The Centre for Health Research & Innovation
Our Research Our Care

NHS
Lancashire Teaching Hospitals
NHS Foundation Trust

Student Midwife/Nurse Welcome Pack

Women's Health Research Team
Gynaecology Out Patient Department

Tel: 01772 52 4628/4769

Baby Beat
Supporting Babies & Mothers across Lancashire & South Cumbria

Katrina Rigby – Senior Research Midwife and Team Leader

Cheryl Wyatt – Research Midwife

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Hello!

Welcome to your research placement.

This handbook has been developed to support you during your placement and may be used towards your personal development plan (PDP).

We have included different aims and objectives that can be used as a guide and checklist of what you can expect throughout your placement with us. Our advice is to have an open-minded approach as this is very different from your previous placements.

We appreciate that you have an array of competencies on PARE needing to be signed off for this placement. It is, therefore, crucial to try and gain as much knowledge and experience as you can. The team are enthusiastic about your placement and will actively encourage you to make the most of it, so any suggestions or interests you have or would like to explore, please ask.

There are opportunities to spend time with other departments who help support research and the Trust and we hope that you will take advantage of these while you are here.

We welcome constructive feedback from you regarding your learning experience and will use this information to inform and enhance the placement that we offer. You will be provided with an evaluation form to complete and we will complete your PARE assessments in a timely manner.

Our Mission Statement:

Our Award Winning Research team will provide an environment where students are well supported to meet individual learning needs, gaining an insight into how the evidence base for practice is developed at the forefront of healthcare delivery.

The Centre for Health Research and Innovation

Lancashire Teaching Hospitals is committed to improving healthcare through research and innovation. The Centre for Health Research and Innovation is a hub of activity supporting the design, conduct and delivery of clinical trials across the Trust. We are proud to have a large multi-disciplinary team that works together to provide our patients with access to innovative treatments and interventions. We offer staff across the Trust opportunities to develop their own ideas into high quality research projects.

Paul Brown
Head of Research and Innovation

Professor Pierre Martin Hirsch
Director of Research & Innovation

Why engage with Research?

Clinical research offers a career path for many health professionals that is highly rewarding and intellectually challenging. Being involved with research and generating new knowledge also means that there are widespread benefits for research participants. Studies suggest that patients who receive care in research active institutions have better health outcomes than patients who are treated in a non-research environment. By joining our team, therefore, you are actively helping improve the standard of healthcare for the patients. By helping to answer research questions, we help build a body of evidence that can lead to a positive change in future healthcare.

Why is Research important in the NHS?

The NHS has a constant challenge to provide a service that is up to date and efficient. Health research plays a vital role in this service by using the evidence from studies to support health strategies and changes in medical practice. The Department of Health's Strategy to improve the health of the nation continues to place research at the forefront of the NHS. The White Paper, *Equity and Excellence*: *Liberating the NHS* (DH, 2010) highlights research in terms of quality, transparency and value for money. It aims to achieve health outcomes as good as anywhere else in the world, and deliver quality care from thoroughly researched evidence based practice.

Research in the NHS is a perpetually evolving landscape yet the key role it has to play in the future of the NHS is clear. The NHS Constitution (2009) cites that "the NHS aspires to the highest standards of excellence and professionalism…through its commitment to innovation and to the promotion and conduct of research to improve the current and future health and care of the population". Also that, "Research is a core part of the NHS. Research enables the NHS to improve the current and future health of the people it serves. The NHS will do all it can to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them". The NHS is therefore putting in place procedures to ensure that patients are notified of opportunities to join in relevant ethically approved research and will be free to choose whether they wish to do so.

The research culture is growing across England for patients and health professionals to take part in multi-centre studies. So, working with the clinical research team you will play a key role in contributing to this culture through clinical trials and/or health related research. By doing this we are continually improving the quality and choices available for patients and healthcare overall.

For more information regarding research in the NHS, you may like to visit www.nhs.uk/conditions/clinical-trials

The National Institute for Health Research

In 2006, the National Institute for Health Research (NIHR) Comprehensive Clinical Research Network (CCRN) was created as part of the Government's Research and Development Strategy to establish the NHS as an internationally recognised centre of research excellence. For further information please go to:

National Institute for Health Research | NIHR

Research at Lancashire Teaching Hospitals NHS Foundation Trust

Serving a population of 1.5 million and providing a range of care in both a secondary and tertiary healthcare setting, Lancashire Teaching Hospitals NHS Foundation Trust is well placed to make a real impact on the health of the region through evidence based practice. We have over 250 on-going studies covering many types of research across a large number of different conditions at this Trust. This offers our patients the opportunity to be involved in trials of new treatments as well as studies involving questions and interviews looking at their quality of life and service improvement. The Trust benefits from its close proximity to a number of quality academic institutions as well as being a provider of a number of specialist services across the region.

Before it begins, all research involving NHS staff, facilities, service users, patients, their carers or relatives, will always have been approved by an independent research ethics committee and will have been reviewed by the Trust to ensure that it is safe and appropriate to conduct the research here at Lancashire Teaching Hospitals NHS Foundation Trust.

About the Directorate

The Department is based in the building next to the Sharoe Green Unit at Royal Preston Hospital. Research Teams in various specialities around the Trust are supported by this Department, based in this Centre. This means that not only can research staff around the Trust work in the department and use desk space/computers, but there are clinic rooms with facilities where research

participants can be seen outside the speciality areas. There are seven parking bays outside the Department for participants to use free of charge when they are attending the Centre. The centre is open Monday to Friday, 08:00 to 18:00.

The Centre for Health Research and Innovation offers a wide range of information, advice and guidance and can offer support with studies, whether it be in in developing an idea, NHS approvals, funding opportunities or finding research collaborators. We can support researchers through the entire research process to completion. It is important that the centre is aware of all research that is being undertaken at the Trust.

Partnering with us gives opportunities for researchers to gain:

- Rapid trial feasibility, start up and completion – our research governance team can support with NHS permissions and we have an average time of 8 days for granting NHS permission
- Access to experienced clinical investigators across secondary and tertiary healthcare
- We have strong links with all NIHR Clinical Research networks
- Wide and varied patient population
- Links to our well established partnerships with local higher educational partners and collaborators
- High recruitment rate to clinical trials in the UK
- We have a dedicated Innovation and Ideas Facilitator to project manage collaborations within the Trust

Staff

The team is led by Head of R&I.
The research delivery team are led by the Research Matron.
There is also a Research Operations manager.

The research teams are:

Lancashire Clinical Research Facility	Division 6 (critical care, ED, surgery)
Neurosciences (stroke, neurology, neurosurgery)	Chronic conditions (diabetes, kidney disease)
Oncology	Women's and Child Heath

Your Placement

You will be based with the Women's Health Research Team, in the Sharoe Green Unit at Royal Preston Hospital. Our Office is at the back of Gynaecology Outpatients. We also have an office at Chorley District General Hospital and it may be that you have the opportunity to visit during your placement if we have clinics at Chorley ANC.

Hours of work

Our core hours are 0800 – 1800, Monday to Friday and we work to the Trust's Flexitime policy. In essence, you negotiate your hours with your team, depending on the needs of the service and ensuring that all visits are covered. Any hours under or over your 37.5 hours need to be reviewed by your assessor or supervisor and balanced by early or late finishes.

Sickness/Absence

If you are going to be absent during your placement, you must call either your assessor or supervisor to advise them that you will not be at work, the reason for your absence, anticipated duration of absence and the next agreed contact date. If your assessor or supervisor is not available, please contact the shift co-ordinator for the day. Please note that you must talk to someone on your first day's sickness and it is not acceptable to text or leave a message on an answer machine.

Policies and Procedures

These are available in the Research section of the Intranet. Our Standard Operating Procedures are stored on Q-Pulse (your assessor/supervisor can help you with this)

Evaluation

At the end of your placement you will be asked to complete an evaluation form (attached). Please complete this open and honestly as all feedback is used to inform any improvements for the benefit of future students.

Uniform Policy

We adhere to the Trust uniform policy. All students should look clean, tidy and well groomed. Uniform should be worn in all areas when working with patients. In the LCRF, there is a Bare Below the Elbows policy for all staff. If you are required not to wear uniform then students are expected to maintain a professional appearance at all times.

Personalised Student Nurse plan

Student Name:

University:

Assessor name and contact details:

Supervisor name and contact details:

The role of a student midwife/nurse within the Research Department is to gain an understanding and insight into the role of the research midwife/nurse.

We hope to give you a flavour of the day to day running of our department and our studies, as well as the role of research within the Trust and the NHS.

Orientation around the Centre is required. It is recommended that you spend some allocated time with as many staff as possible so as to gain a greater understanding of the various roles. Dependent on workload and activities of the team this may vary. Each student should have the opportunity to go to sites or on home visits. Prior to each visit the student should have opportunity to:

- Review the documentation relating to the relevant study briefly
- Discuss the study with the member of the team and consider any similarities or differences from other studies they have been involved with
- Observe study related activities – not all of this will be patient contact
- Complete parts of the work sheet as relevant

What to expect during your placement with us	
First day	• Orientation • LCRF checklist • CRF manager • Microsoft Teams access • Locker • Lone worker policy • Sickness/absence policy • Join for morning huddle and plan for the day • Discuss placement programme and plan for the placement.
Days 1 -2	• Initial meeting with assessor • Complete Good Clinical Practice training • Familiarise yourself with trials being run by your teams • Familiarise yourself with the terms used in the department and at the morning huddle. • Look into different ways of consent • What is ethics and why is it important? • Research into capacity and lack of capacity and capacity assessment (research into national and local policies surrounding this). • Attend recruitment of patients with senior staff, observing with a view to supporting recruitment in the future. • Understand the screening process • Arrange lab training with the team's CTSO. • Understand the role of the NIHR and the portfolio. • Understand the role of the research midwife/nurse • Understand the role of the CTSO
Days 3 - 4	• Start to screen patients for the inclusion and exclusion criteria to trials available, under supervision from trained staff. • Review ongoing patients recruited to study for Adverse Events, have an understanding of this process and its importance in research. • Assist in the recruitment of patients with trained staff

	and assist with randomisation/treatment delivery • Work in link areas (see list below) • Support venepuncture and sample processing, storage and despatch as required. •
Days 4- 5	• Screen patients on the allocated studies, working alongside a trained member of staff. • Support the recruitment of a patient on to a trial (under direct supervision) • Support the randomisation • Support the administration of treatment/intervention • Support the completion of study assessments • Complete study specific documentation under direct supervision.
Final Day	• Complete placement survey to aid the research team and progression for future students. • Complete all paperwork required for final meeting and sign off hours

Link department and opportunities

Other research teams	Although you will be based with the Women's Health team, your assessor/supervisor may be able to arrange for you to spend time with the other research teams.
Research Access Team	Looking at the processes we undertake to ensure that each study is safely and efficiently set up.
Clinical Trials pharmacy	There is a dedicated section in pharmacy with staff who manage their side of our pharmaceutical studies.
Laboratory	Including the Brain Bank

Worksheets for the end of the placement

This section of this pack should help you to review and consider what you have observed or been involved with whilst in the research setting with the team. Some of this can be done alone or can be discussed with the team member.

Consider **one** of the studies you have been involved with or have heard about on this placement. Try to choose two quite different studies or two within different settings or types of patients.

What is the full title of the study?

Is it referred to as anything different? Why?

Is the study a CTIMP?

Is it to research a new intervention?

What is the study hoping to change for future patients?

If drugs were given, were they novel, licensed, unlicensed or used off-label?

Which of the authorisations, approvals and permissions were given for the study? How do you know?

Inclusion exclusion criteria (think about the other studies that you have seen)
Review this in the protocol or study guidance.
What do you think is very specific for this study?

Are there any inclusion or exclusion criteria that you think may be general for most studies?

Did you observe any part of the consent process***?***
Who was involved, what was done?

Were there any special considerations around consent for this study? What did the protocol or study guidance say about this?

How long are the potential subjects given to consider this study? Where did you find that information?

What type of **data** is being collected for the study?

Is there any guidance given re **data collection** for this study?

How is the data collected and recorded and sent back to data management? Who is involved?

What was **source data** and what format was the **data collection tool?**

Did you see any '**essential documents'**? Which were they?

Where and how were they kept?

Is **safety reporting** done for this study? Why is it relevant or not relevant for this study? Are there any **common safety issues** for this study? How do you know what they are?

Having discussed the phases of research, what do these study titles tell you about:-

A. The study phase
B. The study population i.e. disease state, number etc.
C. Type of study i.e.-RCT, observational
D. Study drug or intervention-if any
E. Estimated length of study participation
(There may not be an answer for each)

Example	A randomised, double-blind, parallel group, placebo controlled, phase II study to investigate the safety and efficacy of a novel anionic exchange compound (X) for treatment of hyperphosphataemia in patients on haemodialysis.	a. Phase II b. Patients with on-going disease & symptoms

		c. RCT, double-blind
		d. X versus placebo
		e. 1-3 months
1.	A 12-week, open label, multicentre, titration study, with a 9-month maintenance treatment extension, to demonstrate efficacy of X compared to Y in lowering serum phosphate levels in Chronic Kidney Disease patients	a.
		b.
		c.
		d.
		e.
2.	A phase III, Open-label Comparator Controlled Parallel Group Study to Assess the Efficacy & Safety of X for Reduction of GI Phosphate Absorption & Maintenance of Control of Serum Phosphate in Chronic Renal Failure Patients Receiving Haemodialysis	a.
		b.
		c.
		d.
		e.
3.	A phase I study to compare the safety and immunogenicity of candidate tuberculosis (TB) vaccine X administered by the intramuscular route and the intradermal route	a.
		b.
		c.
		d.
		e.
4.	A randomised, controlled, open-label, multi-centre, parallel-group study to compare the efficacy and safety of X with that of Y administered IV at extended dosing intervals for the maintenance treatment of anaemia in patients with Chronic Kidney Disease	a.
		b.
		c.
		d.
		e.
5.	The pharmacokinetics and tolerability assessment of IV infusion of X in adult patients with chronic impaired renal function	a.
		b.
		c.
		d.
		e.
6.	A randomised, cross-over study to demonstrate equivalence of X Carbonate	a.
		b.

	Powder vs X Hydrochloride Tablets dosed three per day in with Chronic Kidney Disease	c.
		d.
		e.
7.	A double-blind, randomised, multicentre, phase IIIb, parallel-group study to compare the effects of X (10mg) with placebo on assessment of survival and cardiovascular events when given to subjects with end-stage renal failure on chronic haemodialysis treatment (AURORA)	a.
		b.
		c.
		d.
		e.
8.	Randomised, Double-Blind, Equivalence Study of the efficacy of X Manufactured by Serum-Free Bioreactor technology and Y Manufactured by Roller-Bottle Technology for the Treatment of Anaemia in Patients with Chronic Kidney Disease (OPUS)	a.
		b.
		c.
		d.
		e.
9.	A Double-Blind, Randomised, Placebo-Controlled, Multicentre study with an open-label dose titration phase to assess the safety and efficacy of an oral calcimimetic agent (X) in secondary hyperparathyroidism of end-stage renal disease (ESRD) subjects	a.
		b.
		c.
		d.
		e.
10.	A Phase IV Study of X 0.004% in Subjects with X-induced Iris Pigmentation Changes	a.
		b.
		c.
		d.
		e.

Student Placement – Quiz

To be completed at the end of your placement

What is research?

What types of research are there?

Can you name the phases of research and explain these?

Can you explain the term randomisation?

Who can be a participant in research?

Can you participate in more than one clinical trial or study?

What training should be completed every 3 years by staff working in research?

What type of approvals need to be in place before research can be carried out?

What is a delegation log and who is responsible for delegating the duties?

Who should assess eligibility of a patient participating in a CTIMP?

What do the following acronyms mean? Add any more you come across

AE			IMP	
SAE			CTIMP	
SUSAR			CRF	
GCP			CRO	
R&D			R&I	
VIC			GCP	
CTA			ADR	

REC			**SAR**	
CI			**PI**	
CRF			**MHRA**	
NRES			**PIL**	
PIS			**SOP**	

Checklist for the student Nurses:

1.	Induction- R&I /CRF/Rosemere	Named Assessor or Supervisor
2.	Allocation of Computer desks	Named Assessor or Supervisor
3.	Lockers	Liaise with Matthew Johns
4.	DSE Assessment	Liaise with Jane Silverwood
5.	Access to MS Teams & CRF Manager	Liaise with Andy Robinson
6.	Access to Q- Pulse	Liaise with Rebecca/ Kina
7.	Arrange dates for initial/ intermediate & final sign off discussions	Assessors – with conjunction of supervisors feedback
8.	Arrange weekly placements	Liaise with speciality teams
9.	Delegation of Tasks	Please refer Student handbook and students objectives
10	Updating student Task Spreadsheet on MS Teams.	Any of the Research Staff can add an interesting activity that will benefit the student
11.	Sign off Weekly Timesheet on PARE	Assessors/Supervisors
12.	Updating the Student Board	LEM- Sonia Raj

Opportunities:

Pharmacy	Liaise with Jean Kilroy/Louise Hough or Samantha Eccles
Pathology	Liaise with Kate Ashton
Radiotherapy	Liaise with Steph whom to contact
Rapid Access Team	Liaise with Heather Rebecca/Nita
LSCFT	Liaise with Gill
Jacqui Twamley- PPI/Projects	Liaise with JT
CTSO	Liaise with CTSO Team
Clinical Academic Facility	Liaise with Phillipa Olive
BLS/ANTT/BM/ECG Training etc	Liaise with training Cascaders

Student Evaluation Form

We are keen to hear your feedback from your spoke placement. It is important for us to ensure that for future students the content is of interest and relevant for all students. We will review all the feedback and consider these in preparation and planning of future placements

1. What was your overall impression of the placement (please tick one box)?

Excellent	Good	Satisfactory	Below average	Poor

2. Was each learning outcome achieved?

Learning Outcome	Achieved	Partially Achieved	Not Achieved	Comments
Principles / Aspects of Research				
Communication				
Record Keeping				
Benefits of Research				

3. Was the content of the additional learning and quiz at the right level for you?

	Too complex	A bit too complex	About right	A bit simple	Far too simple
Additional learning					
Quiz					

4. Were there enough opportunities for discussion? Yes / No

5. Would you recommend this placement to others? Yes / No

6. What did you enjoy the most about the placement?

7. What did you enjoy least about the placement?

8. What did you learn?

9. How could the placement be improved?

10. Please add any additional comments below:

Please circle at least 3 of the words below that describe the placement

Useful	*Inspiring*	**Difficult**	Practical	***Complicated***
Fascinating	*Entertaining*	VALUABLE	**BORING**	**Waste of time**
INTERESTING	Realistic	***Enjoyable***	Stimulating	
		Exciting		*Basic*

Student Name: ……..

Date: ……

Buddy Name/s: ……..

Thank you for taking the time to complete this evaluation form