Research and Development

Edition 18

Cardiff and Vale UHB April 2017 Newsletter

Staff updates within the R&D department

R&D welcomes Rachel Norman who started on 16th January 2017 who will be the new Clinical Trial Facilitator within the R&D Department. Congratulations also to Felicity Morris who has now left the R&D department to pursue another role. We wish her success in her new job.

Congratulations to Muktha Koppula on her appointment as full-time R&D administration support.

Our Commercial/Contracts Manager Claire Price has now left the R&D office: we wish her every success for the future.

Research and Development Twitter Account

The Research and Development office Twitter account is now up to 303 followers.

Join in and follow us on Twitter www.twitter.com/@CAV_Research and get the latest R&D news and learn about new research opportunities that you can be a part of.

Updated documents from January 2017 Research Governance Group

- ISR-RP-011 Directorate R&D Lead authorisation for research studies

REGISTER NOW!

13th June 2017 R&D Conference

This year's annual R&D conference will be held at UHW, Lecture theatre 4 and will be opened by the UHB's Medical Director, Dr Graham Shortland. The morning of 13th June will be dedicated to presentations on Innovations and Research & Development by the UHB's directorates. This will give delegates an insight into research within the UHB. We will end the day with Clinical board presentations. Cardiff and Vale UHB is proud of its record of research achievements and of its contribution to developing health care and bringing state-of-the-art therapies to Wales.

The event will be of benefit to anyone involved in planning, managing or delivering R&D. Delegates will be Cardiff and Vale University Health Board employees, other NHS organisations and universities.

If you would like to attend the conference please contact Jemma.cross@wales.nhs.uk to book a place or enter the poster competition.

Do you need support to deliver your Research Study?

Cardiff and Vale UHB is changing its system for accessing support to deliver research studies. From 1st January 2017, all requests for support must be made in writing using an application form. The form can be found on the CAV website on the Clinical Research Facility (CRF) and Research and Development (R&D) pages.

Once the forms have been completed they must be returned to: ResearchDelivery.CAV@wales.nhs.uk.

Criteria for awarding support are outlined in the documents on the CRF & R&D pages and there is a flowchart of the process provided for information.

http://nww.cardiffandvale.wales.nhs.uk/portal/page?_pageid=253,4301454,253_4301467&_dad=portal&_schema=PORTAL

http://nww.cardiffandvale.wales.nhs.uk/portal/page?_pageid=253,120595074,253_120595078&_dad=portal&_schema=PORTAL

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

Research project agreement information

Any study agreements received by researchers that are directly associated with any research projects must go through the R&D office contracts team for signatures and approvals.
Study agreements must not be reviewed or signed off within the study team. They must all be reviewed by the R&D contracts team and signed off by the R&D director/Medical Director.

Cardiff and Vale UHB no longer offers a Patient Advice and Liaison Service (PALS)

Useful information when creating a Participant Information Sheet

Like most Health Boards in Wales, Cardiff and Vale UHB no longer offer a Patient Advice and Liaison Service (PALS). If you are creating a Participant Information Sheet (PIS) for use within Cardiff and Vale UHB it is no longer acceptable for your PIS to direct potential participants to PALS.

Also, in order to avoid any unnecessary delays, if you are considering being involved in a study with an external Sponsor it is advisable to inform the Sponsor about this before the study is submitted for review.

An example of suggested wording for use **alongside** the negligent/non negligent harm paragraphs in the '**What if there is a problem?**' section can be found below:

If you have any concerns about any aspect of this trial, you should speak to your trial doctor who will do their best to answer your questions. The telephone number of your trial doctor is provided on page ..... of this Information Sheet.

If you remain unhappy, still have concerns or wish to complain, you can do this via the NHS Concerns or Complaints Procedure.

Email: concerns@wales.nhs.uk
Tel: 029 2074 4095 or 029 2074 3301
Further information and details about the complaints procedure are available on Cardiff and Vale UHB Website or via a member of staff.

NB – the above contact details are current on the date of publishing. Please remember to check these and any other contact details before they are provided.

Research Design & Conduct Service South East Wales
Gwasanaeth Cynllunio a Chynnal Ymchwil De-ddwyrain Cymru

Research Design and Conduct Service (RDCS) - Developing A Successful Research Idea

22 May 2017 | 09:00 - 17:00 |
Glamorgan Building, Cardiff University | £0.00

The Research Design and Conduct Service (RDCS) South East Wales, based in the Centre for Trials Research at Cardiff University, will be hosting a one-day "Ideas!" event (free of charge) on Monday 22nd May 2017. This will take place in the Glamorgan Building on the Cathays campus at Cardiff University.

The All Wales Research Design and Conduct Service (RDCS) supports staff working within the National Health Service and social care to develop high quality research funding proposals.
The event is aimed at those in the health and social care sector who have early stage ideas for research projects. The day will begin with some short presentations about the general process of taking a research idea and growing it into a funded project.

Following that will be an open forum for discussion and development of ideas in small groups, facilitated by RDCS consultants.

Places are free of charge but limited to ensure maximum amount of one-to-one support time. Book now: https://cardiff.onlinesurveys. ac.uk/rdcs-ideas-event-booking-22nd-may

To find out more about the Research Design and Conduct Service (RDCS) South East Wales or to request support, please visit http://www.cardiff.ac.uk/centre-for-trials-research/research/research-design-and-conduct-service

If you have any questions about the event or how the RDCS service could help you, please email rdcs@cardiff.ac.uk

The Research Design and Conduct Service (RDCS) is funded by Health and Care Research Wales

Cardiff & Vale UHB Research & Development Equipment Bid

Cardiff & Vale UHB R&D ran a scheme for equipment to enhance the support provided to deliver high quality research within the NHS organisation and to overcome 'blocks' that exist in the provision of clinical service support.

The bids outlined below have been successful:

Directorate	Item
Clinical Research Facility	AccuVein Device Plus Stand
Clinical Research Facility	3xLED Clocks
Clinical Research Facility	Electric Heat Pack
Dental	Asiga Pico 2 39 405nm 3D printer unit with UV light curing unit, biocompatible dental resins, resin trays and 5 year warrantee.
Critical Care	Refrigerated sample centrifuge
Critical Care	Minus 80 thermal label printer
Integrated Medicine	Networked research laptop: Toshiba laptop 15.5 TOSSPE-836.
Perioperative	Colour printer HP CP5225dn Colour A3 LaserJet Professional Printer with extras
Acute Child Health	Vortex mixer and heads
Acute Child Health	Pharmacy Fridge
Acute Child Health	Calibrated Digital Fridge/ Freezer Thermometer (x4)
Acute Child Health	Desktop "super" Computer
CD&T	HLPC column with guard column and filters
CD&T	3 x Huntleigh Ankle & Toe Pressure Kit 3 x 5MHz Probe 3 x Thigh cuff (free of charge)
Pharmacy	SAS Super 180 S/S Air Sampler
Pharmacy	SAS Daily Head – Contact
Neurosciences	High end PC, screen and KVM switch
Neurosciences	High end Laptop
Obs & Gynae	Weighing Scales for accurate measurement of blood loss
Therapies	Digital voice recorder Olympus VN-741PC
Therapies	Decibel sound level meter, Camcorder & Mouse
Therapies	LaptopTOSSPE-836 550.95 Cardiff & Vale Toshiba Sat Pro A50-C-20X, 15.6 inch HD/Core i5-6200U/4GB/128GB SSD
Haematology	ECG Machine MAC 3500
Haematology	IPAD x 3 for Research Nurses and admin manager to be able to upload data onto ECRF whilst with the patient
Research & Development	2x laptop notebook stone -1210

Urology Clinical Trials team in top 3 recruiters to international trial

http://www.addaspirintrial.org/

The ADD- ASPIRIN trial is an international clinical trial being managed by the Medical Research Council Clinical Trials Unit. It is a phase III, multi-centre, double-blind, placebo-controlled randomised trial with four parallel cohorts. Each of the four cohorts is tumour site-specific (breast, colorectal, gastro-oesophageal and prostate cancer). The aim of the trial is to assess whether regular aspirin use after standard therapy prevents recurrence and prolongs survival in participants with non-metastatic common solid tumours. Participants are randomly assigned to 100mg aspirin, 300mg aspirin or matched placebo.

Patients from Cardiff and Vale University Health Board can currently be recruited across 3 of the cohorts: Prostate, Colorectal and Breast.

The Urology team has been recruiting patients to the Prostate cohort since October 2015 and in the first year 17 patients were recruited. This is lower than our prediction of 2/3 patients per month. However, analysis of the figures shows that 69% of the patients screened were ineligible to enter the trial. This is a much higher proportion than expected. The main reason for ineligibility is that the patient is already taking aspirin, other anticoagulants or other non-permitted concomitant medications. Of the eligible patients we have a 35% recruitment rate, which is excellent. The team has identified that some patients have missed the recruitment window because their treatment was transferred to Velindre. It is hoped that Velindre will open to recruitment for the Prostate cohort soon in order to capture this patient group.

If you would like further information on the ADD-ASPIRIN trial please contact:

Colette Clements, Lead Urology Research Nurse
Colette.clements@wales.nhs.uk 02920 748404.

Primary Care Research Incentive Scheme (PiCRIS)

The PiCRIS funding scheme has been established in order to increase the capacity in Primary Care in Wales to support high quality research.

This funding scheme aims to engage general practices in research and help practices to access the necessary training and support required to embed research into their day-to-day work.

General practices in Wales are invited to apply for funding at one of the four levels:

PiCRIS level	Expectation of research activity	Financial award
Affiliate	There is no set target for study delivery and practices have access to all benefits except the PiCRIS financial award (see section 5 for benefits).	£0
Level 1	Practices are expected to recruit into 2 or more studies during the funding period and have access to all benefits.	£1,500
Level 2	Practices are expected to recruit into 5 or more studies during the funding period and have access to all benefits.	£4,000
Level 2 Plus	Practices are expected to recruit into 7 or more studies during the funding period and have access to all benefits.	Up to £6,000

The PiCRIS Advisory Group met on the 18th January 2017 to discuss and provide recommendations for the PiCRIS awards this year (2016/17). There were 98 applications received in total. The awards for practices in Cardiff & Vale are indicated in the table below:

Practice name	Level Awarded 2016/2017
Bishops Road Medical Centre, Cardiff	Level 1
Caerau Lane, Cardiff	Level 1
Court Road Surgery, Barry	Level 1
Cowbridge & Vale Medical Practice, Cowbridge	Level 1
Crwys Medical Centre, Cardiff	Level 1
Danescourt Surgery	Level 1
Dinas Powys Medical Centre	Level 1
Eryl Surgery, Llantwit Major	Level 1
Llwyncelyn Practice, Whitchurch, Cardiff	Level 1
Stanwell Surgery, Penarth	Level 1
Whitchurch Road Surgery	Level 1
Willowbrook Surgery, Cardiff	Level 1
Woodlands Medical Centre	Level 1
Roath Clifton Surgery, Cardiff	Level 2
Roath House Surgery, Cardiff	Level 2
Rumney Primary Care centre	Level 2
Waterfront Medical Centre, Barry	Level 2
Whitchurch Village Practice, Cardiff	Level 2
Ely Bridge Surgery, Cardiff	Level 2 Plus
Llandaff & Pentyrch Surgery, Cardiff	Level 2 Plus
Llandaff North Medical Centre, Cardiff	Level 2 Plus
Llanedeyrn Health Centre, Cardiff	Level 2 Plus
The Practice of Health, Barry	Level 2 Plus

For all funded practices, the Health and Care Research Wales Support Centre will regularly monitor:

- The number of studies a practice is participating in
- The number of patients practices have recruited into the studies
- Practices may be contacted over the course of the award period e.g. for information on participation, Good Clinical Practice (GCP) training, and on gaining Research Ready Accreditation.

Health and Care Research Wales Support Centre will also require a brief progress report during the year and an annual report at the end of the funding period.

PERIT-PD study

Uned Ymchwil Arennol Cymru
Wales Kidney Research Unit

Cardiff–led study is helping to understand infection responses in peritoneal dialysis patients.

The "Achilles' Heel" of Peritoneal Dialysis remains the susceptibility to recurrent infection with detrimental effects on the process of dialysis through direct peritoneal membrane damage, but also in more severe infection through significant morbidity and mortality.

Over the past decade there has been a shift in infection profiles towards more virulent infections and an increased prevalence of antibiotic resistance. This, together with the already unacceptable cure and relapse rates, and concomitant morbidity and mortality represent significant limitations to PD therapy.

As we approach the post-antibiotic era there is a clear need for novel therapies to fight infections by resistant strains and improve patient outcomes. If we are to limit the susceptibility to infection and the detrimental impact of prolonged inflammation on membrane longevity, we need to better understand the processes causing deleterious alterations to the peritoneal immune response.

The peritoneal cavity in PD serves as unique window to inflammatory scenarios that can be prospectively observed in vivo. It affords easy, continuous access to all relevant cellular and humoral players, and allows us to examine how treatment and infection modulate these processes. We know of no other experimental model that gives such direct insight into human immune responses in a similarly clinically relevant, convenient, non-invasive manner.

We are hoping that PERIT-PD will help understand some of those processes.

PERIT-PD started in Cardiff in September 2008, with sites around the UK joining from April 2014. There are now 23 sites all over the country helping to collect peritonitis samples.

Samples from PERIT-PD have already helped advance our understanding of infection responses in peritoneal dialysis patients. Led by Matthias Eberl in Cardiff University, researchers have shown the importance of novel types of T cells in response to infection, and in subsequent changes to the peritoneal membrane.

The study is sponsored by Cardiff University and aims to recruit 400 patients by 31/12/17. There are 63 additional patients to recruit.

For further information about PERIT-PD please go to:
http://kidneyresearchunit.wales/en/perit-pd-study.htm
or contact the study coordinator Dr Chantal Colmont (colmontcs@cf.ac.uk) or Dr Matthias Eberl (eberlm@cf.ac.uk).

Joint R+D Service for Cardiff University and CVUHB

Allison Hanbury

I have recently been appointed as the Senior Project Manager for the development of a new R+D service for all research projects involving both CU and CVUHB, a jointly funded post between CU and CVUHB.

The first phase of the project will be to conduct a feasibility study for the design and implementation of this service. This involves a review of the current service and investigation of similar services in place between NHS and academic organisations within the UK. The R+D support teams are working together to share information which will improve our understanding of the two different organisations, their processes and the external influences. The findings will be used to make recommendations for improvement.

I will join both the Research Governance Group and the Directorate Research Leads Meetings to get a full perspective of the research work taking place and the issues that both the R+D support teams and researchers face within the current system. I am meeting with clinician and academic researchers to understand their roles, research priorities and the barriers that people are facing when setting up new projects. Thank you to everyone who has given their time to meet with me and for all the open and constructive discussions, this is really helping me to form a picture of where we are now and what we can do to improve the way we work. If I have not contacted you and you would like to share your experiences with me, please send me an email: hanburya2@cardiff.ac.uk and I will gladly come along to meet with you and/or colleagues.

There is a 2 year timescale for this work, however, we know there are things that we can begin to improve immediately, so we will take a phased approach. I look forward to sharing further information and news on this project as it develops.

Findings from Annual Self-Audit for Non-Commercial CTIMPS 2016

An annual self-audit for all non-commercial CTIMPs was undertaken by the R&D office for all studies listed as open on the R&D office database. A self-audit form was issued for 94 trials. There was a satisfactory response rate of 94% (88% for 2015) and no major areas of concern were identified. The results from the audit are used to assess compliance with Good Clinical Practice, as well as to help the UHB fulfil its Research Governance responsibilities. R&D office staff selected two trials for full audit using the criteria described in the self-audit form. One full audit was conducted in November and the second in December 2016. Both full audits have been deemed closed and lessons learnt from the self and full audits are outlined below.

Change in Chief or Principal Investigator (CI or PI)

For five ongoing trials there had been a change in PI. The R&D office had not been notified and the required contractual amendments and R&D approvals were not in place at time of change (three permanent & two temporary changes). For CTIMPs a substantial amendment is required for a permanent change in CI or PI. A substantial amendment is also required to cover a temporary change of CI or PI where an absence is likely to exceed 3 months. Return of a CI or PI following a period of absence is not considered to be a substantial amendment. The REC should be notified (for information only) of the return of a CI (in any study), or a PI in a CTIMP.

Proposed changes in CI or PI should be notified to the R&D office as soon as possible so the necessary approvals can be in place at the time of handover of responsibilities.

Safety Reporting

The audit highlighted that some SAEs/SUSARs has not been reported to the Sponsor and R&D office within the required timelines. PIs must ensure all staff involved with safety reporting are familiar with the requirements of UHB SOP 181 Safety Reporting for Hosted Studies.

Serious Breaches

There is a lack of understanding on what constitutes a serious breach of GCP. PIs should ensure they and the research team are aware of the definition of a serious breach and the reporting requirements (UHB SOP 235 – Notification of Serious Breaches of GCP or the Study Protocol).

Informed Consent

The consent process is not being fully documented in patient records as per protocol and UHB requirements. The UHB requirements for documenting consent in patient medical records are described in section 5.3 of UHB SOP147.

GCP and protocol training records

GCP training evidence could not be verified for all staff throughout the duration of the trial. It's the PIs responsibility to ensure all staff listed on the Delegation Log are GCP trained prior to undertaking any trial activities and training is updated on a two year basis in accordance with UHB SOP 317. A record of all GCP and trial specific training received by staff should be filed in the ISF as per UHB SOP 317- Training Requirements for Research Staff including GCP.

GP not informed of patients' participation in trial

GPs should be informed of patients' participation at the outset of the clinical trial (if consent is given). PIs may want to confirm eligibility with the GP in relation to a participants' past medical history, prohibited medication and any previous (or ongoing) participation in clinical trials. In addition, it is invaluable for GPs to be aware of their patients' participation, as they may need to be aware of known contraindications or potential side effects and it will allow them to alert PIs of any adverse events. There may also be prohibited medication that the GP may need to avoid prescribing for concurrent or unexpected illnesses.

Trial Status

11/94 trials were closed however the R&D records listed all trials as open to recruitment. PIs should notify the R&D office of actual trial end dates so R&D office has the accurate trial status.

Version Control

To ensure the correct approved version of the documentation was being used at any given time, it is good practice to use a Version Control Log. A template is available on the R&D office intranet page (form ref: TR-RG-003). All versions of a document used during the lifetime of the trial must be kept, to allow reconstruction of the trial. It is recommended that files clearly indicate document versions that have been superseded, so that these documents are not inadvertently used.

Investigator Site File (ISF) missing essential documentation

The ISF must be maintained throughout the lifetime of a trial. The audits highlighted essential documents were missing from some ISFs. Any missing essential ISF documentation should be requested from the sponsor and filed accordingly. It is the PIs responsibility to ensure the ISF is maintained.

Research and Development

Research Delivery Team

Tracy Smith – Primary Care Research Nurse

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

I am a Primary Care Research Nurse working for Health Care Research Wales, Research Delivery Team, within R&D at Cardiff and Vale UHB. My remit is to support Primary Care research across South East Wales.

My role is varied, interesting and challenging and I work across all three health boards which includes Cwm Taf UHB, Aneurin Bevan UHB and Cardiff and Vale UHB. My base is currently at 12 Cathedral Rd, Cardiff however, from March 2018, I am looking forward to being based at UHW. My responsibility is to help and support any GP practice within the SE that is interested in undertaking Clinical Research Portfolio research and will support at any point in the study process. This support varies from study to study and can involve giving advice about the approval process or study specific training that may need to be in place before a practice can start. Clinic sessions are held within the GP practices where I can consent, recruit and follow up participants on a portfolio of studies.

An integral part of my role is to liaise closely with study teams that wish to open research in GP practices across Wales and I will often have all-Wales meetings which include my colleagues in the North and South West Wales. Part of my role is to be proactive in engaging with GP practices and I will send out and coordinate study feasibilities to all GPs within the South East, liaising with the study teams and the GP practices to ensure studies are open in a timely manner with the required support in place.

If you require any further information on Primary Care studies occurring in Cardiff and Vale please do not hesitate to email me on tracy.smith3@wales.nhs.uk