Welcome...

to the second edition of the Sheffield Clinical Research Facility (CRF) newsletter.

This month, get an insight into the role of the Clinical Research Data Co-ordinator and see the specialist bone imaging equipment at the Northern General Hospital.

We also feature an interview with Alison Mortimer, the new Lead Nurse for Research and Development and give an overview of how to access CRF support.

Recent CRF Successes

- **Highest UK recruiter** for a large, multicentre urology study
- **Met 150 percent of target** (recruited 15, original target 10) for a commercial cardiology project
- **Only site in UK** to recruit to a multicentre endocrinology study
- **Met 140 percent of target** for an NIHR renal study
- **Highest recruitment retainer** among the centres for a complex respiratory medicine trial
- **First UK site** to get R&D authorisation, first UK patient recruited and first UK site to recruit to target in a global haemophilia trial
- **Recruited four times the original target** and recruitment ongoing for a renal portfolio study

Positive feedback continues...

- *We are very impressed with how dedicated and professional the team are* - Comment from a pharmaceutical company for a highly complex surgical study
- *The CRF have been very helpful and great to work with* - Principal Investigator feedback
- *The CRF and nurses have been invaluable in getting my study completed. The nurses were very dedicated and I am grateful for your support* - Principal Investigator feedback

Contact Us:
For further information about the CRF, please contact Karen French, CRF Manager, E: karen.french@sth.nhs.uk  T: 0114 2713339

The National Institute for Health Research Sheffield Clinical Research Facility is a partnership between the Sheffield Teaching Hospitals NHS Foundation Trust and University of Sheffield.
The CRF currently has 123 open recruiting studies. These cover a broad spectrum of designs including phase II, phase III, phase IV, experimental medicine, epidemiological, observational and healthy volunteer.

CRF wins conference accolade

Sheffield’s CRF has been recognised for its efforts in creating a fast and effective process for the set-up of research projects.

The CRF was ‘Winner of the Popular Vote’ at the UK Clinical Research Facilities 8th Annual Conference, held at Trinity Conference Dublin in July. Its submission beat off 75 other entries.

The CRF Senior Research Co-ordinator team consulted with Directorate and CRO colleagues to agree a simple and effective approach to setting up and co-ordinating research projects utilising the CRF.

Karen French, CRF Manager, said: “It’s great news that our CRF won this poster award. The project has already shown results, with a new streamlined process leading to faster and more efficient set-up.”

Did you know..?
The CRF has a regular programme of Quality Assurance (QA) to ensure the safety of the participants and assurance that research being conducted in the CRF is of the highest possible standard.

Regular, dedicated QA sessions are scheduled to take place in the CRF every Friday morning. The team undertake formal review of four types of QA:

- Site File Review
- Source Data Verification
- Protocol Compliance
- Informed Consent

Please contact Senior Research Co-ordinator Clare Riddle (clare.riddle@sth.nhs.uk) for further information.

Get in touch
For more information about how the CRF could help you in your research, contact Karen French, CRF Manager
☎ RHH: 0114 271 3339
☎ NGH: 0114 271 5779
✉: karen.french@sth.nhs.uk

Roles in Research: Clinical Research Data Co-ordinator

The role of the Clinical Research Data Co-ordinator (CRDC) within the CRF was developed in January 2011. This new role was set up to assist in the delivery of quality care and service to research participants and researchers within the CRF.

The CRDC role also assists the nursing team to facilitate and enhance the work of the CRF: each CRF nursing team has an assigned CDRC, who provides administrative support for the clinical team.

The responsibilities and tasks of the CRDCs continue to grow as the role develops.

Day-to-day activities include:
- producing and maintaining site files
- designing source data worksheets
- collecting and entering data into paper or electronic case report forms
- maintaining the research section of the patient’s medical records
- writing to GPs to inform them of the participants taking part in the trial
- responding to data queries
- recording team activity data and recruitment information
- preparing the documentation for monitoring visits by the sponsor, including the source data, patient notes and site files
- archiving at the end of a study.

CRF Education and Development Programme

The CRF Education and Development sessions are available to all researchers within STH. Upcoming sessions include:

- Research Finance (18th January at RHH CRF)
- Informed Consent (8th February at NGH CRF)

For more details about these and other training sessions please contact Philippa Ledger (Email: philippa.ledger@sth.nhs.uk or Telephone: 0114 2715779)

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Five minutes with the Lead Nurse for Research and Development

Alison Mortimer is the new Lead Nurse for Research and Development at Sheffield Teaching Hospitals (STH) NHS Foundation Trust.

Describe your role in one sentence.
Provide leadership and strategic vision for research nurses within STH and across South Yorkshire.

Why did you want to work in healthcare?
I started in nursing as I wanted to help people less fortunate than myself. Although the focus of my role has shifted, I am still passionate about nursing as a caring profession. I don’t have much direct patient contact any more, which I do find sad but hope that I still impact on the patient experience by ensuring that research is conducted to a high standard and that where possible we are providing patients access to research studies that could have a positive impact on their lives and other patients in the future.

What is your number one priority for next year?
To implement a strategy to increase research awareness within the healthcare profession (non-medics) within the Trust. I want to move away from the view that research is special or even elitist. All health care professionals should be involved in research and it is important that we create the opportunities for everyone to be involved.

How has research nursing changed since you began in this field?
It has changed a lot. There is a much more clearly defined pathway into research nursing and the field continues to grow. STH was one of the first to have a central database of research nurses working in the Trust and it has become increasingly robust in clinical research and clinical governance.

Are there any new or upcoming initiatives in research nursing?
The development of Academic Health Science Networks will impact on research and nursing profession. This is an exciting time in research nursing with work ongoing locally and nationally to promote and acknowledge the contribution of research nurses to the research agenda. We are developing our strategy locally to break down the barriers and to integrate into clinical practice as much as possible.

How do you want to see the sector change in the next five years?
I want to see a "research savvy" workforce and the research agenda being driven forward in training of research nurses and allied health professionals. I believe in the benefit of research for patients and staff. There is also a huge potential cost saving to the NHS, so it is a win-win situation.

Complete these sentences:

I do what I do because... I believe in it and the benefits it brings. I enjoy enabling others to drive the research agenda forward.

My nurse training taught me that ... we are all human and it is important to treat everybody the same.

What are you most excited about in your new role? The opportunities and the potential impact of change.

What is the best part of your job? Meeting lots of people and no two days being the same!

What is the worst part of your job? There is never enough time in a day!

Alison Mortimer, Lead Nurse R&D
“I want to move away from the view that research is special or even elitist”.

Publication highlight
Roles of neutrophils in the regulation of the extent of human inflammation through delivery of IL-1 and clearance of chemokines.

J Leukoc Biol, Aug 17, 2012 [Epub ahead of print]

*Dr Alex Basran, Clinical Fellow and Prof Ian Sabroe, Respiratory Physician; Directorate of Respiratory Medicine

Publications generated from CRF studies since 2006:

Improving healthcare for the benefit of patients
www.sheffield.crf.nihr.ac.uk
How The CRF Can Support Your Research Project

What support does the CRF offer?

The Sheffield CRF is a resource available to all clinical researchers within Sheffield providing a specialist environment for the conduct of high quality research.

The CRF can provide support in a variety of ways:
- setting up the project
- building a research team, including research nurses, support workers, data co-ordinators
- support entering your data
- provide project management for complex studies
- somewhere to conduct study visits
- overnight stays.

Contacting the CRF

Researchers are encouraged to make early contact with the CRF. Dedicated members of staff will meet with you to discuss study requirements and identify how best the project can be facilitated. This is known as a CRF feasibility meeting.

To arrange a feasibility review meeting, please contact Rachel Whelpton, CRF Service Coordinator via rachel.whelpton@sth.nhs.uk or 0114 226 5860

In preparation for the meeting, please provide a copy of the study protocol.

What happens next?

When your study has been reviewed you will be notified of the Board’s decision via email by Professor Ian Sabroe, Chair of SAB.

A PI/CRF Responsibilities document is then signed by both parties, outlining the support the CRF will provide and the responsibilities of the Principal Investigator.

Review by the CRF Scientific Advisory Board

All research undertaken within the CRF is reviewed by the Scientific Advisory Board (SAB), who meet monthly. The composition of the SAB is broad-based to optimise the assessment of applications from diverse disciplines.

The SAB look at the scientific merit of studies and the activity profile of the CRF as a whole, to ensure prioritisation and balance between pilot, grant funded and commercial studies. If the study protocol has not already had a peer or scientific review undertaken, the CRF SAB can also provide full Independent Scientific Review.

Investigators are usually asked to attend the meeting to give a brief overview of the project and to clarify any issues raised by the Board, ensuring a fair and efficient review process.

Further information and support

You can find further information about the CRF on our newly relaunched website:

www.sheffield.crf.nihr.ac.uk
Your research team

Research governance support
The CRF is pleased to offer researchers support navigating the complex legislative environment and standards of research governance and requirements for research project authorisation.

The following support is available through the CRF:
♦ advice on writing research materials including protocols, patient information sheets and consent forms
♦ support obtaining Ethics, MHRA and R&D Approval
♦ obtain research costs from support services
♦ help setting up a master/site file
♦ ongoing help about making changes to the research
♦ advice on good practice and ethical research.

Nursing support
The CRF has nursing teams across both sites, each with expertise in different disease areas. Your CRF nurse:
♦ has a thorough understanding of the research process and in-depth knowledge of the study protocol
♦ will be an advocate for the patient, ensuring their safety and supporting the participant throughout the study
♦ has links with other researchers and members of the multidisciplinary team, raising awareness of the study to maximise referrals and recruitment
♦ coordinates the day-to-day management of a study, liaising with many different departments including pharmacy, radiology, laboratory medicine and finance
♦ will assist with the prompt reporting of adverse events.

The CRF is a ‘one stop shop’ for research support

Data Entry Support
CRF Data Co-ordinator support can be used alongside the nursing team or as a separate service:
♦ provide data entry support
♦ producing and maintaining site files
♦ designing source data worksheets
♦ maintaining the research section of the patient’s medical records.

Other specialist support
Room only, clinical support workers for phlebotomy and blood sample processing, overnight stays.

All types of studies can be supported including (but not limited to):
♦ Phase I through to Phase IV studies
♦ Observational studies
♦ Comparator studies
♦ Experimental Medicine
Specialist Bone Imaging Equipment in the CRF

Our outstanding imaging facilities housed in the CRF at the Northern General Hospital allow us to use a variety of densitometry techniques to study bone and the effects musculoskeletal diseases.

**Discovery A DXA scanner**

Dual energy x-ray absorptiometry (or DXA) of the whole body, spine, hip and wrist is performed using a Discovery A (Hologic Inc.) scanner to provide measures of bone mineral density.

Whole body images can be examined further to gain body composition information including fat distribution and body composition.

**DXA-based vertebral fracture assessment (VFA)**

High definition images of the upper (thoracic) and lower (lumber) spine can be acquired using a technique known as DXA-based vertebral fracture assessment, or VFA. When used alongside DXA bone mineral density measurements, VFA can improve the prediction of fracture risk and is a valuable tool for detecting new and existing vertebral fractures.

**XtremeCT**

A more recent addition to our facilities, the XtremeCT device (Scanco Medical AG) is used to acquire 3D images of the wrist and lower leg, using high resolution peripheral quantitative computed tomography (HR-pQCT). This state-of-the-art imaging device is one of only three in the UK and allows the in-depth study of the micro-architectural properties of bone including trabecular number, separation and thickness. The images acquired can be analysed further to reveal additional information about cortical bone such as porosity, and bone strength can be determined by applying micro-finite element mathematical modelling techniques to each image slice.
The Academic Unit of Bone Metabolism (AUBM), led by Professor Richard Eastell, is currently investigating the effect of osteoporosis treatments on bone density, bone micro-architecture and fracture. One study has been designed to assess the effect of anabolic bone treatment, teriparatide (Forsteo), on bone structure and strength. A number of imaging techniques are being used to study the changes in bone with treatment duration, including DXA, VFA, HR-pQCT.

Collaborations with Medical Imaging and Medical Physics
The AUBM has worked closely with radiology departments within STH on imaging in projects. A recent collaboration with the Department of Medical Imaging and Medical Physics (MIMP) has led to the introduction of high resolution quantitative computed tomography (or HR-QCT) of the spine. This imaging technique is being used to assess alteration in bone micro-architecture in the spine following teriparatide treatment.

Bone densitometry techniques are also being used to study the effects of obesity on bone structure and strength. The interactions between fracture risk and cardiovascular risk are being examined using DXA, VFA and HR-pQCT. Again working closely with MIMP at STH, a means of measuring subcutaneous and visceral fat during abdominal CT has been developed.

Future work
The AUBM is also working closely with the Sheffield Children’s Hospital. Projects include:
- The effect of obesity on trabecular and cortical bone structure and strength in 8 to 30 year olds
- The development of Magnetic Resonance Imaging (MRI) sequences for the analysis and quantification of bone and bone marrow in children
- The acceptability and efficacy of intra-gastric balloons for the treatment of severe adolescent obesity

For enquiries into the use of our imaging services for your research studies, please contact Dr Margaret Paggiosi (Academic Unit of Bone Metabolism) Email: m.a.paggiosi@sheffield.ac.uk.