEBO EFFECT
A physical or emotional change, occurring after an inactive substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.

RANDOMIZED ALLOCATION
A method based on chance by which study participants are assigned to different treatment groups. This minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms, thereby avoiding “selection bias.” Randomization allows for researchers to comparably test different treatments in similar groups.

ENROLLMENT
The number of participants in a clinical study. The "estimated" enrollment is the target number of participants that the researchers need for the study.

INVESTIGATOR
A researcher involved in a clinical study. Related terms include site principal investigator, site sub-investigator, study chair, study director, and study principal investigator.

OBSERVATIONAL STUDY
A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment.

CLINICAL TRIAL
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

CLINICAL TRIAL AGREEMENT
Contract of general terms & conditions between two parties, such as a laboratory and a sponsoring organisation, which may be used to support work for a number of clinical trials. Trial-specific terms, conditions, details, roles and responsibilities are then further defined in other documented agreements.

CLINICAL TRIAL SAMPLES
Any biological sample collected from a participant of a clinical trial as required by the protocol. Samples may include but are not limited to whole blood, plasma, serum, urine, faeces, tissue, and a range of other bodily fluids.

COSTING TEMPLATE
Clinical research templates of costs to provide a framework for transparent cost display and calculation. The main aim of the templates is to support swift local site budget negotiations when performing clinical trials in both primary and secondary settings within the NHS.

INFORMED CONSENT
Informed consent explains risks and potential benefits about a clinical trial before someone decides whether to participate.

PRINCIPAL INVESTIGATOR
A Principal Investigator is a doctor who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants' health to determine the study's safety and effectiveness.

PRIMARY OUTCOME MEASURE
In a clinical study's protocol, the planned outcome measure that is the most important for evaluating the effect of an intervention/treatment. Most clinical studies have one primary outcome measure, but some have more than one.

QUALITY ASSURANCE PROCESSES
All those planned and systematic actions that are established to ensure that the trial is performed, and data are generated, documented (recorded), and reported in compliance with Good Clinical Practice and the applicable regulatory requirement(s).

QUALITY CONTROL (QC)
A formal process for the systematic checking of processes and data to ensure accuracy (monitoring).

SOURCE DATA
Equivalent to the term "raw data" used in laboratories. Both terms mean all information in original records and certified copies of original records of clinical findings, observation, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

SOURCE DOCUMENTS
Original documents, data, and records.

SPONSOR
The organisation or person who initiates the study and who has authority and control over the study.

SPONSOR REPRESENTATIVE
An individual(s) appointed by the sponsor who will act on their behalf with respect to activities undertaken as part of a clinical trial.

TYPES OF CLINICAL TRIALS
- *Interventional trials* – studies that aim to investigate a particular intervention, or treatment for a specific disease. People taking part are put into different treatment groups, so that the research team can compare the results.
- *Non-interventional trials* - studies where the medicinal product(s) is prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study.

- *Observational studies*- these aim to monitor the progression of participants in different situations. The research team observes the people taking part, but they don't influence what treatments people have, they just collect data at pre-defined timepoints that will allow a range of research questions to be answered.

VALIDATION
A documented process that demonstrates that a computerised system is suitable for its intended purpose.

8. Introduction to Pathology & Clinical Biochemistry - Environment, Facilities and Equipment

York Teaching Hospital NHS Foundation Trust provides a comprehensive range of acute hospital and specialist healthcare services for approximately 530,000 people living in and around Selby, York, Scarborough, Whitby and Ryedale - an area covering 3,400 square miles**.**

The directorate of Laboratory Medicine covers the laboratories at York, Scarborough and Bridlington. The Clinical Biochemistry department at York and Scarborough process an approximate total of 4500 samples/day. These are standard of care samples; the handling and processing of clinical research samples is co-ordinated and carried out by the Research Laboratory Team (Healthcare Science Associate Practitioners R&D)

The department of Biochemistry at York is comprised of:

- Automated Chemistry and Immunoassay
- Manual Chemistry – including Sebia Protein Electrophoresis system, Tosoh HbA1c analyser, HPLC, osmometer and manual ELISA.

The department also has a POCT service that is responsible for all the on-ward analysers within the Trust, including Scarborough and Bridlington Hospital sites and also satellite units such as Easingwold and the community. The team covers all POCT disciplinaries, such as Roche blood gas analysers, glucose analysers, ketone analysers, urinalysis, urine pregnancy and COVID-19 analysers.

<u>Haematology/Transfusion/Immunology</u>
The Haematology department, including Blood Transfusion and Immunology, provides a high-quality diagnostic service and is committed to achieving and maintaining the highest possible standards. Haematology/Blood transfusion deliver a 24 hour, 7 day per week comprehensive consultative and diagnostic service throughout the Trust and beyond, providing blood results and products for use in clinical emergencies and routine procedures. Immunology is run on a 9am-5pm every weekday basis and is based solely at the York site.

<u>Microbiology</u>
The department of Microbiology offers a high-quality, 24-hour interpretative diagnostic Microbiology service to local hospitals and the community. As well as routine bacteriological culture, the department offers serological testing, liquid mycobacterial culture, and rapid molecular detection techniques for the diagnosis of a range of infectious diseases. The department works in collaboration with the HPA and regional CCDCs to contribute to epidemiological surveillance and public health medicine. The Microbiology department operates across the York and Scarborough sites. A number of research trials involve integration and support from Microbiology.

<u>Histopathology</u>
Histopathology aims to provide a high-quality diagnostic pathology service to York Teaching Hospital NHS Foundation Trust and the wider community. Investigations undertaken to

achieve this include routine histological technique and a wide range of special staining methods, while rapid diagnosis is available through the utilization of frozen section techniques. This allows sections/clusters f damaged tissue to be thoroughly investigated to provide an accurate diagnosis. In Immunocytochemistry, a comprehensive repertoire of antibodies is used to identify tissue antigen sites as an aid to diagnosis, particularly in cancer. They are also responsible for the archiving of tissue samples following their initial testing, so that they can be revisited by another clinician or used in an upcoming research trial following participant consent.

Mortuary

The York Teaching Hospital Mortuary provides a high-quality mortuary service to patients who die either in hospital or in the community and to their bereaved family and friends on both the York and Scarborough site. Scarborough Hospital is licensed with the Human Tissue Authority as a satellite location under the York Trust license. The Mortuary service ensures respect, dignity, and sensitivity in handling the deceased and in playing a vital role in supporting bereaved families whilst also ensuring strict health and safety guidelines are followed. Mortuary staff perform around 500 postmortems per annum from the hospital and local community as well as provide a coronial service for the York and Selby area. Staff work closely with the Trust Porter staff, Trust Patient and Liaison Services, Funeral Directors, the Coroner and Coroner's Office and the Police Service.

Staff Resources

The Head BMS and operational manager coordinate staffing - there is a mix of BMS (Band 7, 6 and 5) and MLA/support staff on both sites (York& Scarborough). The R&D Unit coordinates staff cover for the Laboratory Research service HSAP R&D (Band 4).

Quality Management

The Laboratory has full UKAS ISO 15189 accreditation and IBMS approved training status. Laboratory Medicine has a Quality Manager who is responsible for ensuring that the Quality Policy is adhered to and that all standards continue to be met.

There is a Quality Policy (LM-POL-Quality) and a Quality Manual (LM-INF-QualMan). The department has a quality assurance policy and participates in external quality assurance programmes wherever possible.

Health & Safety

Research & Development and Laboratory Medicine are committed to ensuring our laboratories are a safe place to visit and work within and staff are always expected to work in adherence to Trust and local policies and procedures. As a member of staff your personal responsibilities are to:

- Comply by Trust Policies, Local Rules and departmental standard operating procedures (SOP's) at all times to ensure the safety of yourself, your colleagues, patients and other staff / visitors.
- Use appropriate personal protective equipment (PPE) where necessary
- Promptly report to your line manager or senior laboratory staff any:
    - Untoward incidents
    - Accidents or near misses
    - Dangerous occurrences or practices

A number of important documents will be circulated electronically for you to read both on Laboratory Medicine Q-Pulse & Corporate Q-Pulse to acknowledge as part of your induction – please refer to your line manager if you require further information or have any questions. Some of the information gained from these electronic documents will also be discussed and signed off in the Competencies Booklet enclosed with this document.

Paul Sudworth, Directorate Manager is the Directorate and Departmental Safety Officer and currently chairman of the directorate safety committee which meets regularly. Clinical Biochemistry (York) also has the trade union (Unite) nominated Health and Safety Representative – Polly Boyes. Thomas Too is the health and safety representative for Biochemistry in Scarborough. There is a laboratory safety policy. There is annual review of risk assessments; all SOP's have COSHH assessments. There are regular documented safety inspections. There is a Health and Safety notice board displaying current and relevant information at both sites.

9. Introduction to the HSAP role in support of clinical research projects

The overall handling and processing of clinical trial samples is overseen by the team of HSAPs (Laboratory Research Team) who hold responsibility for the conduct, documenting and reporting of the laboratory work in support of clinical research studies. These individuals are in post to ensure that all laboratory work is performed in compliance with the clinical trial protocols, clinical trial protocol amendments, the contract, any associated work instructions/laboratory manuals and standard operating procedures.

Prior to the initiation of a clinical study locally, the Labs Research Team, in co-ordination with R&D Research Delivery Facilitators, Principal Investigators and Research Teams, carry out assessments and make provisions to ensure that sufficient resources are available for the timely and compliant conduct of a study. Lines of communication are being established and documented between the study sponsor or their representative and the Laboratory Research Team to ensure timely and efficient communication during the study conduct, including reporting of protocol deviations and suspected serious breaches, as well as timely reporting of abnormal results (where applicable) which may impact on trial participants' safety.

All work related to research samples must be performed in accordance with the clinical study protocol and work instructions. Timely reporting of deviations is crucial to ensure that the sponsor or their representative is able to determine the significance and impact of the deviation on the safety and wellbeing of the study participants and on the integrity and reliability of the trial data. The impact of any deviations from the laboratory's standard operating procedures or study protocols should be assessed and documented. Where there is potential for a deviation to impact on the integrity or reliability of the trial data, patient or subject confidentiality, consent or safety, the issue must be reported immediately to the sponsor or their representative, and the investigator team made aware.

All deviations should be reported within 24hrs from being aware that a deviation occurred; suspected serious breaches should also be reported to the R&D Unit to ensure timely review should expedited reporting to the Medicine and Healthcare Regulatory Agency is required. Please refer to R&D SOP/ S94 & S04.

The Laboratory staff should not perform any work on clinical research samples that is not specified in the clinical trial protocol. If additional work is requested by the sponsor or their representative, this should be submitted via a formal amendment process. The laboratory staff should seek assurance from the sponsor and/or the R&D Unit that the additional work does not conflict with the requirements of the clinical study protocol, compromise the informed consent given by the study participants or impact on the ethics committee approval and/or the authorisation given by the competent authority (where applicable). However, if unscheduled research samples are taken for urgent clinical reasons, for example, as a result

of adverse events, then such samples must be accepted without a delay and the request documented within the study Laboratory File.

All R&D HSAPs supporting delivery of clinical trial samples should undertake appropriate level of study specific and technical training commensurate with their roles and responsibilities related to handling and processing clinical trial samples. Competencies listed in this booklet, as well as the 2 weekly induction plan is there to ensure that new R&D HSAP staff are competent to perform the techniques required by research protocols, work instructions or laboratory manuals.

A record of training should be maintained for each individual involved in handling and processing of clinical research samples within their Training File and the relevant Laboratory Study Files. Training records will periodically be reviewed by Laboratory and R&D Unit management to ensure the information they contain is up to date and remains relevant. Copy of the training file, including this training manual & competencies booklet will be retained within the R&D Unit when staff leave the organisation.

Patient Safety

The safety of research study patients' takes precedence over any other aspect of the study. The SOP for reporting of deviations and suspected serious breaches (R&D SOP/S04) must be followed and the specified timelines adhered to (including the Adverse incident Reporting System and Policy (AIRS) where applicable). Normal ranges should be established for safety tests prior to the start of a research study for any samples that are analysed via the standard of care Laboratory pathways but required by the study protocol. If clinically significant deviations from these ranges are recorded, a process must be established and followed to communicate this information to the investigator and the sponsor, or their representative, as quickly as possible.

Informed consent

Research Teams are responsible for informing the Laboratory staff in a timely manner if patient's consent to participate in a research study is withdrawn for any of the research participants. This is crucial to ensure that research samples are not processed and/or shipped for analysis without a valid written consent from a patient. Please refer to R&D SOP/S94.

Contracts, review of costs and local agreements

Contractual agreements between relevant parties should be in place prior to the initiation of any work for a clinical research project. These are legally binding contracts signed by the sponsor (or their representative) and the R&D Unit management.

Contracts and agreements between the York Teaching Hospital NHS Foundation Trust and the study sponsor should not conflict with the requirements outlined in the clinical trial protocol or Laboratory Manuals. To ensure this, the R&D Research Delivery Facilitators and Laboratory HSAP follow an established study set up procedure consisting of several stages to enable thorough review of costs and research costing templates, workload, other resource implications and practical aspects of the processing, storing and shipping of study samples, including any specific staff training that may be required. Please refer to R&D SOP/S35. Laboratory readiness must also be confirmed prior to participant recruitment, to ensure that, where applicable, the appropriate lab kits and documentation have been received. The laboratory research team will be provided with a copy of the full clinical trial protocol and associated Laboratory Manuals or SOPs (and amendments). The R&D SOPs applicable to all research staff are in palace to ensure that any amendments to the clinical protocol and study documentation that are relevant to the work of the laboratory are supplied accordingly. Please refer to R&D SOP/S78.

Sample labelling, receipt, storage and chain of custody

An audit trail of the movement of each clinical research sample from when it is taken to the arrival to Laboratory, through storage, shipping and analysis or recipient by the central labs, must be documented and maintained as specified in the Laboratory Research Standard Operating Procedures.

All data should be recorded directly, promptly, accurately, and legibly. It should be possible to determine the date on which the entry was made, and work performed, and the identity of the person who conducted the work. Any change to the data should be made so as not to obscure the previous entry.

All equipment used for processing and storage of clinical research samples must be fit for its intended purpose. For this reason, all equipment used for research purposes is being regularly inspected, cleaned, maintained, and calibrated according to standard operating procedures or the manufacturer's manuals.

Blinding

In many cases clinical trials will be blinded. Maintaining the integrity of the blinding process is an essential part of conducting a clinical trial. If the blinding is compromised the validity of the trial may be put at risk.

The sponsor is responsible for ensuring that appropriate measures are implemented to ensure blinded individuals are not party to information which will compromise the blinding. Laboratories that perform the analysis or evaluation of clinical trial samples should exercise due diligence to ensure they do not inadvertently compromise the blinding process.

In situations where samples from blinded trials are supplied to a laboratory and the data generated by the laboratory may un-blind the trial, it is important that data is only sent to an established point of contact.

Retention of data & Archiving of Laboratory Research Files

Documents should be retained in accordance with the requirements of GCP and clinical trials legislation. R&D SOP/S34 must be followed and the Laboratory Study File amalgamated with the main study ISF prior to archiving.

10. Key Personnel

Title	Name
Directorate Manager (Laboratory Medicine)	Joanna Andrew
Operational Manager Biochemistry	Carl Burkinshaw
Senior BMS Staff	Emma Lovie (Chief) Rachel Navin/Polly Boyes/Alan Shepherd/Stuart Wilkinson
Operational Manager Haematology	Richard Adams
Operational Manager Histopathology	Helen Armitage
Operational Manager Microbiology	Lisa Mead
Clinical Lead	Alison Jones
Consultant Clinical Biochemist	Daniel Turnock
Consultant Chemical Pathologist	Deepak Chandrajay

Principal Clinical Biochemist	Claire Lloyd
Senior Clinical Biochemist	Maria de Ferrars
Quality Manager (Laboratory Medicine)	Elizabeth Fox
Deputy QM and H&S Lead	Angela Too
Head of R&D	Lydia Harris
Research Adviser	Deborah Phillips
Senior Research Nurses	Laura Griffiths/Kate Howard
Head of Research Delivery (clinical)	Cate Laven
Head of Research Delivery (non-clinical)	Mags Szewczyk
R&D Healthcare Sciences Associate Practitioners	Megan Worthington/Sarah Bell/ Jessica Goodliffe
Research Delivery Facilitators	Lisa Carr-Knot/Richard Furnival
Trial Managers	Tom Szczerbicki/Greg Forshaw Mia Porteous/Monica Haritakis
R&D Administrators	Angela Jackson (EDGE & Amendments)/Sarah Sheath (SOPs & Finance)

11. Self-assessment & reflective questions

Now you have read the underpinning knowledge please answer the reflective questions below. Discuss your answers with your mentor.

1.) What do you think the laboratory team should consider before agreeing to process samples as part of a clinical trial?

2.) What do you think are the main concerns patients have when they are considering participating in a clinical trial?

3.) What is your understanding of Good Clinical Practice? What are some of the key ways it guides clinical trials?

4.) What does it mean if a study is double-blinded?

5.) What are the essential documents for a clinical trial that are kept in the laboratory site file?

6.) Please also refer to R&D SOP/F30 for further self-assessment questions for GCP compliance on individual basis, as well as within the facility so that corrective & preventive actions can be planned for and undertaken.

12. Training Booklet

These tasks will need to be completed in order to deem you comprehensive in all aspects of the Healthcare Science Associate Practitioner role.

Table 1 requires direct discussion/observation to be completed. Table 2 requires reflection, evidence and a final signature by a member of the team who has fully completed all training.

TRAINING CHECKLIST TASK **Table 1**	Training commenced (Discussion/Observation)			Able to perform task in accordance with standard laboratory procedures in a lone environment		
	Date	**Signature**		**Date**	**Signature**	
		Trainer	**Trainee**		**Trainer**	**Trainee**
1. Full GCP Training						
2.Corporate Induction						
3.Laboratory Research Email Use						
4. Regular Meetings						
5. How to use Learning Hub & Q-Pulse						
6. Pathology Fire Safety (LM-SOP-FIRE)						
7. Read & Understood Pathology H&S Documents (LM-TEM-CA-H&S-BASIC LM-TEM-COMP-H&S)						
8. Research CV & Training File						
9. New Study Stage 1 Completion (R&D/S35)						
10. New Study Stage 2 Completion (R&D/S35)						
11. New Study Stage 3 Completion (R&D/S35)						
12. New Study Stage 4 Completion (R&D/S35)						
13. Use & Maintenance of Storage Equipment						
14. Booking research samples in/ booking shipping etc. Use of the Labs calendar						
15. Tutela Temperature Monitoring (R&D/S41)						
16. Short & Long Term Storage of Research Samples						
17. Research Analysers						
18. Request & process tissue from Histopathology						
19. Ordering of trial specific consumables						
20. Use of E-rostering system						
21. Dangerous Goods Training						

TRAINING CHECKLIST TASK **Table 2**	Training commenced (Discussion/Observation)			Able to perform task in accordance with standard laboratory procedures in a lone environment		
	Date	**Signature**		**Date**	**Signature**	
		Trainer	**Trainee**		**Trainer**	**Trainee**
1.Costing Template Completion						
2. Attend SIV/SSV/ Study specific training						
3. Amendment to Implementation						
4. File maintenance (including X-drive)						
5. Deviation Procedure/ Serious Breaches & DATIX reporting						
6. Completion of a file note						
7. Receiving & Processing research samples						
8. R&D/S38 Use of Beckman Allegra Centrifuge						
9. R&D/S84 Use of Heraeus Centrifuge						
10. Use of Piston Pipettes						
11. Multiple Sample Aliquoting						
12. All aspects of Sample Shipping						
13. Archiving						
14. Complete Induction Checklist						

The tasks outlined in Table 2 (above) will require reflection, evidence and a final signature by a member of the team who has fully completed all training.

See Section 13 for details.

13. Local Competencies

Our aim is to support you in your role and ensure the knowledge attained during your training period is relevant, insightful and overall highly informative.

The tasks outlined in Table 2 (above) will require reflection, evidence and a final signature by a member of the team who has fully completed all training.

Local Competencies and associated evidence should also be stored within your Research Training File.

13.1 Costing Template Completion

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……..
Authorised By Print Name: ……..Sign: ……..
Date: ……..

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	C		Has read and understood the costing template section of ***R&D/S35*** - *Laboratory Research Clinical Trial Set-Up* and can give an explanation of the purpose of costing template review.		
DD/MM/YY	C		Can explain the difference between standard-of-care testing, study specific testing via the routine sample pathway outside standard-of-care and study specific testing.		
DD/MM/YY	C		Can give examples of items that would usually be provided by the study Sponsor or included on the costing template.		
DD/MM/YY	C		Can describe the key differences between setting up commercial and non-commercial studies with reference to documentation.		
DD/MM/YY	C		Secondary Care Industry Costing Template: can identify the relevant sections to review, including; recruitment target, MMF, set up fee and all procedures and/or investigations.		
DD/MM/YY	C		HRA SoA & SoE: can identify the relevant sections to review.		
DD/MM/YY	C		Can explain why it is necessary to obtain Local Laboratory costing		

			template approval.		
DD/MM/YY	A, B, C & D		Completes four costing template reviews, including two commercial and two non-commercials, raises any necessary change requests with the Sponsor via the assigned RDF and obtains the necessary permissions from the Local laboratory.		

Competency will be assessed using the following approaches:

A: Written Assessment

B: Observation

C: Verbal Assessment

D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐
Authorised By Print Name: ……Sign: ……
Date: …….

**Not Competent* – More training required - Action Plan:

Target Date:
Action Plan Details:

13.2 Attending SSV & SIV's

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……..
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B		Add SSVs and SIVs into calendar / accept calendar invites.		
DD/MM/YY	B		Ensure relevant set up stages are complete prior to SSV/SIV		
DD/MM/YY	A		Prepare relevant notes before the meeting and questions you wish to ask		
DD/MM/YY	A		Annotate any documents received prior on testing that is relevant to our role and will directly affect the research laboratory		
DD/MM/YY	B		Attend 2 SSVs		
DD/MM/YY	B		Attend 2 SIVs		
DD/MM/YY	C		Make notes and feedback information to Lab Research		

Competency will be assessed using the following approaches:
A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐
Authorised By Print Name: ……..Sign: ……
Date: ……

**Not Competent* – More training required - Action Plan:

Target Date:
Action Plan Details:

13.3 Amendments to Implementation

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B		Ensure amendment is related to a study we are involved in		
DD/MM/YY	B & C		Read & Fully understood **R&D/S78**		
DD/MM/YY	B		Is aware of 35 day window from being informed and implications of a missed window		
DD/MM/YY	A		Correct completion of Amendment Log		
DD/MM/YY	B & A		Can create a folder in the study specific file and save the amendment documents, documenting the action on column E of the Amendment Log Spreadsheet		
DD/MM/YY	B		Can review amendment by documenting changes and determining impact on the Research Laboratory		
DD/MM/YY	B		Approval/Rejection email template correctly used and sent to Research Governance		
DD/MM/YY	B		Can save and supersede protocols and lab manuals both electronically and in the site file (lab manual only)		
DD/MM/YY	D		Can assess if amendment does impact Laboratory Research, take into account cost implications, workload, other resource implications, practical aspects of processing, storing and shipping of study samples and staff training requirements.		
DD/MM/YY	B		Understands that whichever department's involvement has changed, that they are informed and that they also approve.		
DD/MM/YY	B		Understands that changes are not implemented until the entire team approves		
DD/MM/YY	A		Documents the CCaC & Completing the Amendment Log within the site file		
DD/MM/YY	A, B, C, D		Completed 3 Amendments in a lone capacity (note trial and amendment number below) 1. _____ 2. _____ 3. _____		

Competency will be assessed using the following approaches:
A: Written Assessment
B: Observation

C: Verbal Assessment **D**: Assessment of Problem Solving Skills
OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below) Competent ☐ Authorised By Print Name: ……..Sign: ……Date: ……
**Not Competent* – More training required - Action Plan: Target Date: Action Plan Details:

13.4 Laboratory File Maintenance & Auditing

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B		Read & understood **R&D/S71**		
DD/MM/YY	B		Read & Understood **R&D/F13**		
DD/MM/YY	C		Can communicate the need for audits within research		
DD/MM/YY	C		Understands the need for file maintenance		
DD/MM/YY	A, B, C, D		Has audited 5 files (list trials and date below) 1. 2. 3. 4. 5.		

Competency will be assessed using the following approaches:
A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐
Authorised By Print Name: ……..Sign: ……Date: ……

**Not Competent* – More training required - Action Plan:

Target Date: Action Plan Details:

13.5 Deviation Procedure

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required

Trainee Print Name: ……..Sign: ……

Date: ……

Authorised By Print Name: ……..Sign: ……

Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B		Read and understood **R&D/F31**		
DD/MM/YYM/YY	B		Read and understood **R&D/S05**		
DD/MM/YY	C		Understands what classifies as a deviation		
DD/MM/YY	C		Understands the impact deviations can have on patients		
DD/MM/YY	A, B, C		Has completed a DATIX Report		
DD/MM/YY	B		Has highlighted/actioned a CAPA to prevent an incident in the future		
DD/MM/YY	A, B		Can correctly complete the QA Spreadsheet		
DD/MM/YY	A		Can correctly file correspondence relating to a deviation		
DD/MM/YY	C		Understands that the quality of information provided to summarise the deviation should be as extensive as possible		
DD/MM/YY	C		Knows who to contact based on the severity and type of deviation		
DD/MM/YY	A, B, C, D		Has completed Deviation Procedure 10 times – see below for quick reference evidence and specific trial file for full deviation log. Trial……..Deviation……Date…….. Trial……..Deviation……Date…….. Trial……..Deviation……Date…….. Trial……..Deviation……Date…….. Trial……..Deviation……Date…….. Trial……..Deviation……Date…….. Trial……..Deviation……Date…….. Trial……..Deviation……Date…….. Trial……..Deviation……Date…….. Trial……..Deviation……Date……..		

Competency will be assessed using the following approaches:

A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below) Competent ☐

Authorised By Print Name: ……..Sign: ……..Date: ……

**Not Competent* – More training required - Action Plan:

Target Date: Action Plan Details

13.6 Completion of a File Note

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B, C		Read & Understands how to correctly complete **R&D/T20**		
DD/MM/YY	B		Can complete **R&D/F59** in conjunction with **R&D/T20**		
DD/MM/YY	C		Understands the scenario in which a file note would be appropriate		
DD/MM/YY	B		Observe file notes which have previously been completed by Laboratory Research to gain insight into contents and tone.		
DD/MM/YY	C		Understands that file notes should be as extensive as possible to ensure complete record of event.		
DD/MM/YY	A, B, C, D		Has correctly completed 3 file notes (list below) 1. 2. 3.		

Competency will be assessed using the following approaches:

A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐
Authorised By Print Name: ……..Sign: ……Date: ……

**Not Competent* – More training required - Action Plan:

Target Date: Action Plan Details:

13.7 Receipt & Processing Research Samples

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B		**Read & Understood R&D/S94**		
DD/MM/YY	B		Can correctly receive samples and thoroughly check tubes against Requisition Forms		
DD/MM/YY	A, B		Can correctly transcribe labels 3 separate times (document below with date and Trial) 1. 2. 3.		
DD/MM/YY	C		Understands the need for anonymised research ID numbers		
	C		Is aware of sample variance received by Laboratory Research		
DD/MM/YY	C		Understands the need to prioritise processing based on the SOP and specific sample requirements		
DD/MM/YY	B		Read & Understood **LM-HSR-HIGHRISK** relating to processing and handling of High Risk Samples		
DD/MM/YY	A, B, C		Can use Telepath when required by specific trials		
DD/MM/YY	C		Understands the need for complete, legible, and accurate form completion within the Laboratory File		
DD/MM/YY	C		Understands the circumstances in which a sample is unsuitable for testing		
DD/MM/YY	C		Understands what actions to take if there is an issue with the sample		

Competency will be assessed using the following approaches:

A: Written Assessment

B: Observation

C: Verbal Assessment

D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐

Authorised By Print Name: ……..Sign: ……..Date: …….
**Not Competent* – More training required - Action Plan: Target Date: Action Plan Details:

13.8 R&D/S38 Use of Beckman Allegra Centrifuge

Appendix A

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	C		Can identify the samples to be centrifuged.		
DD/MM/YY	C		Knows to leave the blood to clot prior to centrifugation.		
DD/MM/YY	B		Can safely operate the centrifuge; lids on buckets & balance the samples in the centrifuge.		
DD/MM/YY	B		Can change the settings and use the correct program; centrifuge.		
DD/MM/YY	C		Knows the procedure if a sample has broken (or is suspected to be broken) in the centrifuge.		
DD/MM/YY	B		Knows the maintenance procedure of the centrifuge.		

Competency will be assessed using the following approaches:
A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐
Authorised By Print Name: ……..Sign: ……Date: ……

**Not Competent* – More training required - Action Plan:

Target Date: Action Plan Details:

13.9 R&D/S84 Use of Heraeus Centrifuge

Appendix A

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	C		Can identify the samples to be centrifuged.		
DD/MM/YY	C		Knows to leave the blood to clot prior to centrifugation.		
DD/MM/YY	B		Can safely operate the centrifuge; lids on buckets & balance the samples in the centrifuge.		
DD/MM/YY	B		Can change the settings and use the correct program; centrifuge.		
DD/MM/YY	C		Knows the procedure if a sample has broken (or is suspected to be broken) in the centrifuge.		
DD/MM/YY	B		Knows the maintenance procedure of the centrifuge.		

Competency will be assessed using the following approaches:

A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐
Authorised By Print Name: ……..Sign: ……Date: ……

**Not Competent* – More training required - Action Plan:

Target Date: Action Plan Details:

13.10 Use of Piston Pipettes

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……
Date: ……..

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B & C		Read & Fully Understood **LM-SOP-PIPETTES**		
DD/MM/YY	B & C		Appropriate use of PPE within the Research & Development Lab		
DD/MM/YY	C		Adjustable pipettes should not be used below 25% of their capacity		
DD/MM/YY	B		First stop & final stop outline		
DD/MM/YY	C		Importance of accurate pipetting techniques		
DD/MM/YY	B & C		Pipette tips – ordering, correct use & disposal (including tip types)		
DD/MM/YY	B		*Set Volume* - The required volume is set. The piston moves to the appropriate position.		
DD/MM/YY	B		*Preparation* - Can hold the instrument in a nearly vertical position. Depress the plunger smoothly to the first stop position.		
DD/MM/YY	B		*Aspiration* – Can immerse the pipette tip in the liquid*. Allow the plunger to move up smoothly to the rest position. Wait one second so that all the liquid has time to move up into the tip.		
DD/MM/YY	B		*Dispense* – Can place the pipette tip at an angle (10° to 45°) against the inside wall of the receiving vessel. Depress the plunger smoothly to the first stop position.		
DD/MM/YY	B		*Purge* – Can wait one second, then depress the plunger to the second stop position. This purge stroke removes any remaining sample from the tip. Remove pipette tip end from sidewall by sliding it up the wall. *Home* - Allow the plunger to move up to the rest position.		
DD/MM/YY	B		Understands the theory behind pre-rinsing the pipette		
DD/MM/YY	B		Understands the need for regular cleaning and decontamination		

			procedure		
DD/MM/YY	A & D		Servicing/Calibration		

Competency will be assessed using the following approaches:

A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐
Authorised By Print Name: ……Sign: ……Date: ……

Not Competent* **– More training required - Action Plan:
Target Date: Action Plan Details:

13.11 Multiple Sample Aliquoting

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	C		Understands complex visits requiring multiple blood/urine samples		
DD/MM/YY	B		Can pre-label - correct, relevant, required labelling		
DD/MM/YY	B		Can correctly use Pasteur Pipettes		
DD/MM/YY	B		Can correctly use Using Micro Pasteur Pipettes		
DD/MM/YY	B, C		Understands the need for Priority		
DD/MM/YY	B, C		Can cool/heat the centrifuge prior to visits when required		
DD/MM/YY	C		Understands the need and reasoning behind bijou pooling.		
DD/MM/YY	B		Is aware of differing aliquot receptacles for specific trials		
DD/MM/YY	B		Is aware of differing storage requirements for specific trials		
DD/MM/YY	A, B, C, D		Can process 'extensive visits' in a lone capacity 3 times (list trial and date below) 1. 2. 3. 4. 5.		

Competency will be assessed using the following approaches:
A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐
Authorised By Print Name: ……..Sign: ……Date: ……

**Not Competent* – More training required - Action Plan:

Target Date: Action Plan Details:

13.12 Sample Shipping

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……..
Date: ……..
Authorised By Print Name: ……..Sign: ……..
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B & C		Read & Fully understood **R&D/S94**		
DD/MM/YY	C		Understands person responsible for shipping and need for being informed of the sample processing involved ahead of time.		
DD/MM/YY	D		Able to calculate time needed to process particular samples against a shipment pick-up		
DD/MM/YY	C		Understands that samples must reach shipping temperature before being packaged		
DD/MM/YY	B		Understands need to establish if samples can be shipped in the future if DOC shipping if not possible		
DD/MM/YY	D		Can locate dry ice if it has not been received in Pathology within the time-frame you would expect		
DD/MM/YY	C		Preferred shipping days and dry ice sublimation		
DD/MM/YY	C		Documents to be shipped with national and international shipments		
DD/MM/YY	C		Is aware of how to ship samples; knowledge of correct storage condition, frequency of shipping & Dangerous Goods Shipping; UN3373 Biological Substance Category B.		
DD/MM/YY	C		Knows where to file requisition copies & shipping receipts		
DD/MM/YY	A & B		Understands the reasoning behind Back-up samples & their destruction		
DD/MM/YY	A		Can correctly enter Data into the Laboratory File		
DD/MM/YY	A		Can documenting shipping deviations		
DD/MM/YY	D		Can contact Couriers when required		
	A, B, C, D		Has shipped samples in a lone capacity 5 times (note trial and date below) 1. _____ 2. _____ 3. _____ 4. _____ 5. _____		

Competency will be assessed using the following approaches:

A: Written Assessment
B: Observation
C: Verbal Assessment

D: Assessment of Problem Solving Skills
OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below) Competent ☐ Authorised By Print Name: ……Sign: ……Date: …….
**Not Competent* – More training required - Action Plan: Target Date: Action Plan Details:

13.13 Archiving

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note: all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D Standard Operating Procedures, local Laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist or the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……
Date: ……
Authorised By Print Name: ……..Sign: ……
Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B		Read & Fully understood **R&D/S11 & R&D/S34**		
DD/MM/YY	C		Understands who the R&D Archivist is.		
DD/MM/YY	C		Is aware of legalities of storing information		
DD/MM/YY	C		Aware that documentation to ensure that there is no unnecessary duplication.		
DD/MM/YY	A		Can organise documents in suitable binders, box files or wallets, all of which should be clearly labelled with the Sponsor's name, Sponsor's ID number, Short study title, the name of the CI (or PI for hosted studies)		
DD/MM/YY	A		Can ensure no blanks throughout documents – fill with unknown		
DD/MM/YY	A		Can complete a file note relating to archiving if necessary		
DD/MM/YY	A, B, C		Can ensure all forms and logs are fully completed including checking that all samples have been shipped or destroyed as per the study protocol.		
	D		Can organise shipping with the Sponsor if required		
DD/MM/YY	B		Organise to and complete delivery of file ready for archiving to relevant team		
DD/MM/YY	A, B, C, D		Has archived 3 Studies: (List below) 1. _____ 2. _____ 3. _____		

Competency will be assessed using the following approaches:

A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐
Authorised By Print Name: ……..Sign: ……Date: ……

*_Not Competent_ – More training required - Action Plan:

Target Date: Action Plan Details:

13.14 Complete Induction

Trainee should sign and date below to confirm that they have fully understood the training provided. Please note; all sample handling & maintenance of records should comply with Clinical Trials Regulations and GCP requirements, R&D standard operating procedures, local laboratory procedures and the relevant study specific Protocols/Laboratory Manuals. If any of the instructions are unclear please seek advice from the R&D Laboratory team in first instance, or Research QA Manager, Biomedical Scientist, the study Sponsor if further clarification is required.

Trainee Print Name: ……..Sign: ……Date: ……

Authorised By Print Name: ……..Sign: ……Date: ……

Date	Assessment Type	Assessor	Task	Evidence	Status
DD/MM/YY	B		Acknowledged all documents in Q-Pulse (Lab & Corporate)		
DD/MM/YY	B		Completed all E-Learning		
DD/MM/YY	B		Completed all competencies		
DD/MM/YY	B		Research Training File Complete		
DD/MM/YY	C		Any questions about the service we provide?		

Competency will be assessed using the following approaches:

A: Written Assessment
B: Observation
C: Verbal Assessment
D: Assessment of Problem Solving Skills

OVERALL COMPETENCY LEVEL: NOT Competent ☐ (See action plan below)
Competent ☐

Authorised By Print Name: ……Sign: ……Date: ……

**Not Competent* – More training required - Action Plan:

Target Date: Action Plan Details: