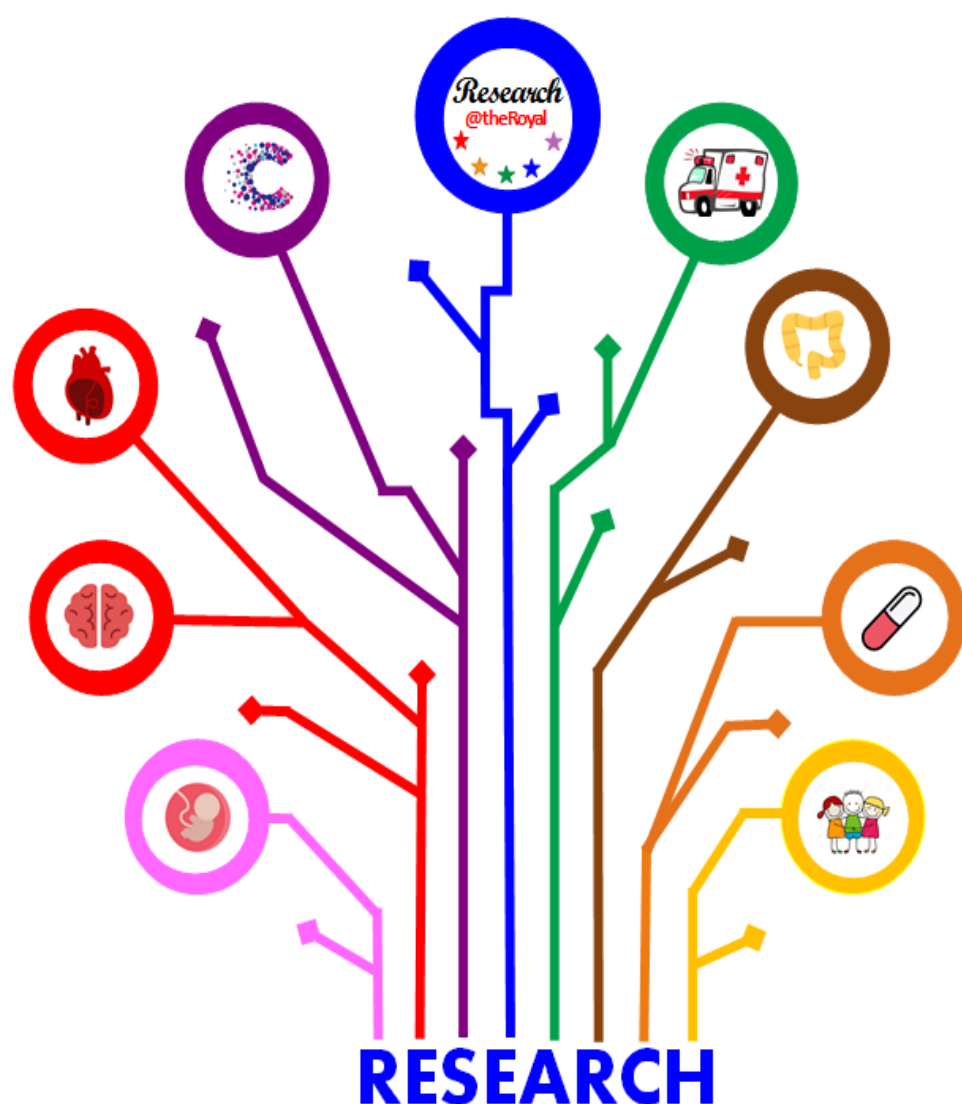


# CLINICAL RESEARCH

## STUDENT HANDBOOK



# **The Clinical Research Team**

Consists of:

**Karen Moxham** – General Manager for Research & Development

**Dr. Justin Cooke** – Medical Clinical Research Lead

**Amanda Whileman** – Matron for Research

**Tom Spencer** – Research & Development Lead

## **Research Nurses/Practitioners:**

**Emily Hall** (Cardiology/Generic)

**Rachel Gascoyne** (Stroke/Generic)

**Lesley Stevenson** (Haematology and R&D)

**Amanda Smith** (Paediatric)

**Kelly Pritchard** (Haematology/Bowel and Lung cancer)

**Vittoria Sorice** (Generic)

**Stephanie Wright** (Generic)

**Jodie Bradder** (Generic/Breast)

## **Research Midwives:**

**Mary Kelly-Baxter** (Midwifery/Generic)

## **Administration Staff:**

**Jan Woodward** (Research & Education)

**Sarah Hazeldine** (Research & Education)

**Sian Edwards** (Data Manager for Haematology)

**Nicky Ford** (Data manager for Oncology & Generic)

## **Learning Environment Manager:**

**Emma Moakes** (Adult nursing)

## **Welcome to Clinical Research**

The clinical research team would like to welcome you to your placement and we hope your time with us will be enjoyable and informative. The department is made up of two main sections, the Research and Development office (Education centre) and the Clinical Research Facility (8 Sycamore Drive). However, some of our Research staff work in clinical areas, situated within the main hospital.

## **What is Research?**

Healthcare is evolving all the time and one of the main reasons for change and improvement is the information we obtain from research. There are many questions about health, illness and the effects of treatments which have not yet been answered. Research seeks to answer these questions but also helps improve practice, building on foundations of previous research. The process of taking part in research helps to develop evidence to inform and underpin health and social care policy, with the aim of continuously improving services and treatments for patients. This improvement may take the form of something new and innovative, but it may also be as simple as putting a stop to outdated practices proven to no longer be beneficial. There are many types and methods of research.

Any research activity within the NHS is subject to the UK Framework Policy for Health and Social Care Research which sets standards for the research process and formalises the responsibilities of all those involved. The policy has only recently substituted the 4 Research Governance Frameworks, but as the RGF it states that

research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. If the study we are considering is also involving Investigational Medicinal Products we have to consider the Medicines For Human Use regulations of 2004 which is enforced by the MHRA. Also any research undertaken is also subject to the standards laid out in Good Clinical Practice (GCP) which is defined as “an international, ethical, scientific quality standard for the design, conduct and recording of research involving humans”. The UK & Europe have now a legal obligation for any participants in medicinal trials to be treated in accordance with GCP. GCP has 14 core principles arose from the Declaration of Helsinki in 1962.

At Chesterfield Royal Hospital NHS Foundation Trust we believe that participation in research is an integral part of our mission to deliver quality health care to our local community. As a hospital our involvement in research gives our patients extra choices, choices they may not otherwise have had. It gives the opportunity to help shape practice for the future, the choice to help answer long standing medical questions, the choice to help in developing new treatments that are potentially more effective or have fewer side effects, and the choice of trying an alternative treatment that may otherwise not have been available to them. Although not all participants will benefit directly from taking part in research studies, they will in some measure be contributing positively to future developments in healthcare.

Please take time to consider the below image illustrating the different phases of Research:



## **Research Activity at Chesterfield Royal Hospital NHS Foundation Trust**

The Chesterfield Royal Hospital NHS Foundation Trust conducts a variety of research studies across numerous topic areas. We participate in many studies which involve patients having some form of intervention. This may be a new drug or a new device such as an inhaler for patients with asthma. It could be a psychological therapy or a form of education about a patient's condition. Interventional studies are often the studies that require more patient time and involvement, with frequent appointments at the research department as patients need regular monitoring, particularly when involved in drug trials. Some patients involved in interventional studies comparing chemotherapy regimens spend extensive time in hospital, and can be in-patients for at least a month for just one cycle of their treatment.

We also conduct many non-interventional studies. An example of this would be a study giving patients a series of questionnaires about their experience while an inpatient; it may be a statistical analysis or an observational study. The main point with these studies is that the patient does not receive any additional therapy. The researcher may gather information from a patient or staff member or sometimes just as

a phone contact, but the information would be purely observational. These studies are less likely to require visits to the research department. By doing both interventional and non-interventional studies we are able to contribute to research involving frontline treatments but we are also able to be involved in research that aims to improve ways of working within NHS hospitals, thus enabling patients to have a more positive experience when accessing the NHS.

**The research department works closely with many clinical areas across the hospital. Areas with the largest amount of research activity are:**

**Cancer** – The hospital works closely with the North Trent Cancer Research\_Network and is involved in trials researching breast cancer, lung cancer, and cancer of the bowel, upper gastrointestinal tract cancers and haematological (blood) cancer. These are largely interventional and may involve a new medication or chemotherapy regime. We work very closely with ward staff and specialist Nurses. These patients are usually seen by us in the main hospital.

**Gastroenterology** – Gastroenterology is a vastly expanding area within research at Chesterfield, largely due to the interest of the gastroenterology consultants. We participate in trials involving ulcerative colitis & Crohns disease, hepatitis, irritable bowel disease and Barrett's oesophagus.

**Cardiology** – Dr Cooke is one of our consultant cardiologists and is the cardiovascular lead for the Trent CLRN. He is involved in many studies involving acute coronary syndrome (heart attacks and unstable angina), testing new drugs in response to cardiac events. We have conducted studies in AF (atrial fibrillation) and heart failure, working closely with the heart failure specialist nurses.

**Stroke** – We work closely with the TIA outpatient clinic and Eastwood ward (Stroke Unit) and we have a large number of studies that cover this area.

**Paediatrics and obstetrics** – The research department has a paediatric nurse and a midwife. Paediatric research is steadily growing at Chesterfield, with support from the Medicines for Children Research Network. Our paediatric nurse is involved in trials including cystic fibrosis, wheezy children, flu and childhood nephrotic syndrome. She also is responsible for any research studies on the Neonatal Unit. Our midwife works on trials concerned with the health of the pregnant mother, as well as trials involving newborn babies. Both paediatric and obstetric staff work closely in caring for newborns that may be enrolled on a clinical trial.

There are many other areas involved in research throughout the hospital including surgery, orthopaedics, orthodontics, urology, neurology, chest medicine, rheumatology, palliative care, education, critical care, gynaecology, ophthalmology, emergency care, dermatology and a variety of academic projects. This is constantly expanding with the Trust willing to consider research projects from any speciality, provided that it has the infrastructure available to successfully run these studies.

Taking part in research at CRHFT is hugely variable on time and involvement depending on the study in which a person takes part. The research department is a huge asset to the hospital as it places the hospital and its patients at the forefront of leading research, be it on a national or global scale. It means that our patients no longer have to travel to teaching hospitals in order to participate in research. We have a comfortable, custom made department geared to increasing and maintaining a research culture in North Derbyshire.



## Student Nurse Experience in clinical Research

**AIM:** To gain an insight into research nursing, the varying types of research undertaken in the district general and the ethics that govern research

### **Learning outcomes:**

During the placement the student will:

- Spend time with as many of the team members as possible in specific speciality areas to gain an insight into how differently each study is carried out and what it entails for the patients and the research nurses.
- Gain a basic understanding of the principles of 'International Conference on Harmonisation- Good Clinical Practice'
- Observe the screening process, recruitment to research studies and subsequent patient visits.
- Have a basic understanding of the Research infrastructure.



- Understand the difference between audit and research

### Timetable\*

DAY	A.M	P.M
MONDAY	<ul style="list-style-type: none"> <li>• <b>Vittoria</b> LEM Pre-assessment</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Vittoria</b> Intro to Research and Generic Studies</li> </ul>
TUESDAY	<ul style="list-style-type: none"> <li>• <b>Mary</b> Midwifery</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Jodie</b> Generic/Breast Research</li> </ul>
WEDNESDAY	<ul style="list-style-type: none"> <li>• <b>Lesley/Kelly</b> Haematology Research</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Lesley/Kelly</b> Haematology Research</li> </ul>
THURSDAY	<ul style="list-style-type: none"> <li>• <b>Rachel</b> Stroke Research</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Amanda S.</b> Paediatric</li> </ul>

<b>FRIDAY</b>	<ul style="list-style-type: none"> <li>• <b>Amanda W./ Emily</b> <b>Cardiology</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Vittoria</b> <b>LEM</b> <b>Quiz</b> <b>Evaluation</b></li> </ul>
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\*Please note this is just a generic timetable. Every student has a personalised one.

## Useful links

### What is research?

- UK Framework Policy for Health and Social Care  
<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

### Research activity at Chesterfield Royal Hospital NHS FT

- East Midlands Clinical research network  
[www.nihr.ac.uk/nihr-in-your-area](http://www.nihr.ac.uk/nihr-in-your-area)

### Taking part in research

- Department of Health  
<https://www.gov.uk/government/organisations/department-of-health>
- Medicines and healthcare regulatory authority (MHRA)  
[www.mhra.gov.uk](http://www.mhra.gov.uk)
- Good Clinical Practice:  
<http://ichgcp.org>

### Introduction to CLRN

- National institute for health research  
[www.nihr.ac.uk](http://www.nihr.ac.uk)

Complete at the beginning of placement (ideally on the first day)

**Department Of Clinical Research**  
**Pre-assessment Form**

Our Department of Clinical Research Welcomes you today. This form is used to quickly acknowledge that we are here to provide you with support and training during your time with us and also to aid your personal development as a professional. Please take time to think whilst filling out this form, as it will provide a benchmark for your progress throughout your time here.

Answer all the statements according to the following 1 to 5 scale:

**1 = Strongly Disagree (SD), 2 = Disagree (D), 3 = Neutral (N), 4 = Agree (A) and 5 = Strongly Agree (SA)**

I have a core knowledge and basic understanding of key concepts of Clinical Research.	1	2	3	4	5
I'm aware of the differences among Research Methods	1	2	3	4	5
I know what a Research Protocol is	1	2	3	4	5
I can define what an AUDIT is	1	2	3	4	5
I'm aware of the meaning and importance of Evidence Based Practise and how Clinical Research relates to it	1	2	3	4	5

Please take time to reflect on the following topics/questions and provide a brief definition/answer for each one.

1. Clinical Research

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2. Evidence Based Practise

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3. What is the Role of a Research Nurse?

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4. Aims and Objectives I'd like to meet during my time in this Department:

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Complete at the end of placement (ideally on the last day)

**Department Of Clinical Research**  
**Summative Assessment**

Please take time to reflect on the following topics/questions and provide a brief definition/answer for each one.

1. What is G.C.P.?

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2. What's the difference between Audit and Research?

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3. A Research question is:

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4. A Research Protocol is:

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5. Do we obtain informed consent? Which characteristics it has to have to be considered valid?

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6. What are the benefits of Clinical Research for the NHS and who receives them?

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7. What are the Research nurse main Priorities?

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8. Define the following Acronyms:

- AE & SAE:

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- NIHR:

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- CRF

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**Department of Clinical Research**  
**Student's Feedback Form**

**Please take a few minutes to complete this evaluation form at the end of your placement. Your objective feedback would be greatly appreciated.**

Answer all the statements according to the following 1 to 5 scale:

**1 = Strongly Disagree (SD), 2 = Disagree (D), 3 = Neutral (N), 4 = Agree (A) and 5 = Strongly Agree (SA)**

**Circle a number** between 1 and 5 to indicate which response best fits your experience in our Department.

		SD	D	N	A	SA
<b>Establishing Effective Working Relationship / Creating An Environment For Learning</b>						
	Appropriate Welcome and Orientation to the Department was provided	1	2	3	4	5
	Ongoing and constructive support was given at all times	1	2	3	4	5
	An effective professional and inter-professional relationship was built to support learning	1	2	3	4	5
	I felt supported during my time in the department	1	2	3	4	5
<b>Facilitation And Evaluation Of Learning / Creating An Environment For Learning</b>						
	There was a clear introduction to Research	1	2	3	4	5
	The aims and objectives established in the pre-assessment have been met	1	2	3	4	5
	The time spent in the department was well organised for me to experience all different areas of interest	1	2	3	4	5
	The Student Handbook Pathway was very helpful	1	2	3	4	5

	The Summative Assessment was of reasonable length and content	1	2	3	4	5
<b>Assessment And Accountability / Leadership</b>						
	Constructive feedbacks were always provided to me	1	2	3	4	5
	I felt comfortable asking questions and expressing my opinions	1	2	3	4	5
	I felt prepared to complete the Summative assessment at the end of my learning experience	1	2	3	4	5
	The Pre-assessment form helped me focus on the learning opportunities of this area	1	2	3	4	5
	I was involved in many and various opportunistic learning experiences	1	2	3	4	5
	The good outcome of my experience in the Department was prioritised at all times	1	2	3	4	5
<b>Context Of Practise / Evidence Based Practise</b>						
	I have now a better understanding of how Clinical Research supports practise development and the importance it has	1	2	3	4	5
	Professional Boundaries were maintained at all times	1	2	3	4	5

I **liked** the following things:

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The pathway might be **improved** by:

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**THANK YOU FOR YOUR TIME!**