

## 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](http://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 April 2017 Research Governance Group

- GR-RG-008 Sponsor Assessment Process (SAP) Guideline
- Venepuncture for Non Clinically Qualified Research Staff Policy
- Guidance for Non-Medical Research Staff in Gaining Competence in Receiving Valid Informed Consent

## Annual R&D Forum dates

For the Annual R&D forum date please follow the link below: <http://www.annualrdforum.org.uk/2017-programme/>

## Innovation celebrated at UHB's R&D Conference

Cardiff and Vale UHB held another successful Research and Development (R&D) Conference on Tuesday 13 June which celebrated the valuable work of the R&D Directorate.



Professor Chris Fegan, R&D Director, speaking at the event said: "As we know Cardiff and Vale UHB has a massive research portfolio. The conference gives an insight into the breadth and depth of research that goes on to improve the opportunities for research and eventually improve the outcomes for patients.

The conference is really important for us to come together because we all work in different areas and in different organisations. It's a good chance to cross fertilise ideas and methods of doing things, how to access money, how to get permissions, and what skills do you need and how to develop the workforce to enable the studies to take place.

I've been delighted by the talk today. The patient story was fantastic. Together we must do more for these patients."

Dr Graham Shortland, Medical Director, applauded the R&D office for all their hard work and effort in setting up the conference. He said: "Research, Development and Innovation are pivotal to how we shape and deliver our services to the increasingly complex dynamic needs of our population. This work places Cardiff and Vale UHB as an international centre of excellence.

## Health and Care Research Wales conference 2017



5 October 2017 | SWALEC Stadium, Cardiff | £0.00

## Save the date

**Theme: Inequalities in health and social care**

#ResearchWales17

If you would like to be notified when registration for the conference is open, please email:

[healthandcareresearch@wales.nhs.uk](mailto:healthandcareresearch@wales.nhs.uk)



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

## Leaving the EU: Opportunities and Implications

The UK Clinical Research Collaboration has collected the views of its partners (NHS, research funders, industry, regulatory bodies, Royal Colleges, patient groups and academia) to identify the main opportunities, implications and legislation/regulation for the clinical research sector that need to be considered in leaving the EU.

The information was collated in late 2016 and as the situation is dynamic, the views may not necessarily be representative of individual organisations, the UK Government or Devolved Nations (Wales, Northern Ireland, England and Scotland).

[Leaving the EU Summary final version](#)

Welsh Government/Health and Care Research Wales are partners in the UK Clinical Research Collaboration and Professor Jon Bisson was involved in developing the summary.

## Good Research Practice Sessions for 2017

The following Good Research Practice (GRP) sessions are planned for the remainder of 2017:

05/09/2017 - Human Tissue Act & Research

11/10/2017 - How to apply for ethical approval

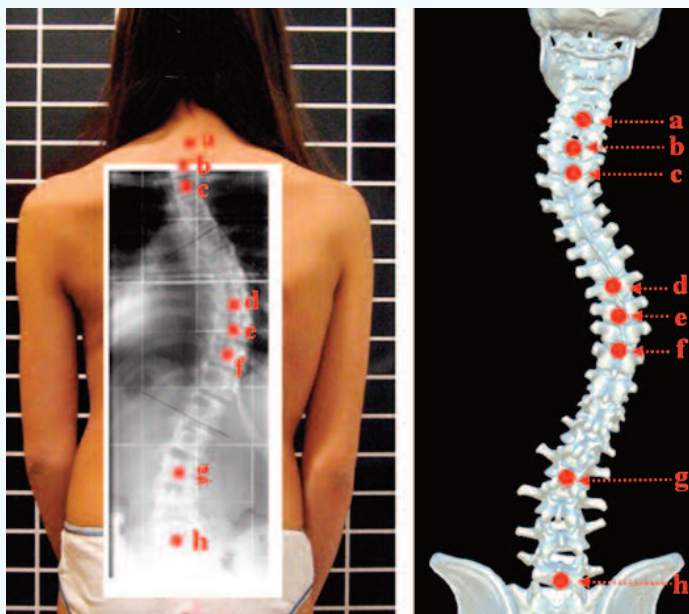
16/11/2017 - Informed Consent

12/12/2017 - Approvals process

For further information on how to book GRP sessions, please email [Jemma.cross@wales.nhs.uk](mailto:Jemma.cross@wales.nhs.uk)

## Digital Human Model to Facilitate Postural Assessment and Accurate Measurement of Clinical Outcomes

Poor sitting posture linked to musculoskeletal deformity has been identified as one of the major causes of pressure ulcers as well as significantly affecting comfort, physiology, function and mobility of wheelchair users. During routine postural assessment, healthcare professionals use anthropometric measurements to infer internal musculoskeletal configuration and inform the prescription of, for example, custom contoured seating systems tailored to individual needs. Current assessment processes do not readily facilitate communication of musculoskeletal configuration between healthcare professionals or the accurate comparison of changes over time (that, in turn, would indicate the success or otherwise of interventions thus providing a measure of clinical outcome), especially in the case of individuals with complex body shapes. There are many imaging techniques measuring musculoskeletal configurations such as MRI, CT or X-RAY. However, most are very resource intensive and do not readily lend themselves to widespread use in, for example, community based services for which there is a need for an easy to use, accurate, visualization tool for postural assessment.



*Left: Scoliosis patient, Source: Weiss HR. Scoliosis 2007, 2:19. PMID: 18163917. doi:10.1186/1748-7161-2-19. Right: Spinal shape visualisation produced from DHM algorithm using anatomical markers (a to h – also superimposed left to facilitate comparison) with the Zygote skeletal mesh visible.*

In order to seek to address this unmet need, a novel 3D interactive Digital Human Model (DHM) has been developed at the University of South Wales in collaboration with Cardiff and Vale University Health Board's Rehabilitation Engineering Unit (REU). The research team comprises: Professor Colin Gibson (Head of RE, CVUHB), Dr Janusz Kulon (Reader, USW), Michael Voysey (PhD Student, USW), Sebastian Haigh (PhD Student, USW), Dr Adam Partlow (Trainee Clinical Scientist, REU) and Dr Paul Rogers (Principal Clinical Engineer, REU). The model has been based on the skeleton mesh from Zygote Media Group Inc., Provo, UT, USA. A new heuristic method has been developed to dynamically position the DHM to represent the spinal shape from a set of anatomical landmarks positioned along the spine. The DHM enables clinical engineers to visualise and accurately record internal skeletal configuration as indicated by the anatomical landmarks in comparison to external body shape. The project has been jointly funded by the Knowledge Economy Skills Scholarships programme, Cardiff and Vale University Health Board and the University of South Wales.

# The Research Delivery Team

The Health and Care Research Wales Delivery Team are part of the R&D Office and consist of Research Nurses, Clinical Studies Officers and Research Officers who support high quality studies at various time points within the UHB from study set up to archive. The staff have been issued with new polo shirts to ensure they are easily identifiable to researchers and clinical teams within the UHB. Members of staff within the photo from left to right are Linda Phillips, Paediatric Research Nurse Tracey Smith, Primary Care Research Nurse and one of our newest recruits Bethan Morse Research Nurse.



## Quality in Organ Donation (QUOD) Symposium

Mr Elijah Ablorsu (Consultant Transplant Surgeon) is pleased to invite you to Annual QUOD Symposium, which is being held in Cardiff this year.

The meeting will be held at **the Life Sciences Hub Wales** (the Chris McGuigan Hub 3 Assembly Square, Cardiff CF10 4PL) on **17 October 2017**.

The Conference is organised by the QUOD Consortium which governs unique organ donors tissue bio-bank (e.g. blood, urine, spleen, kidney and liver tissue) and coordinates nationwide QUOD program. The aim of this program is to facilitate research and potentially to determinate pathways of injury and repair in organs and identify biomarkers which can be used to better predict the outcomes of transplantation.

Up to now, more than 2200 donors have been enrolled to the program (with over 38k samples and 220k biobank items) and 15 research projects approved access to QUOD bio-bank. Now the bio-bank is well established and continuously expanding, the QUOD committee is willing to grant access to the bio-bank also to non-transplant research projects.

The symposium is a great opportunity to find out more details about the present and future of QUOD program and ongoing research activities as well as potential for future research collaboration and would also love to hear your thoughts, opinions and suggestions.

Should you have further queries or wish to register please contact (Sharon.Daniels@wales.nhs.uk), Tel no: 02920 746647.

## Health and Care Research Wales

Health and Care Research Wales is pleased to announce the launch of its public facing video - What is research? This video is an introduction to health and social care research, highlighting the importance of research and the different ways people can take part.

You can view the video on the Health and Care Research Wales YouTube channel:

<https://www.youtube.com/channel/UCKR5m1jTmj06DnECTA5XTfg>

Please can you share and promote the video by:

- Identifying public-facing screens where it could be shown (please inform the Health and Care Research Wales communications team)
- Sharing it with your university or health board communications team and asking them to promote it
- Adding it to your website
- Promoting it via social media (tweet it, share it on Facebook, etc.)
- Including it in your e-bulletins
- Showing it at events/conferences (download it to an iPad or laptop)

If you have any other ideas for promoting the video, or need the video as a link to download, please get in touch with the Health and Care Research Wales communications team [healthandcareresearch@wales.nhs.uk](mailto:healthandcareresearch@wales.nhs.uk)

Health and Care Research Wales also launched its Facebook page on 17 May. Please visit the page, like it and share it with your contacts. If you have any public-facing content that you would like to promote on this page, please contact the Health and Care Research Wales communications team [healthandcareresearch@wales.nhs.uk](mailto:healthandcareresearch@wales.nhs.uk)

Many thanks  
The Health and Care Research Wales communications team



## Researchers,

Since the development of the ICH GCP Guideline the scale, complexity, and cost of clinical trials have increased.

### **An integrated amendment of the ICH E6; Guideline for Good Clinical Practice, has now been released and will become effective in the EU on June 14 2017.**

The guideline has been amended to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting while continuing to ensure human subject protection and reliability of trial results. Standards regarding electronic records and essential documents intended to increase clinical trial quality and efficiency have also been updated. The amendment impacts directly on sponsors, investigators and institutions. Whilst most of the changes are related to functions of the sponsor some are investigator/institutional changes.

Investigators should read the full version which can be found at: [http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R2\\_\\_Step\\_4.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf).

For your convenience, a summary of the key changes has been outlined in the enclosed document called Addendum to ICH-GCP E6 (R2) Summary of Changes Communication for Investigators.

We hope that you find this summary useful. Please ensure you disseminate this information to your research team. If you have any questions on how these changes will impact a particular trial please get in touch with your Sponsor who will be able to advise accordingly.

## Single IRAS form

## announcement

### A single form replaces separate ethics and R&D application forms on a UK-wide basis

From the evening of 28 June 2017 a combined IRAS form that merges the REC and R&D forms will be used across the UK. Already in place for projects where the lead NHS R&D office is based in England, the single IRAS form should be used for projects where the lead NHS/HSC R&D office is based in Northern Ireland, Scotland or Wales.

The streamlined single system is a result of the work of the Four Nations NHS/HSC Compatibility Programme and contributes to making it easier for applicants to undertake research in the NHS/HSC. Adoption of the single IRAS form UK-wide will save time and effort for applicants and sponsors and help build UK-wide consistency.

For projects led from Northern Ireland, Scotland, or Wales, although a single form will replace the separate REC and R&D forms, this single IRAS form will continue to be separately submitted for ethical review (where applicable) and review against NHS/HSC standards as per current processes. The single electronic submission of the IRAS form and accompanying documents for both ethical review and for review against NHS/HSC standards will remain in place for projects led from England.

Over the coming year more work will be carried out to further streamline the application process, so that the current submission functionality for projects led from England is extended to projects led from Northern Ireland, Scotland and Wales.

Applications for Research Tissue Banks, Research Databases and for research projects not taking place in the NHS/HSC will continue to use the REC Form. Applications for studies where the lead NHS R&D office is based in England are not affected by this change.

Applicants are encouraged to read the advice and guidance within IRAS and to seek support from their lead NHS/HSC R&D office.

## Our Library Service

The Cardiff & Vale UHB Library Service is ready and willing to help you with your research project. You may have an idea in mind and you want to make sure it hasn't been done before, or maybe you need some articles to support your proposal. The Librarian will find relevant and current information for you, and she will help you to find the articles you need. The service is open to all UHB staff and to GPs in the C&V area.

We are also keen to help with innovation projects, by providing information to support and enhance development and implementation.

Two useful resources were purchased specially for the UHB and can be found on the Clinical Portal. They are UpToDate, a point-of-care tool, and Clinical Key, which offers a wider range of material including book chapters, articles and 600+ electronic journals. We offer training on these resources and on general library sources.

For help or more details, please contact the C&V UHB Librarian, Rosemary Soper 02920 715497 or email [soper@cardiff.ac.uk](mailto:soper@cardiff.ac.uk)

# Research and Development

## UHB Research Performance Report 2016/17

The UHB is performance managed against a number of Key Indicators set by Welsh Government. The indicators include the number of Commercial and Health and Care Research Wales Clinical Research Portfolio (Portfolio) studies and recruitment to these studies; how quickly the UHB set up studies; how quickly the first patient is recruited and the overall recruitment to time and target. There is also an expectation that the UHB has only a few non-recruiting studies.

A summary of how the UHB has performed in 2016/17 is presented in the table below:

Key indicator	Target	Number/Percentage Achieved
Number of Portfolio studies	198	176
Patients recruited to portfolio studies	4917	5064 ☺
Number of Commercial studies	41	47 ☺
Patients recruited to commercial studies	459	351
Permission within 40 days for Portfolio studies	80%	65%
Permission within 40 days for Commercial studies	80%	92% ☺
First patient recruited in 30 days (Portfolio)	80%	57%
First patient recruited in 30 days (Commercial)	80%	64%
Portfolio studies (open) recruiting to time and target	80%	36%
Portfolio studies (closed) recruiting to time and target	80%	43%
Commercial studies (open) recruiting to time and target	80%	25%
Commercial studies (closed) recruiting to time and target	80%	18%
Non-recruiting Portfolio studies	<10%	14%
Non-recruiting Commercial studies	<10%	39%

Study teams are reminded to carefully consider what target recruitment number they include on the Site Specific Information Form/agree with the Sponsor. Over estimating likely recruitment can have a detrimental effect on performance metrics.

## Paediatric Clinical Research Facility (PCRF)

The first Paediatric Clinical Research Facility (PCRF) in Wales has opened. The PCRF is already supporting the RHINO, CAP IT and Trial Net studies, offers the first protected space for under 18s. The dedicated space provides significant opportunity to expand and enhance the current levels of research and development within paediatric services across Wales.

It is a flexible area for paediatric research studies, which includes 4 bed spaces, treatment and consultation rooms and a lab area.

There will be an official opening for the facility later this year. If you have a study which would benefit from using the PCRF please contact Rhian Thomas-Turner to discuss [rhian.thomas-turner@wales.nhs.uk](mailto:rhian.thomas-turner@wales.nhs.uk)



## R&D Stand 19th May 2017 for International Clinical Trials Day

R&D along with the Clinical Research Facility and Health and Care Research Wales set up a stand on the 19th May 2017 in the UHW concourse to celebrate International Clinical Trials Day that is globally celebrated on the 20th May.

We used this opportunity to provide research information to encourage and promote research activity within the Health Board.

The R&D stand was well attended by clinicians and members of the public and there was a lot of information that would be useful for up and coming research in the UHB. C&V R&D office had an interactive stand in order to promote research within the Health board and members of the R&D office distributed information for patients, clinicians and study teams regarding research studies, including how to identify a project as research and how to go about submitting a study application.