# Bundle Audit & Risk Assurance Committee 25 August 2020

5.6 Research & Development Department Governance Review Update

*Presenters: Dr Philip Kloer/Dr Leighton Phillips*

- R&D Department Governance Review Update ARAC August 2020
- Appendix 1 - Research activity since the start of COVID-19 pandemic
- Appendix 2 - R&D Sub-Committee Annual Report 2019/20
- Appendix 3 - Final IA Report (original)
- Appendix 3 - Final IA Report with expanded management response

Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

# PWYLLGOR ARCHWILIO A SICRWYDD RISG
# AUDIT AND RISK ASSURANCE COMMITTEE

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| **DYDDIAD Y CYFARFOD: DATE OF MEETING:** | 25 August 2020 |
| **TEITL YR ADRODDIAD: TITLE OF REPORT:** | Research & Development Department Governance Review Update |
| **CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:** | Dr Philip Kloer, Medical Director and Deputy CEO |
| **SWYDDOG ADRODD: REPORTING OFFICER:** | Dr Leighton Phillips, Deputy Director, Research and Innovation, Dr Caroline Williams, Senior Operations Manager, R&D |

| **Pwrpas yr Adroddiad** (dewiswch fel yn addas) **Purpose of the Report** (select as appropriate) |
|---|
| Er Sicrwydd/For Assurance |

## ADRODDIAD SCAA
## SBAR REPORT

### Sefyllfa / Situation

At the Audit & Risk Assurance Committee (ARAC) meeting held on 25th February 2020, members requested that the findings of the audit report relating to the Research and Development (R&D) Department governance be contextualised in view of recent changes to the Department's structure and in advance of providing detailed responses to the recommendation raised. An additional section has been added to the Audit report and is summarised within this SBAR, to identify the salient points for committee members.

### Cefndir / Background

At the previous ARAC meeting, the Deputy Director for Research and Innovation explained to members that many of the issues raised by the audit, and associated recommendations, had resulted from a period of turbulence and change within the department. The conclusion of an Organisational Change Process, with the establishment of a new structure, and appointments in several key areas has reduced the likelihood of similar issues recurring. The Deputy Director also described the dual reporting and governance that exists for Research and Innovation, which provides some unique but not irresolvable reporting challenges. The Committee Chair suggested that it would be helpful to set this out as a means of contextualising the response to the recommendations and to provide increased assurance that similar issues would not occur in the future.

Background to Research and Development in Hywel Dda University Health Board

The Research and Development Department in HDdUHB performs three main functions, each supported by a team (members of each team work across all functions):

- Research Delivery – this team facilitates and supports the local set up and delivery of Health and Care Research Wales Portfolio studies and a number of commercial studies. The team is predominantly made up of research nurses and assistants but also includes other staff essential to the conduct of research, including pharmacy and laboratory services. There is a research team at each of the Health Board's hospital sites;

- Core R&D functions (including finance and governance) – this team deals with the local NHS Support and Management of R&D, including study set up, applications for regulatory approvals, ethical and NHS permissions. The governance team specifically deals with monitoring and auditing sponsored studies to ensure compliance, reporting to the Medicines and Healthcare Products Regulatory Agency (MHRA) on adverse events, breaches and urgent safety measures; and

- Researcher Development – this includes supporting researchers to submit bids to grant funders, running pilot and feasibility studies, developing a greater number of principal and chief investigators within the organisation, and supporting the development of in-house research and evaluation. This team generates an income to ensure that the R&D functions can remain sustainable and secure impact for the Health Board.

The Research and Development Department receives the majority of its funding from Health and Care Research Wales (circa £1m per annum) to support the activities of these teams. In addition, it is encouraged to supplement this income by applying for research grants or entering agreements with commercial research funders (e.g. a drug company wishing to undertake a trial of a new medication). The benefits of generating high levels of research activity within the NHS are well documented, and include improving care for patients, providing evidence on the efficacy of new healthcare treatments, supporting continuous improvement, assisting recruitment and retention and income generation.

A high performing Research and Development function is critical to Hywel Dda University Health Board, as demonstrated by its significant recent contribution to the research endeavours associated with the Coronavirus/COVID-19, which has in several ways boosted the profile of research activity within the organisation (Appendix 1). The context offered by the clinical services strategy also provides a significant and ongoing role for research, as does the Health Board's commitment to retain its University Health Board status.

<u>Reporting and Governance</u>

The Research and Development Department has two reporting lines.

It is accountable to Health and Care Research Wales (HaCRW) and the Welsh Government for how it spends the circa £1m grant it receives on an annual basis and several research performance indicators. The key performance indicators include contributions towards:

- Number of applications to National Institute for Health Research (NIHR) Evaluation, Trials and Studies (NETS), (and any similar UK funding schemes in which Health and Care Research Wales participates);
- Commercial income generated;
- Number of papers published in journals;
- Number of Health and Care Research Wales PhD Studentships awarded;
- Number of Health and Care Research Wales Fellows obtaining Principal Investigator (PI) portfolio eligible grant funding within 3 years of completion of their award;
- Number of full NHS Ethics applications processed;
- Number of recruiting NHS Clinical Research Portfolio (CRP) studies;
- Number of NHS Clinical Research Portfolio and commercial studies receiving NHS Research Permissions;
- Number of participants recruited to NHS Clinical Research Portfolio studies;
- Number of recruiting NHS commercial sponsored studies;
- Number of studies on the social care portfolio;

- Number of samples in supported tissue banks; and
- Number of Health and Care Research Wales funded students or fellows in a mentorship scheme.

Hywel Dda University Health Board is recognised nationally as having a very strong R&D Department, which has received significant increases in the funding it is allocated over a 10 year period. It strictly adheres to Health and Care Research Wales guidelines and the funding it receives is a direct reflection of the activity it generates.

The R&D Department is also accountable to Hywel Dda University Health Board, now through the Research and Development Sub Committee and the Quality, Safety & Experience Assurance Committee – R&D Sub-Committee Annual Report 2019/20 attached at Appendix 2. The leadership and management of the R&D Department is within the Medical Department. The Health Board's level of involvement in the governance and management of Research and Development increased from 1st October 2016, when the staff within the national research workforce were transferred into Health Boards and integrated team structures were established.

The reality is that the Research and Department has to continuously take into account two perspectives, as HaCRW hold to account and offer a number of advisory functions to the Health Board, including specialist input in respect of research matters, which the Health Board's corporate functions are not used to routinely dealing with. This might be, for example, ensuring a contract with a pharmaceutical company to enable the testing of a new and novel drug. Advising on such a contract would be considered specialist and the R&D Department would look to HaCRW for assurance.

## Asesiad / Assessment

The overall audit opinion should be read in the context of a challenging period for the R&D Department. The fundamentals of the Department remain strong and many of the recommendations made by internal audit have been straightforward to address. While a detailed response is offered to each of the recommendations in the standard internal audit format, ARAC is asked to note that the root causes of the main issues raised have now been addressed, notably:

- the Department has concluded a restructure to ensure that the size of the department and leadership structures are optimally configured to deliver high quality research, while meeting the standards and expectations of the Health Board. The organisational change process guiding the restructure was introduced in acknowledgement that the old arrangements were not fit for purpose in view of the substantial growth experienced by the R&D function. High levels of research activity place additional pressures on team members recruiting into trials and following up patients, study set up and governance. A key appointment as part of the restructure is a senior operational manager sitting across the three functions of the Department to ensure high management standards;

- business continuity arrangements are significantly stronger. There have been significant gaps in the leadership structure, with staff leaving to take on new opportunities, maternity leave, and sickness absence. While some absence is to be expected in any team, unfortunately the absences have been lengthy and in key areas. There has also been insufficient succession planning and cover arrangements within the team. This has and will continue to be addressed, with succession planning and equipping more than one person in every team with the ability to cover the jobs of others being a key responsibility for all team members; and

- the fragility experienced in service delivery arrangements has also been felt in research, limiting the number of principle and chief investigators that are able to supervise research within the organisation. Furthermore, when services are stretched, time for research is usually the first thing that is compromised. While making such decisions might seem reasonable in the short term, in the medium to long term it could compromise the organisation's ability to retain talented clinical staff. It is also well documented that research active clinicians are often those who excel in delivering high quality care. While acknowledging there is no easy fix to this, all parts of the Health Board must continue to recognise and support staff to become research active and, in doing so, the wider operations of the department will benefit. Most decisions regarding time for research sit outside of the core functions of the Research and Development Department.

In conclusion, while on the surface, the audit opinion is disappointing, nearly all of the issues raised have been resolved in part due to wider developments in the R&D Department that were in motion in advance of the audit taking place.

The one additional issue raised at ARAC on 25th February related to moving from the interim leadership arrangements to a substantive solution. The work to address this point has been slower than anticipated for two reasons. The first is a recently announced review of the role of Research and Development Directors, commissioned by HaCRW. As they fund all R&D Directors, it will be important to take account of their conclusions in the job description for the new role. By the time ARAC receives this report, a discussion will have taken place with HaCRW to agree a way forward. Secondly, the R&D Department has prioritised its work on the COVID-19 research studies that have formed the third point of the Government's four point plan to address this awful disease including testing new therapies, ventilators, and understanding the immune response (See Appendix 1). A combination of these factors mean that the substantive solution will now not be in place until the autumn of 2020. The interim arrangements have not in any way delayed the implementation of the recommendations and have ensured robust governance and decision making, including much stronger links to the Quality, Safety & Experience Assurance Committee.

As part of the R&D Department's continuous improvement drive, supported by HaCRW, it will now undertake a peer review exercise to learn from another high performing team in the UK. It also stands ready to take account of any findings from the follow-up audit that it understands to now be underway.

**Argymhelliad / Recommendation**

The Audit & Risk Assurance Committee is requested to take assurance that actions have been taken to adequately address the issues and recommendations made through the audit process.

| **Amcanion: (rhaid cwblhau)**<br>**Objectives: (must be completed)** | |
|---|---|
| Committee ToR Reference<br>Cyfeirnod Cylch Gorchwyl y Pwyllgor | 5.1 The Committee shall review the adequacy of the UHB's strategic governance and assurance arrangements and processes for the maintenance of an effective system of good governance, risk management and internal control, across the whole of the organisation's activities (both clinical and non-clinical) that supports the achievement of the organisation's objectives. |

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|---|---|
| | 5.3 In carrying out this work, the Committee will primarily utilise the work of Internal Audit, Clinical Audit, External Audit and other assurance functions, but will not be limited to these audit functions. It will also seek reports and assurances from directors and managers as appropriate, concentrating on the overarching systems of good governance, risk management and internal control, together with indicators of their effectiveness. |
| Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol:<br>Datix Risk Register Reference and Score: | IA 1920-09 |
| Safon(au) Gofal ac Iechyd:<br>Health and Care Standard(s): | Governance, Leadership and Accountability |
| Amcanion Strategol y BIP:<br>UHB Strategic Objectives: | All Strategic Objectives are applicable |
| Amcanion Llesiant BIP:<br>UHB Well-being Objectives:<br>Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019 | 9. All HDdUHB Well-being Objectives apply |

| **Gwybodaeth Ychwanegol:<br>Further Information:** | |
|---|---|
| Ar sail tystiolaeth:<br>Evidence Base: | Please read in conjunction with the: Research & Development Department Governance Review. Final Internal Audit Report. February 2020, original and revised version (Appendix 3) |
| Rhestr Termau:<br>Glossary of Terms: | None |
| Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Archwilio a Sicrwydd Risg:<br>Parties / Committees consulted prior to Audit and Risk Assurance Committee: | None |

| **Effaith: (rhaid cwblhau)<br>Impact: (must be completed)** | |
|---|---|
| **Ariannol / Gwerth am Arian:<br>Financial / Service:** | No financial impact or capital requirements. |
| **Ansawdd / Gofal Claf:<br>Quality / Patient Care:** | No adverse quality and/or patient care outcomes/impacts. |
| **Gweithlu:<br>Workforce:** | No adverse existing or future staffing impacts. |
| **Risg:<br>Risk:** | All risks raised by the Audit now addressed through a full response to the findings and recommendations. |

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| **Cyfreithiol:**<br>**Legal:** | No legal impacts or likelihood of legal challenge. |
| **Enw Da:**<br>**Reputational:** | No potential for political or media interest or public opposition. |
| **Gyfrinachedd:**<br>**Privacy:** | No potential impact on individual's privacy rights or confidentiality and/or the potential for an information security risk due to the way in which information is being used/shared. |
| **Cydraddoldeb:**<br>**Equality:** | Not applicable. |

## APPENDIX 1 – RESEARCH IN HYWEL DDA SINCE START OF COVID 19 PANDEMIC

| URGENT PUBLIC HEALTH NATIONAL/INTERNATIONAL PORTFOLIO STUDIES OPEN IN HYWEL DDA | NO. OF PATIENTS RECRUITED INTO THE STUDY FROM HDdUHB |
|---|---|
| **RECOVERY - IRAS 281712**<br>A platform randomised trial looking at the effectiveness of re-purposed drugs for patients with suspected or confirmed COVID-19<br>Patients are randomised between one of the drug arms and normal treatment.<br>Outcomes are measured at 28 days<br>https://www.recoverytrial.net<br><br>A paediatric arm was also opened in Glangwili General Hospital (GGH).<br>Over 9,000 patients have been recruited into this study across the UK.<br>The first outcomes from this study have been released. | 18 |
| **CCP-UK Tier 0 - IRAS 126600**<br>Near real-time analysis and reporting of the clinical characteristics of patients admitted to hospital with SARS-CoV-2 infection, to inform the research and public health responses.<br><br>Data collection only on patients who test positive for COVID-19.<br>Data collected on Day 1, Day 3, Day 6, Day 9 & outcome<br>https://isaric4c.net<br><br>Early results from this study have been released in a pre-publication paper. | 260 |
| **GENOMICC - IRAS 269326**<br>A study which looks at how differences in a person's DNA could influence how sick they become when they are infected with COVID-19. It is an Intensive Care Unit (ICU) study and involves collecting a single blood sample along with data collected at Day 0, Day 3 & Day 60<br>https://genomicc.org<br><br>Study opened on 11.05.2020 | 2 |
| **PHOSP-COVID – IRAS 285439**<br>The study shall recruit individuals post-hospitalisation with a COVID-19 discharge diagnosis to study the short (0-3 months), medium (3-6 months) and long (6-12 months) effects of the disease. The study will analyse routine clinical data with linkage to retrospective and prospective health and social care records (Tier 1), enhanced clinical data and research-specific bio-sampling (Tier 2). | To open tier 1 in GGH/WGH and Tier 2 in PPH |

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|---|---|
| **PRINCIPLE – IRAS: 281958**<br><br>**P**latform **R**andomised trial of **IN**terventions against **C**OVID-19 **I**n older **P**eop**LE** - A Primary Care study to evaluate the use of Hydroxychloroquine in community healthcare settings with the aim of reducing the need for hospital assessment.<br><br>The study is being coordinated by Health and Care Research Wales (HaCRW)<br><br>https://www.phctrials.ox.ac.uk/principle-trial | Seven GP practices in HDdUHB are taking part<br>• Meddygfa Emlyn (Newcastle Emlyn)<br>• Meddygfa Teilo (Llandeilo)<br>• Borth Medical Practice<br>• Lampeter Medical Practice<br>• The Robert Street Practice (Pembroke Dock)<br>• Barlow House Surgery (Milford Haven)<br>• Preseli Practice - Newport & Crymych Surgery |
| **FLU-CAT - IRAS: 30029**<br>Surveillance study open since 2017 to collect data on any viral pandemics. A prospective analysis, linking criteria in a GP's assessment of patients presenting with influenza like illness, to immediate management decisions and patient outcomes.<br><br>https://www.nihr.ac.uk/covid-studies/study-detail.htm?entryId=30029 | Data collected by GPs participating in the Clinical Practice Research Datalink (CPRD) |
| **Neonatal complications of coronavirus. IRAS: 282127**<br>Surveillance study opened in April 2020 to collect data on any viral pandemics. This study will collect information about new-born babies who have Coronavirus or who are born to mothers who have Coronavirus.<br>https://www.nihr.ac.uk/covid-studies/study-detail.htm?entryId=282127 | The study is being carried out through the British Paediatric Surveillance Unit (BPSU)<br>www.rcpch.ac.uk/work-we-do/bpsu |
| **UK Obstetric Surveillance System (UKOSS). IRAS: 112935**<br>Opened in April 2020 to collect data on any viral pandemics. A national Surveillance study of women hospitalised with confirmed COVID-19 in pregnancy.<br><br>https://www.nihr.ac.uk/covid-studies/study-detail.htm?entryId=112935 | Anonymous information is collected through the existing UK Obstetric Surveillance System (UKOSS) reporters, who are based in all maternity units in the UK |
| **EMBARC (COVID arm). IRAS: 165833**<br>Registry of bronchiectasis patients open since 2015, now open with a COVID-19 arm. | Medical records of existing patients in the EMBARC study are being reviewed every week to see if they have had a positive COVID-19 test. |

| HYWEL DDA SPONSORED STUDIES | |
|---|---|
| **CTEX RG7 - IRAS: 282487 (HDdUHB Sponsored multisite device study)**<br>A study to provide preliminary and very limited indications of the effectiveness, acceptability and safety of the CTEX WG7 CPAP device. This is a multi-site study across Wales. | 1 |
| **Characterising the immune response in COVID19. IRAS: 283234 (HDdUHB Sponsored study).**<br>To identify patterns of immune response in people with COVID-19 at different stages / severity of illness.<br>Blood samples taken from patients admitted with COVID-19 | 9 |
| **Hywel Dda BioBank.**<br>The Hywel Dda biobank stores various tissue types and information about patients' health which can be used to help further research. Currently the Biobank is recruiting people who either have COVID-19 or who have recovered from COVID-19 | 22 |

| COVID Research studies in set-up | Update |
|---|---|
| **REMAP-CAP – IRAS 237150**<br>A Randomized, Embedded, Multifactorial Adaptive Platform trial (REMAP) to trial a variety of re-purposed drugs and new treatments. For ICU patients only,<br>https://remapcap.org | Awaiting response from the sponsor |
| **CROWN CORONATION – IRAS 282280**<br>An International, Multi-site, RCT Trial Assessing the Effectiveness of Varied Doses of Oral Chloroquine in Preventing or Reducing the Severity of COVID-19 Disease in Healthcare Workers | Awaiting MHRA decision re Hydroxychoroquine. |
| **BASIL C-19 – IRAS 249030**<br>Behavioural Activation in Social Isolation - Whether a talking treatment called Behavioural Activation (BA) can help improve a person's physical and psychological functioning, for example self-care and mood. Adapted for COVID-19 | HaCRW coordinating (primary care). |

## START/RESTART OF STUDIES THAT WERE SUSPENDED TO ALLOW COVID 19 FOCUS

An internal Assessment & Prioritisation panel meets weekly to consider re-starting suspended and starting new studies using a scenario based risk assessment. This activity has been reported to QSEAC.

| Date | IRAS | Title | Clinical Area | New/Restart | Location |
|---|---|---|---|---|---|
| 6.7.20 | 265317 | Source Isolation | Infection Control | N | HBWIDE |
| 6.7.20 | 241788 | MK7264-030 | Respiratory | R | PPH |
| 6.7.20 | 256824 | THINK Cancer | Cancer | N | Primary Care |
| 6.7.20 | 92703 | UKITPR | Haematology | N | HBWIDE |
| 13.7.20 | 64202 | BSRBR | Rheumatology | R | WGH |
| 13.7.20 | 268217 | Hydrodilation | Orthopaedics | N | HBWIDE |
| 20.7.20 | 268899 | Unlicensed 'special' medicines | Community Pharmacies / GPs | N | Primary Care |

| | | | | | |
|---|---|---|---|---|---|
| 20.7.20 | 137785 | POSNOC | Cancer (Breast) | R | WGH |
| 20.7.20 | 220360 | ASSESS-MESO | Cancer (mesothelioma) | R | HBWIDE |
| 25.7.20 | 284289 | Unite COVID | ICU / COVID | N | GGH |
| 25.7.20 | 161432 | ARRISA-UK | Respiratory (Asthma) | R | Primary Care |
| 4.8.20 | 202342 | HORIZONS | Cancer | R | WGH/BGH |
| | | | | | |

## GRANT APPLICATIONS AND RESEARCHER DEVELOPMENT

- In 2019/20 funding bids totalling £3,638,057.62 were submitted with £160,196.00 of funding being awarded. The decision for £856,410.00 is pending.

- Two 'Research for Patient and Public Benefit' grant applications have progressed to next stage.

- 34 / 50 places in the Pfizer/British Medical Journal publication course have been filled.

- Research & Development newsletter and communications materials were prepared for International Clinical Trials Day on 20th May 2020. This had an excellent response with 13,000 views of the video by Dr Philip Kloer, 8,000 views of the video by Linda O'Brien one of the research nurses, and 250 downloads of the newsletter. A quarterly newsletter continues to be produced.

- A Research & Development Handbook is in preparation.

- A 'Getting into Research' webinar series started on 1st June 2020. This is designed to support staff to develop their interest in research. 78 members of staff have so far applied for access to this.

- A staff survey has been completed and the results from this have been reported in a paper that has been submitted to the BMJ Open. The paper is still under review by the journal. It has also been sent to the Director of Nursing and to the Bronze Acute group via a General Manager to enable lessons to be learned. Based on this work a Staff Mental Health and Wellbeing Research group has been established and the first meeting occurred on 8th July 2020, with plans for them to recur monthly.

Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

**PWYLLGOR ANSAWDD, DIOGELWCH A SICRHAU PROFIOD**
**QUALITY, SAFETY AND EXPERIENCE ASSURANCE COMMITTEE**

| | |
|---|---|
| **DYDDIAD Y CYFARFOD: DATE OF MEETING:** | 09 June 2020 |
| **TEITL YR ADRODDIAD: TITLE OF REPORT:** | Research & Development Sub-Committee Annual Report 2019/20 |
| **CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:** | Dr Philip Kloer, Executive Medical Director and Director of Clinical Strategy |
| **SWYDDOG ADRODD: REPORTING OFFICER:** | Dr Lisa Seale, Senior R&D Manager |

| **Pwrpas yr Adroddiad** (dewiswch fel yn addas) **Purpose of the Report** (select as appropriate) |
|---|
| Ar Gyfer Penderfyniad/For Decision |

**ADRODDIAD SCAA**
**SBAR REPORT**

**Sefyllfa / Situation**

The purpose of this paper is to present the Research & Development (R&D) Sub-Committee Annual Report 2019/20 to the Quality, Safety & Experience Assurance Committee. The R&D Sub-Committee Annual Report provides assurances in respect of the work that has been undertaken by the Sub-Committee during 2019/20 and outlines the main achievements which have contributed to robust integrated governance across the University Health Board (UHB).

**Cefndir / Background**

The Health Board's Standing Orders and the Terms of Reference for the Research and Development Sub-Committee require the submission of an Annual Report to the Quality, Safety and Experience Assurance Committee to summarise the work of the Sub-Committee and to identify how it has fulfilled the duties required of it.

The fundamental purpose of the Research and Development Sub-Committee is to assure the Board, via the Quality, Safety and Experience Assurance Committee, that it is discharging its functions and meeting its responsibilities with regards to the quality and safety of research activity carried out within the organisation.

The Annual Report specifically comments on the key issues considered by the Sub-Committee in terms of quality, safety and performance management of research activities, and the adequacy of the research governance and quality assurance systems and processes in place.

Asesiad / Assessment

The R&D Sub-Committee has been established under Board delegation with the Health Board approving terms of reference for the Quality, Safety & Experience Assurance Committee at its Board meeting on 26th January 2017. The terms of reference of the R&D Sub-Committee were approved at its meeting on 21st May 2018.

These terms of reference clearly detail the Sub-Committee's purpose to provide assurance to the Quality, Safety & Experience Assurance Committee around the organisation's research

activities, ensuring that there is an accurate reflection of quality, safety, and performance management to deliver against gaps in assurance.

In discharging this role, the Sub-Committee is required to oversee and monitor the research agenda for the Quality, Safety & Experience Assurance Committee in respect of its provision of advice to the Board, and ensure the implementation of the research agenda against the following areas of responsibility:

**Assure the Board in relation to arrangements for ensuring compliance with all relevant frameworks, standards, legal and reporting requirements**

- The UK Policy Framework for Health and Social Care Research (2017).
- The Medicines for Human Use (Clinical Trials) Regulations (2004) as amended.
- The Medical Devices Regulations (2002) as amended.
- The General Data Protection Regulations (2018).
- International Conference for Harmonisation of Good Clinical Practice (ICH-GCP) standards (1996).
- Human Tissue Act (2004).

**Consider the implications for the Board of the outcomes arising from relevant external Regulatory Agency Inspections, reviewing progress with resulting Corrective And Preventative Action plans (CAPAs) and authorising their completion**

- The Medicines and Healthcare products Regulatory Agency (MHRA).
- The Human Tissue Authority (HTA).

**Oversee the development of the Board's R&D documentation in line with local and national priorities and guidance, for sign off by the Board after scrutiny by the University Partnership Board**

- Research and Development Strategy.
- R&D Strategic Objectives.
- R&D Annual Plan.
- R&D Policies.
- R&D Standard Operating Procedures.
- R&D Guidelines for Researchers.

**The Research & Development Sub-Committee will endeavour to ensure the Health Board maintains its University status by monitoring and driving improvement in those metrics associated with University status against which it will be judged by Welsh Government**

- Establishing and maintaining University Links.
- Contribution to Health Education and Training.
- Contribution to Quality Care.
- Contribution to Healthcare Research.
- Contribution to other Health related activities.

**The Research & Development Sub-Committee will provide general assurance to the Board by:**

- Ensuring strong relationships and effective communication with associated Higher Education Institutions and other external organisations.
- Reviewing new research applications pertaining to a member's specialist field / management responsibilities when requested by the R&D Manager.
- Promoting increased staff involvement in research activity, including facilitating access to relevant training to enhance research capacity and capability.

- Encouraging multi-disciplinary and multi-agency R&D, including patient/public involvement where appropriate.
- Reporting on R&D activity to relevant health community Committees and Health Board via the R&D Director or their nominated person.
- Promoting the dissemination of research findings in order to contribute to clinical effectiveness and evidence-based healthcare delivery, Value Based Healthcare and to demonstrate the impact of research outcomes.
- Agreeing issues reported via the Research Quality Management Group to be escalated to the University Partnership Board with recommendations for action.
- Providing assurance that the ring-fenced NHS R&D Funding from Health and Care Research Wales is spent according to Welsh Government guidelines and requirements.

**Research and Development Sub-Committee Groups**
The Sub-Groups reporting to the Research and Development Sub-Committee during 2019/2020 were as follows:

- **Sponsor Review Panel Group** was established to consider whether, for in-house research proposals, the Health Board is able and willing to fulfil its responsibilities as Sponsor as laid out in the UK Policy Framework for Health and Social Care Research (2017). The Sponsor Review Panel considers research proposals in terms of:
  - Scientific quality and validity.
  - Information use and dissemination, including value and impact of findings.
  - Health and safety of researchers and participants.
  - Finance, resource use and Intellectual Property Rights.

- **R&D Senior Management Team Group** was established to oversee the strategic objectives of the R&D Department. Issues considered include:
  - Change management and restructuring of the R&D Department via the Organisational Change Policy.
  - Staff management, prioritising and appointing to new posts and making temporary posts permanent.
  - Ensuring compliance with the NHS R&D Finance Policy, and advising the research community on the Terms and Conditions affecting management of their Investigator research accounts.

- **R&D Research Quality Management Group** was established to oversee the quality and safety of research activity carried out within the organisation: Issues considered include:
  - Monitoring the production of research standard operating procedures and associated documentation
  - Oversight of routine and triggered audits and monitoring visits for research studies
  - The delivery of essential research governance training
  - Management and oversight of the BioBank
  - Data quality and study set up risk monitoring

The R&D Sub-Committee Annual Report 2019/20 is intended to outline how the Sub-Committee and its Groups have complied with the duties delegated by the Quality, Safety & Experience Assurance Committee through the terms of reference set, and also to identify key actions that have been taken to address issues within the Sub-Committee's remit.

**Constitution**

From the Terms of Reference approved 21st May 2018, the membership of the Research and Development Sub-Committee is as follows:

- R&D Director (Chair)
- Deputy R&D Director (Vice Chair)
- Independent Member
- Quality Assurance Officer (Research)
- Senior R&D Manager
- R&D Manager
- Grant & Innovation Manager
- Representative of the Medical Directorate
- Representative of the Director of Nursing (with a responsibility for research)
- Representative of the Director of Therapies and Health Science (with a responsibility for research)
- Lay representative
- Researchers
- Representatives from Pathology, Pharmacy and Radiology (as required)
- Aberystwyth University representative
- Swansea University representative
- The University of Wales Trinity Saint David representative
- R&D Finance Business Partner
- Lead Research Nurse representative
- Medical Education and Knowledge representative
- Workforce and Organisational Development representative
- Representative from Swansea Trials Unit, Swansea University

**Meetings**

Research and Development Sub-Committee meetings have been held on a quarterly basis as follows:

- 07th May2019
- 11th November2019
- 27th January/2020

During 2019/2020, the Sub-Committee met on 3 occasions and was quorate at all meetings.

During 2019-2020, the Research and Development Sub-Committee was accountable to the University Partnership Board for its performance. Following each meeting, the Research and Development Sub-Committee would usually provide an assurance to the Committee through a formal written update report which would be received at the subsequent Committee meeting. However, given that the University Partnership Board meeting in August 2019 was cancelled as a result of the impending Corporate Governance restructuring, the only Research and Development Sub-Committee update report presented to the University Partnership Board, was the update from the meeting held on 7th May 2019.

**Sub-Committee Terms of Reference and Principal Duties**

In discharging its duties, the R&D Sub-Committee has undertaken work during 2019/20 against the following areas of responsibility in relation to its terms of reference:

**Feedback from Sub-Groups:**

- **Sponsor Review Panel Group** reports quarterly to the Sub-Committee to highlight key areas of work scrutinised and identifying key risks and issues and matters of concern

during 2019/20. The Sponsor Review Panel meets monthly whenever there is a research study to consider. In 201/20, 3 studies were reviewed:

- IRAS 270736 'COPD Pal Phase 1: Assessing the usability and acceptability of a self-management app for Chronic Obstructive Pulmonary Disease.'
- IRAS 235302 'COPD Pal Phase 2: Assessing the uptake, engagement, and safety of a self-management app for Chronic Obstructive Pulmonary Disease. A pilot expediency study in a real-world setting.'
- IRAS 279439 'Investigating a novel method using the 3D surface and biomechanical properties of facial soft tissue to create a custom Automatic Positive Airway Pressure (APAP) mask cushion.'

Following review, all were approved, with Hywel Dda University Health Board as the sponsor and two have now been completed. In relation to the third study (IRAS 279439), this was subsequently postponed by the applicant due to the Covid-19 pandemic prior to obtaining regulatory approval.

- **R&D Senior Management Team Group** update reports from meetings held monthly, except when there was a meeting of the Research and Development Sub-Committee. Reports from 10 meetings during 2019/20 highlighting key areas of work scrutinised and identifying key risks, issues and matters of concern, were received by the Research and Development Sub-Committee during 2019/20, including the following:
  - Organisational Change management.
  - Recruitment and retention of key staff (strategic, operational and clinical support services) following staff retirement or leaving R&D.
  - Increased oversight of Investigator Research accounts to ensure robust financial governance and implementing the recommendations of the All Wales NHS R&D Finance Policy (February 2017).
  - Overseeing the R&D Department's financial reporting to Health and Care Research Wales to demonstrate compliance with the 'Purpose and Use of NHS R&D Funding Guidelines'; ensuring that the Annual Spending Plan, Quarterly Financial Returns and Annual Financial Returns were submitted to Welsh Government on time.
  - Submitting research data reports to the Business Planning and Performance Assurance Committee to demonstrate compliance with Health and Care Research Wales Key Performance Indicators and targets.

- **R&D Research Quality Management Group** update reports from meetings held bi-monthly were received by the Research and Development Sub-Committee during 2019/20, including the following:
  - Outcomes from the Research Quality Assurance Team's Research Governance Audit programme (Routine Audits and Monitoring Visits).
  - Received reports from Triggered (for cause) Audits, agreeing the Corrective And Preventative Action plans (CAPAs) and authorising their completion.
  - Scrutinising key risks, issues and matters of concern, and agreeing an action plan to address these (Research Quality Assurance Team in liaison with other R&D Teams and the Health Board's research community.
  - Agreed mechanisms to share learning, incorporating audit findings into ongoing research training provision across the Health Board and its research partners, providing Research Quality Assurance advice, mentoring, ad hoc training and guidance to novice and experienced researchers.

- Agreed escalation of issues to the Research and Development Sub-Committee or to the Board, via the Medical Director, Independent Member of the Board and Corporate Governance Team as required.
- Following Triggered Audits, preparing assurance reports as requested by the Medical Director, Independent Member of the Board and Corporate Governance Team
- Overseeing applications from internal and external researchers to receive or access surplus human tissue samples held in Hywel Dda University Health Board's Biobank for their own research.
- Overseeing the management of research-related Adverse Events, Serious Adverse Events or Suspected Unexpected Serious Adverse Reactions reported to the R&D Department.
- Monitoring progress in relation to R&D Policies, Procedures, Guidelines, Checklists, Templates and Forms.

**Other Areas of Responsibility**

During 2019/20, the Research and Development Sub-Committee also received, and considered the following:

- Challenges in R&D Financial Management due to a restructuring of the Health Board's Finance Department, resulting in a lack of Finance support for the R&D Department (January 2019 to June 2019).
- Feedback from Conferences and training events attended by R&D staff.
- The development of a bespoke Biobank Database, in a research collaboration between the Health Board's Biobank Lead and Aberystwyth University, to improve the governance and management of human tissue sample chain of custody for research.
- Problems with a lack of reports received from the Health Board's academic research partners.
- The appointment of a new Deputy Director for Research and Innovation in June 2019, as a joint post with Swansea University, was welcomed.
- The support of the Libraries at the 5 main hospital sites was acknowledged, including Librarians acting as Health Board Research Champions.
- Acknowledgement that the Health Board currently has to outsource scans for Commercial clinical trials via a Service level Agreement with Swansea Bay University Health Board due to the lack of an Administration of Radioactive Substances Advisory Committee (ARSAC) licence. The Health Board would apply for a new licence in early 2020, and the Sub-Committee recognised the importance of this to support Oncology clinical trials.
- Discussion about whether the Sub-Committee should have an Independent Chair, in line with other Health Board Committees.
- An Internal Audit Inspection of the R&D Department Research Governance arrangements was undertaken between October and December 2019, and a report issued in February 2020.
- Transition towards a possible new Needs Based approach to NHS R&D Funding from Health and Care Research Wales, Welsh Government, from April 2020.
- The need to appoint a new R&D Director, following the resignation of the current R&D Director from 1st December 2019. An Interim R&D Director was appointed to support the Deputy R&D Director from this date.

**Key Risks and Issues/Matters of Concern**

During 2019/20, the following key risks and issues/matters of concern were raised to the University Partnership Board:

- Lack of space for clinical research staff across all sites, resulting in a downturn in

HDdUHB's research activity which in turn would jeopardise the organisation's annual NHS R&D Activity Based Funding allocation received from Welsh Government.

- In addition, the University Partnership Board was advised that the organisation's 'University' Health Board status could be under threat if a lack of R&D infrastructure adversely affected the number of collaborative research studies undertaken with Hywel Dda's partner Universities.
- Persistent problems with the Health Board authorising vacant posts resulting in delays to appointing new and replacement staff, despite assurances that the posts will be funded via ring-fenced R&D funding from Health and Care Research Wales, Welsh Government.

**Matters Escalated to the University Partnership Board**

During 2019-2020 the following matters requiring University Partnership Board level consideration or approval were raised:

- Health and Care Research Wales Key Performance Indicators (KPIs) and Targets.
- Concerns were again raised that the Commercial study KPI targets would not be achieved by the end of 2019-2020, partly attributable to a lack of Chief and Principal Investigators across the Health Board however also due to the loss of key R&D staff and a lack of dedicated space for research.
- In November 2019 the Deputy Director for Research and Innovation again highlighted the ongoing issue of a lack of dedicated space for R&D and advised that research activities would need to be reduced at each hospital unless allocation of space could be improved. This was escalated to the University Partnership Board to be formally reported to the Executive Team.

**R&D Sub-Committee Developments for 2020/21**

The following developments are planned for the Research and Development Sub-Committee during 2020-2021:

- Further review of the Sub-Committee membership will be undertaken, with a particular focus on the University partners.
- Each Group will be required to produce a summary annual report to facilitate the Research and Development Sub-Committee's Annual Report to the Quality, Safety and Experience Assurance Committee (previously reported to the University Partnership Board).

**Argymhelliad / Recommendation**

QSEAC is requested to endorse the R&D Sub-Committee Annual Report 2019/20.

| **Amcanion: (rhaid cwblhau)**<br>**Objectives: (must be completed)** | |
|---|---|
| Committee ToR Reference:<br>Cyfeirnod Cylch Gorchwyl y Pwyllgor: | 10.4.1 Report formally, regularly and on a timely basis to the Board on the Committee's activities. This includes the submission of a Committee update report, as well as the presentation of an annual report within six weeks of the end of the financial year. |

| | |
|---|---|
| Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol:<br>Datix Risk Register Reference and Score: | Not Applicable |
| Safon(au) Gofal ac Iechyd:<br>Health and Care Standard(s): | Governance, Leadership and Accountability |
| Nodau Gwella Ansawdd:<br>Quality Improvement Goal(s): | All Quality Improvement Goals Apply |
| Amcanion Strategol y BIP:<br>UHB Strategic Objectives: | Not Applicable |
| Amcanion Llesiant BIP:<br>UHB Well-being Objectives:<br>Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019 | 10. Not Applicable |

| **Gwybodaeth Ychwanegol:<br>Further Information:** | |
|---|---|
| Ar sail tystiolaeth:<br>Evidence Base: | Agendas, papers and minutes of the XXX Sub-Committee meetings 2019/20 |
| Rhestr Termau:<br>Glossary of Terms: | Included within the body of the report. |
| Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Ansawdd, Diogelwch a Sicrhau Profiod:<br>Parties / Committees consulted prior to Quality, Safety and Experience Assurance Committee: | R&D Sub-Committee Chair and Lead Director |

| **Effaith: (rhaid cwblhau)<br>Impact: (must be completed)** | |
|---|---|
| **Ariannol / Gwerth am Arian:<br>Financial / Service:** | A sound system of internal control, as evidenced in the R&D Sub-Committee's Annual Report, will assist with ensuring financial control, and the safeguard of public funds. |
| **Ansawdd / Gofal Claf:<br>Quality / Patient Care:** | SBAR template in use for all relevant papers and reports. |

| | |
|---|---|
| **Gweithlu:**<br>**Workforce:** | SBAR template in use for all relevant papers and reports. |
| **Risg:**<br>**Risk:** | SBAR template in use for all relevant papers and reports. |
| **Cyfreithiol:**<br>**Legal:** | A sound system of internal control, as evidenced in the R&D Sub-Committee's Annual Report, ensures that any risks to the achievement of the Health Board's objectives are identified, assessed and managed.<br><br>Compliance with the Health Board's Standing Orders, and the R&D Sub-Committee's Terms of Reference, requires the submission of an Annual Report to the Quality, Safety & Experience Assurance Committee. |
| **Enw Da:**<br>**Reputational:** | Not Applicable |
| **Gyfrinachedd:**<br>**Privacy:** | Not Applicable |
| **Cydraddoldeb:**<br>**Equality:** | Not Applicable |

# Hywel Dda University Health Board

# Research & Development Department Governance Review

## Final Internal Audit Report

## February 2020

## Private and Confidential

## NHS Wales Shared Services Partnership

## Audit and Assurance Services

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|---|---|
| **Review reference:** | HDUHB-1920-09 |
| **Report status:** | Final Internal Audit Report |
| **Fieldwork commencement:** | 10th September 2019 |
| **Fieldwork completion:** | 29th January 2020 |
| **Draft report issued:** | 4th February 2020 |
| **Management response received:** | 10th February 2020 |
| **Final report issued:** | 11th February 2020 |
| **Auditor/s:** | Gareth Heaven & Sian Bevan |
| **Executive sign off:** | Philip Kloer (Medical Director) |
| **Distribution:** | Leighton Phillips (Deputy Director of Research & Innovation)<br>Keir Lewis (R&D Director – *at time of fieldwork*)<br>Subhamay Ghosh (Consultant/ Interim R&D Director) |
| **Committee:** | Audit & Risk Committee |

Audit and Assurance Services conform with all Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Institute of Internal Auditors.

**ACKNOWLEDGEMENT**
NHS Wales Audit & Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

**Disclaimer notice - Please note:**

This audit report has been prepared for internal use only. Audit & Assurance Services reports are prepared, in accordance with the Service Strategy and Terms of Reference, approved by the Audit & Risk Committee.

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## 1. Introduction and Background

The review of the management of Research & Development (R&D) Department within the Health Board was completed in line with the Internal Audit Plan 2019/20. The relevant lead Executive Director for the assignment was the Medical Director.

## 2. Scope and Objectives

The overall objective of the review was to assess the adequacy of arrangements for the management of R&D in order to provide assurance to the Audit & Risk Assurance Committee that risks material to the achievement of systems objectives are managed appropriately. The scope of the review was to ensure that:

- There is an appropriate process that ensures that guidance is in place for R&D and that research is approved and of an appropriate quality and relevance to the Health Board; and
- The R&D department is appropriately managed and governed.

The main areas that the review sought to provide assurance on are:

- There are appropriate organisational arrangements in place for the management of research & development, including the structure for R&D within the Health Board, management of the R&D team, reporting and monitoring, also considering the links with HCRW;
- The Health Board produces appropriate guidance and training for the management of research & development studies/trials which is distributed appropriately throughout the Health Board;
- Approval processes ensure that research is of an appropriate quality, and relevant to the Health Board; and
- All R&D projects in the Health Board are appropriately peer and risk reviewed, approved, and comply with research governance standards and statutory requirements.

## 3. Associated Risks

The potential risk considered in the review was as follows:

- R&D does not deliver work aligned to the overall strategic objectives of the Health Board nor Health & Care Research Wales (HCRW);
- R&D is of poor quality;
- Patient harm due to poor management of trials/research; and
- Lack of governance and management of the R&D Department.

## OPINION AND KEY FINDINGS

### 4. Overall Assurance Opinion

We are required to provide an opinion as to the adequacy and effectiveness of the system of internal control under review. The opinion is based on the work performed as set out in the scope and objectives within this report. An overall assurance rating is provided describing the effectiveness of the system of internal control in place to manage the identified risks associated with the objectives covered in this review.

The level of assurance given as to the effectiveness of the system of internal control in place to manage the risks associated with the Research and Development Department Governance Review is **Limited** assurance.

| RATING | INDICATOR | DEFINITION |
|---|---|---|
| **Limited Assurance** |  | The Board can take **limited assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. More significant matters require management attention with **moderate impact on residual risk** exposure until resolved. |

The overall level of assurance that can be assigned to a review is dependent on the severity of the findings as applied against the specific review objectives and should therefore be considered in that context.

A review of the management and governance processes of the Research & Development (R&D) Department identified the establishment of a statutory sub-committee supported by local groups that review and manage the performance and development of research studies and grants. However, we identified a number of high priority findings that require addressing, including:

- The R&D Sub-Committee (RDSC) annual report for 2018/19 has not been submitted to the University Partnership Board meeting within six weeks of the end of the financial year.
- Quarterly investigation account reports, introduced in June 2019, were required to been submitted to Health & Care Research Wales (HCRW). However, the first set of quarterly reports were submitted in November 2019.
- No adequate arrangements were in place to ensure that invoices received from Swansea University in relation to the R&D Director were support by a breakdown of costs.

- No finance reports or updates have been submitted to the RDSC since February 2019.

We also noted a number of medium priority findings in relation to the publication of an unapproved R&D Strategy document, no R&D entries on the staff interests/ gifts/ hospitality/ sponsorship registers since 2017, lack of updates noted on the risk register, instances of non-compliance for the management of sickness absence and PADR objectives.

The appropriate guidance and training for the management of research and development studies and trials was evident through the suite of standard operating procedures. However, a medium priority finding was identified with 16 extant SOPs that have not yet been reviewed or submitted for approval.

Whilst we noted that research studies undertaken by the Health Board had been review and approved by the R&D Department and Ethics Committee prior to their commencement, a high priority finding was identified where the signatures of the grant applicant and R&D Director were not evident on retained documents provided to Internal Audit.

## 5. Assurance Summary

The summary of assurance given against the individual objectives is described in the table below:

| | | Assurance Summary* | | | |
|---|---|---|---|---|---|
| **Audit Objective** | |  |  |  |  |
| **1** | There are appropriate organisational arrangements in place for the management of research & development, including the structure for R&D within the Health Board, management of the R&D team, reporting and monitoring, also considering the links with HCRW | | ✓ | | |
| **2** | The Health Board produces appropriate guidance and training for the management of research and development studies/trials which is distributed | | | ✓ | |

| Audit Objective | | Assurance Summary* | | | |
|---|---|---|---|---|---|
| | |  |  |  |  |
| | appropriately throughout the Health Board | | | | |
| **3** | Approval processes ensure that research is of an appropriate quality and relevant to the Health Board | | | ✓ | |
| **4** | All R&D projects in the Health Board are appropriately peer and risk reviewed, approved, and comply with research governance standards and statutory requirements | | | | ✓ |

** The above ratings are not necessarily given equal weighting when generating the audit opinion.*

## Design of Systems/Controls

The findings from the review have highlighted **three** issues that are classified as weakness in the system control/design of governance arrangements within the Research and Development Department. These are identified in the Management Action Plan as (D).

## Operation of System/Controls

The findings from the review have highlighted **10** issues that are classified as weakness in the operation of the designed system/control of governance arrangements within the Research and Development Department. These are identified in the Management Action Plan as (O).

## 6. Summary of Audit Findings

The key findings are reported in the Management Action Plan at Appendix A.

**OBJECTIVE 1: There are appropriate organisational arrangements in place for the management of research & development, including the structure for R&D within the Health Board, management of the R&D team, reporting and monitoring, also considering the links with HCRW**

Strategy

The Health Board has a *Research and Development Strategy 2016-2020* in place that sets out the strategic direction for Research and Development (R&D) within the organisation. A 'version 3' copy of the strategy document was approved by the University Partnership Board (UPD) in April 2016 and was published on the R&D internet site. However, a 'version 4' had also been uploaded on the Health Board site. Concluding discussion with the Senior R&D Manager and Information Governance Manager, they were unaware of a 'version 4' strategy document; whilst there was no evidence of its approval in UPB minutes in May 2018.

**See Finding 6 in Appendix A.**

R&D Sub-Committee

The R&D Sub-Committee (RDSC) was established in 2015 as a sub-committee of the University Partnership Board (UPB) and can confirm that an approved term of reference was in place. The supporting groups of the RDSC are the Research Quality Management Group (RQMG) and the Sponsorship Review Panel (SRP). We can confirm reports from both supporting groups were submitted to the RDSC during 2019.

The RDSC is required to provide regular formal reports of the sub-committee's activities and an annual report to be submitted within six weeks of the end of the financial year to the UPB as outlined in the term of reference. Whilst we can confirm the RDSC regular reported to the UPB for the period April 2018 to September 2019, the annual report for 2018/19 had not been submitted to the UPB within six weeks of the end of the financial year (i.e. May 2019 meeting).

**See Finding 1 in Appendix A.**

Declaration of Interest, Gifts, Hospitality & Sponsorship

A review was undertaken to establish assurance that staff within the R&D Department were aware of the requirements of the declaration of interest, gifts and hospitality policy.

Whilst all R&D employees updated their Declaration of Interests forms in June 2019, a review of the organisational registers published on the Health Board's

website (including gifts, hospitality and sponsorship) noted that entries had not been updated since 2017.

**See Finding 7 at Appendix A.**

Risk Management

The R&D Department has an operational risk register in place. A review was undertaken of the operational risk register as at 17th December 2019. Concluding our review, we noted the following:

- One risk (Ref. 145) had not been updated since May 2018.
- One risk (Ref. 149) appears to have implemented satisfactory actions to mitigate the risk, yet the risk remains on the register.

We can confirm that the risk register was regularly submitted to the RDSC during 2019 and evidence of discussion and scrutiny of the listed risks were evident in the sub-committee minutes.

**See Finding 8 at Appendix A.**

Finance

In June 2019, a new dedicated finance team was established to support the R&D Department. The finance team, in conjunction with the Deputy Director for Research & Innovation, have undertaken work on establishing governance arrangements and internal controls in regard of R&D finances, including the identification of budget holders and a scheme of financial delegation in line with Standing Financial Instructions and Standing Orders.

The Finance Department are required to submit regular update reports to the RDSC. However, a review of the RDSC meetings for 2019 noted that a Finance report had not been submitted to the since February 2019.

The R&D Finance Team have established regular monthly meetings with the R&D Department to discuss and review the financial position and performance. In addition, the Senior R&D Manager also has access to the QlikView system to monitor finances.

A number of identified researchers are responsible for investigation accounts, with quarterly reports required to be submitted to Health & Care Research Wales via the Finance Department. The first set of reports were due to be submitted in June 2019. However, the first set of submissions were made in November 2019.

The R&D Director has an honorary contract with the Health Board as a Consultant within Respiratory Medicine in addition to the R&D role for one session. Payment of the R&D Director salary is made via regular invoices from Swansea University.

Following receipt of the invoice into the Finance Department, authorisation was sought from the Assistant General Manager (General Medicine) prior to processing the payment.

However, information of the R&D Director's financial breakdown in relation to work undertaken was unable to be provided with no reconciliatory checks undertaken to ensure submitted costs were accurate prior to approval of payment.

In December 2019, the R&D Director stood down from his role within the R&D Department. The R&D Department should ensure that payments for the role of R&D Director are not included in future invoices received from Swansea University.

**See Findings 2, 3 & 4 at Appendix A.**

Workforce

A sample of 10 periods of sickness were selected and tested to ensure appropriate actions had been taken and documented in line with the *NHS Wales Managing Attendance at Work Policy*. Of the 10 periods of sickness chosen within our sample, documentation relating to two periods of absence could not be located. However, we have noted that the Return to Work (RTW) forms have now been completed retrospectively. Of the eight periods of sickness where documents were retained on file, we noted:

- A sickness absence for one employee where the self-certificate was incomplete with no start or end dates of sickness recorded and no manager signature, whilst the return to work interview was undertaken 16 days after the employee returned to work.

- A sickness absence for one employee where self-certificate employee and manager signatures were dated incorrectly, whilst the RTW form employee signature was dated incorrectly.

Five employee personal appraisal development review (PADR) forms were tested to ensure personal objectives align with the Health Board's Policy referring to the use of SMART objectives. Of the five PADRs selected within our sample, 18 personal objectives had been created. We noted that some objectives were not measurable or timely, whilst an older version of the PADR form was evident for one individual. We also noted that one employee's PADR did not have any set personal objectives.

**See Findings 9 & 10 at Appendix A.**

Incident Reporting

Incidents involved in research studies will prompt a trigger audit by the R&D Department. A review of the Research Quality Management Group meetings for the period January – September 2019 noted that the reporting and scrutiny of triggered audits was evident.

Travel Claims

A sample of five employees with the highest travel claim costs were selected from a claims report obtained from the e-Expenses system for the period September 2018 to August 2019. Of the five employees tested, we were able to reconcile two employees travel claims to their personal electronic diaries. However, three employees were unable to be tested due to terminating employment with the Health Board or being on leave.

**See Finding 11 at Appendix A.**

## OBJECTIVE 2: The Health Board produces appropriate guidance and training for the management of research and development studies/ trials which is distributed appropriately throughout the Health Board

A review of research and development standard operating procedures (SOPs) was undertaken to ensure all had been approved and distributed throughout the Health Board. Concluding our review, we noted that three SOPs had recently been reviewed and distributed to R&D Sub-Committee members for review and feedback prior to their publication in January 2019 on the organisation's intranet site. However, due to the organisational constraints pending the outcome and approval of an Organisational Change Process and the prioritisation of audits within the R&D Department, 16 extant SOPs had not been reviewed.

**See Finding 12 at Appendix A.**

## OBJECTIVE 3: Approval processes ensure that research is of appropriate quality relevant to the Health Board

All research studies undertaken by the Health Board require review and approval from the R&D Department and Ethics Committee prior to their commencement. A sample of four research studies was selected from the Research Database Application (ReDA) active studies report.

We can confirm that approval by the R&D Department and relevant Ethics Committee was evident and that the appropriate steps in drawing up a study (sponsored and non-sponsored) were followed as per the Standard Operating Procedures for Research & Development. Whilst we noted that research study information was retained on the ReDA system, some Health Board documents such as the 'Research Application Checklist' were not always fully completed.

Concluding a review of four successfully applied grants for 2018/19, we identified two submissions, *Patient Involvement PtP* and *Research to Publication*, where the signatures of the grant applicant and R&D Director were not evident on retained documents provided to Internal Audit.

**See Findings 5 & 13 at Appendix A.**

## OBJECTIVE 4: All R&D projects in the Health Board are appropriately peer and risk reviewed, approved and comply with research governance standards and statutory requirements

All research projects are risk assessed by the R&D Department prior to the application submission. Of the four studies selected for testing, we can confirm that a risk assessment had been undertaken and captured on local R&D forms.

The Quality Assurance Officer (Research) is responsible for undertaking routine & triggered audits and monitoring visits for all successful research projects to ensure compliance with governance standards and statutory requirements. These audits and visits are captured on a local register and are prioritised on a risk-based approach. Of the four research studies tested, only LungCast had been audited to date. The three other studies within our sample were scheduled to be audited in 2020 due to their low risk assessment that was evident on retained local R&D forms.

**No matters arising.**

## 7. Summary of Recommendations

The audit findings and recommendations are detailed in Appendix A together with the management action plan and implementation timetable.

A summary of these recommendations by priority is outlined below.

| Priority | H | M | L | Total |
|---|---|---|---|---|
| **Number of recommendations** | **5** | **8** | **0** | **13** |

| Finding 1 – RDSC Annual Report 2018/19 (O) | Risk |
|---|---|
| The RDSC annual report for 2018/19 has not been submitted to the UPB meeting within six weeks of the end of the financial year as explicitly noted in the RDSC TOR. | Lack of governance and management of the R&D Department. |
| **Recommendation 1** | **Priority level** |
| **The Research & Development Sub-Committee should ensure that the annual report for 2018/19 is submitted to the appropriate committee meeting and future reports should be submitted within six weeks of the end of the financial year.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| The report is complete and will be circulated to Committee members, in advance of its formal agreement at the next R&D Sub-Committee on 20.4.20.<br><br>A formal and time bound process of producing end of year reports as part of the Health Board planning arrangements is currently being produced to ensure timely future annual reports. This will be presented at the next Senior Management Team meeting on 17.2.20 for approval and once approved will be completed in time for the annual report completion for the year ending April 2020. | Senior Research and Development Operations Manager<br><br>20th April 2020 |

| Finding 2 – HCRW Financial Returns (O) | Risk |
|---|---|
| A number of identified researchers are responsible for investigation accounts, with quarterly reports required to be submitted to Health & Care Research Wales via the Finance Department. The first set of reports were due to be submitted in June 2019. However, the first set of submissions were made in November 2019. | Lack of governance and management of the R&D Department. |
| **Recommendation 2** | **Priority level** |
| **R&D Management should ensure individual researchers assigned investigation accounts promptly complete and submit their quarterly returns to Health & Care Research Wales via the Finance Department.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| Information taken from the Hywel Dda UHB R&D Finance Process (Appendix 2) is as follows:-<br>• Spending plans (for amounts over £1,000) are to be provided to and reviewed by the R&D Senior Team at least 6 monthly.<br>• Spending plans must detail outline or planned spending / expenditure against income accrued, plus anticipated new income generated per annum.<br>• If income is less than anticipated (e.g. lower than expected recruitment), early discussion with the R&D Senior Team is essential.<br>• Any ad-hoc spend of £1,000 or more has to be approved by the R&D Senior Team. | Deputy Director for Research and Innovation<br><br>17th February 2020 |

| | |
|---|---|
| • Failure to provide spending plans may result in the accrued income not being reinstated at the start of the new financial year.<br>• This income will be put into a general research support fund, managed by the R&D Department.<br><br>While investigators are routinely asked to submit a spending plan for their 'investigator accounts', the response rate has been low. The Deputy Director for Research and Innovation issued a request for the return of spending plans, so that plans can be reviewed by the Research and Development Sub-Committee on 20.4.20. Where plans are not submitted, any money held on accounts will be added to the general research support fund, for which there is a plan.<br><br>A revised plan for managing this process in the future will be presented by the finance lead at the next senior management team meeting on 17.2.20. | |

| **Finding 3 – R&D Director Payments (D)** | **Risk** |
|---|---|
| The former R&D Director has an honorary contract with the Health Board as a Consultant within Respiratory Medicine in addition to the R&D role for one session. Payment of the R&D Director salary is made via regular invoices from Swansea University. However, no supplementary information is provided to validate the R&D Director's financial breakdown in relation to work undertaken. In December 2019, the R&D Director stood down from his post within the R&D Department. The R&D Department should ensure that payments for the role of R&D Director are not included in future invoices received from Swansea University. | Lack of governance and management of the R&D Department. |

| Recommendation 3 | Priority level |
|---|---|
| **The R&D, General Medicine and Finance Departments should come together and establish a reconciliation arrangement to ensure invoices received from Swansea University for the tenure of the former R&D Director are accurate and correct prior to payment by the Health Board.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| The former R&D director is not paid directly by R&D. Invoices from Swansea University are received by Unscheduled Care and 0.2 sessions were recharged to R&D for the work that he did in supporting R&D. R&D have no input into invoicing arrangements with Swansea University. Finance have ensured that the recharges have dropped to 0.1 now that the former director has dropped his sessions, and if he steps back fully from R&D we will ensure that the recharges stop. This is all managed internally within finance. Part of the ongoing control of this will also be the monthly finance file which is sent out to the Senior Research & Development Operations Manager and Deputy Director for Research & Innovation which will enable us to identify anyone who is being paid inappropriately. | Finance Business Partner<br><br>10th February 2020 |

| Finding 4 – Finance Update Reports (O) | Risk |
|---|---|
| A review of the R&D Sub-Committee 2019 meeting agendas and papers noted that a Finance report/update had not been submitted since February 2019. | Lack of governance and management of the R&D Department. |

| Recommendation 4 | Priority level |
|---|---|
| **The Finance Department should ensure that an R&D financial position update should be reported to the R&D Sub-Committee on a regular basis.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| A change in Finance Team and reporting arrangement and systems has meant that a written report has not gone to the last three Sub-Committee meetings. Finance have been working on a new finance report, which has now been completed. It will be brought to the R&D Senior team meeting on 17.2.20 for review and sign off, and an updated version (to year-end April 2020) brought to the next subcommittee.<br><br>Circulation of the quarterly returns to the R&D Sub-Committee had been considered (so that they are aware of the figures being reported to WG), however the wide circulation of this and other reports is made difficult by the personal salary information and names contained within the reports. A process has now been developed to overcome this. | Finance Business Partner<br><br>10th February 2020 |

| Finding 5 – Grant Submissions (O) | Risk |
|---|---|
| Testing was undertaken on a sample of four grant submissions to ensure appropriate approval was evident. Concluding a review of the grant documents, we identified two submissions where the signatures of the grant applicant and | Patient harm due to poor management of trials/research. |

| | |
|---|---|
| R&D Director were not evident on retained documents provided to Internal Audit. | |
| **Recommendation 5** | **Priority level** |
| **Management should ensure that signed and dated copies of all grant submission documents are retained on file.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| This is accepted. Management will ensure the documentation for all 'awarded grants' and live studies is held on file. All signed documents will be stored electronically and hard copies within a study specific Trial Master File or Grants Log. | Senior Researcher Development & Grants Manager<br><br>1st April 2020 |

| **Finding 6 – R&D Strategy Document (D)** | **Risk** |
|---|---|
| The Health Board's internet site has uploaded the *Research and Development Strategy 2016-2020* (version 4). However, no evidence to support its submission or approval was evident at the University Partnership Board (UPB) in May 2018 nor by the Senior R&D Manager or Information Governance Manager. Approval by the UPB was evident for *Research and Development Strategy 2016-2020* (version 3). | R&D does not deliver work aligned to the overall strategic objectives of the UHB nor Health and Care Research Wales (HCRW). |
| **Recommendation 6** | **Priority level** |

| **Management should ensure that only a formally approved Research & Development Strategy document is uploaded onto the Health Board's internet page.** | **MEDIUM** |
|---|---|
| **Management Response** | **Responsible Officer/ Deadline** |
| The document in question (Strategy v4) has been uploaded into the document library on the internet site, however it has not been activated so is not visible to people viewing the page in the normal way. The version visible to people viewing the site is v3.<br><br>Regarding the formal approval of v4:<br>• There is an email trail (dated 10.5.18) from the Policy Co-Ordination Officer to the Senior R&D Manager requesting that the document be reviewed by the R&D sub-committee following minor changes. These were to change any reference to the 'Data Protection Act' to 'the Data Protection Act/General Data Protection Regulations (2016) or any subsequent legislation to the same effect'. This was forwarded (10.5.18) to the Research Governance Officer who was servicing the R&D sub-committee.<br>• There is evidence that this item was on the agenda under AOB (Agenda item 11.1) for the sub-committee meeting dated 21.5.18.<br>• The table of actions following this meeting contain the entry (no.23) "Minor changes to R&D Strategy (GDPR) approved by Committee members. The Research Governance Officer to inform the Policy Co-Ordination Officer". A further entry on this table of actions states | Senior R&D Manager<br><br>17th February 2020 |

| | |
|---|---|
| "Complete 23.05.18. Action to be removed".<br><br>The issue would therefore appear to be incorrect completion of the front section of the strategy v4 (referring to UPB approval rather than RDSC approval), and our failure to ensure that v4 is visible and v3 is removed.<br><br>An email has been sent to the Policy Co-Ordination Officer asking her to revise the front page of v4 so that it is correct. Once this has been done v3 of the strategy will be removed from the internet and v4 used in its place. | |

| **Finding 7 – Declarations on Corporate Registers (O)** | **Risk** |
|---|---|
| A review was also undertaken to establish whether R&D Department staff had registered any interests, gifts or hospitality/ sponsorship in line with the Health Board's Standing Orders. Whilst all R&D employees updated their Declaration of Interests forms in June 2019, a review of the organisational registers published on the Health Board's website (including gifts, hospitality and sponsorship) noted that entries had not been updated since 2017. | Lack of governance and management of the R&D Department. |
| **Recommendation 7** | **Priority level** |
| **R&D Management should ensure the Health Board registers of gifts, sponsorship and hospitality are accurate and up-to-date, with staff reminded of their requirement to comply with the Standards of Behaviour Policy.** | **MEDIUM** |

| Management Response | Responsible Officer/ Deadline |
|---|---|
| A process for routinely updating registers through the R&D SMT and management structures across research and development has now been introduced. In addition, the question will be added to the start of every meeting agenda (starting with Senior Management Team meeting on 17.2.20) to ensure it is a routine part of R&D business. | Senior Research and Development Operations Manager<br><br>17th February 2020 |

| Finding 8 – Risk Register (O) | Risk |
|---|---|
| A review of the R&D risk register, as at 17th December 2019, noted that one risk (Ref. 145) had not been updated since May 2018, whilst another risk (Ref. 149) appears to have implemented actions, yet the risk remains on the register rather than accepting the mitigating risk. | Lack of governance and management of the R&D Department. |
| **Recommendation 8** | **Priority level** |
| **R&D Management should review the risk register to ensure all actions are updated on a regular basis and the application of risk treatment is accurate and correct.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| A strengthened process of risk management has now been introduced. Management of individual risks have been re-assigned to ensure they are 'owned' by a named person. Risks and associated action plans to mitigate the risks will be reviewed monthly by the Senior Management Team, with | Senior Research and Development Operations Manager<br><br>17th February 2020 |

| | |
|---|---|
| escalation to the R&D sub-committee where necessary, and removal of the risk where appropriate. | |

| **Finding 9 – Sickness Absence (O)** | **Risk** |
|---|---|
| Of the 10 periods of sickness reviewed, documentation relating to two sickness absences could not be located. However, we noted that the Return to Work forms have now been completed retrospectively. Of the eight periods of sickness tested, we noted:<br><br>• A sickness absence for one employee where the self-certificate was incomplete with no start or end dates of sickness recorded and no manager signature, whilst the return to work interview was undertaken 16 days after the employee returned to work.<br>• A sickness absence for one employee where self-certificate employee and manager signatures were dated incorrectly, whilst the RTW form employee signature was dated incorrectly. | Lack of governance and management of the R&D Department. |
| **Recommendation 9** | **Priority level** |
| **Department managers and leads should ensure that the management of all periods of sickness complies with the NHS Wales Managing Attendance at Work Policy.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |

| | |
|---|---|
| Management arrangements have been strengthened through an OCP and management gaps have been addressed. A team based structure is now in place with each team leader managing a maximum of 6 staff. An email has been sent to all team leaders reminding them of the NHS Wales Managing Attendance at Work Policy and requesting that they attend an update. This will be checked in their next 1:1s. | Senior Research and Development Operations Manager<br><br>1st April 2020 |

| **Finding 10 – PADR Form (O)** | **Risk** |
|---|---|
| Of the 18 personal objectives reviewed, the majority of objectives were specific, measurable, achievable, realistic and timely. However, we noted that one employee did not have any objectives set out in their PADR form, whilst three objectives were not measurable or timely. In addition, the PADR forms used to capture employee's appraisals did not match the latest approved PADR forms. | Lack of governance and management of the R&D Department. |
| **Recommendation 10** | **Priority level** |
| **R&D Department management should ensure all objectives recorded in employee PADRs are consistent with the SMART principle set out in the Performance Appraisal and Personal Development Plan Policy, and are captured on the latest approved PADR proforma.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| PADRs are undertaken on a regular basis throughout the year. Figures from team leaders suggest that upwards of 90% of staff have a current PADR. Those | Senior Research and Development Operations Manager |

| | |
|---|---|
| PADRs which are out of date are planned.<br><br>There are a number of new team leaders within the R&D department. A workshop on writing SMART objectives is planned for March. Line-managers will ensure that everyone has been on the Health Board PADR training session and this will be reviewed in 1:1s. Staff will be reminded to download the most up-to-date version of the PADR form when preparing for their next PADR. | 1st April 2020 |

| **Finding 11 – Travel Claims (D)** | **Risk** |
|---|---|
| Travel claims were unable to be reconciled for three employees due to the unavailability of their diaries to line managers in their absence due to terminating their employment or being on leave. | Lack of governance and management of the R&D Department. |
| **Recommendation 11** | **Priority level** |
| **Management should ensure all R&D employees accurately maintain their diaries to enable line mangers to reconcile submitted travel claims.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| All managers routinely check and reconcile claims but a reminder of the requirement to make sure calendars can be accessed by others has been issued. This will continue to be checked in 1:1s. | Senior Research and Development Operations Manager<br><br>1st April 2020 |

| Finding 12 – Standard Operating Procedures (O) | Risk |
|---|---|
| There are currently 16 extant SOPs that require reviewing. However, due to the organisational constraints pending the outcome and approval of an Organisational Change Process and prioritisation of audits, this has delayed the drafting of these documents. | R&D is of poor quality. |
| **Recommendation 12** | **Priority level** |
| **Management should ensure that all extant Research & Development standard operating procedures are reviewed, submitted for approval and published on the organisation's intranet site.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| A timeline for the review of SOPs has been prepared for discussion in the SMT on 17.2.20. This will ensure that all SOPs are reviewed on a rolling programme. All 16 outstanding SOPs will be reviewed, approved and published by January 2021. | Senior R&D Manager<br><br>31st January 2021 |

| Finding 13 – Research Application Checklist (O) | Risk |
|---|---|
| 'Research Application Checklist' documents were evident for the four research studies sampled. However, we noted that some forms were partially completed (e.g. IDEAL-2). This was raised at the time of testing with the R&D Manager who informed us that the information would be on saved the ReDA system. | Patient harm due to poor management of trials/research. |

| Recommendation 13 | Priority level |
|---|---|
| **Management should assess the need to maintain the research application documents and checklists given that evidence is captured and retained on the IRAS system.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| As described in the 'finding' section above, all the information is captured electronically in ReDA, ie ReDA Cymru and in more recent months in ReDA3 (LPMS).<br><br>The office checklist is not a requirement for good management of trials/research - it is in addition as an aide memoir for staff working on study set-up on a day to day basis to easily refer to when queries come in, therefore only limited information is completed e.g. outstanding issues, acronyms etc.<br><br>In recent weeks, the Study Set Up Manager, as part of a task and finish group in HCRW has developed a new checklist for in-office assistance to be used as required (in paper or electronic format). It is not mandated, nor is there a need for it to be fully completed as the ReDA3/LPMS system is used for this purpose (our current data completeness is recorded as 100% in LPMS). | R&D Manager<br><br>10th February 2020. |

# Appendix B - Assurance Opinion and Action Plan Risk Rating

## 2019/20 Audit Assurance Ratings

 **Substantial Assurance** - The Board can take **substantial assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Few matters require attention and are compliance or advisory in nature with **low impact on residual risk** exposure.

 **Reasonable Assurance** - The Board can take **reasonable assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Some matters require management attention in control design or compliance with **low to moderate impact on residual risk** exposure until resolved.

 **Limited Assurance -** The Board can take **limited assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. More significant matters require management attention with **moderate impact on residual risk** exposure until resolved.

 **No Assurance** - The Board has **no assurance** arrangements in place to secure governance, risk management and internal control, within those areas under review, which are suitably designed and applied effectively. Action is required to address the whole control framework in this area with **high impact on residual risk** exposure until resolved.

## Prioritisation of Recommendations

In order to assist management in using our reports, we categorise our recommendations according to their level of priority as follows.

| Priority Level | Explanation | Management action |
|---|---|---|
| **High** | Poor key control design OR widespread non-compliance with key controls.<br>PLUS<br>Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement. | Immediate* |
| **Medium** | Minor weakness in control design OR limited non-compliance with established controls.<br>PLUS<br>Some risk to achievement of a system objective. | Within One Month* |
| **Low** | Potential to enhance system design to improve efficiency or effectiveness of controls.<br>These are generally issues of good practice for management consideration. | Within Three Months* |

* Unless a more appropriate timescale is identified/agreed at the assignment.


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# Hywel Dda University Health Board

# Research & Development Department Governance Review

## Final Internal Audit Report

## February 2020

## Private and Confidential

## NHS Wales Shared Services Partnership

## Audit and Assurance Services

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| **Auditor/s:** | Gareth Heaven & Sian Bevan |
| **Executive sign off:** | Philip Kloer (Medical Director) |
| **Distribution:** | Leighton Phillips (Deputy Director of Research & Innovation)<br>Keir Lewis (R&D Director – *at time of fieldwork*)<br>Subhamay Ghosh (Consultant/ Interim R&D Director) |
| **Committee:** | Audit & Risk Committee |

Audit and Assurance Services conform with all Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Institute of Internal Auditors.

**ACKNOWLEDGEMENT**
NHS Wales Audit & Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

**Disclaimer notice - Please note:**

This audit report has been prepared for internal use only. Audit & Assurance Services reports are prepared, in accordance with the Service Strategy and Terms of Reference, approved by the Audit & Risk Committee.

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## 1. Introduction and Background

The review of the management of Research & Development (R&D) Department within the Health Board was completed in line with the Internal Audit Plan 2019/20. The relevant lead Executive Director for the assignment was the Medical Director.

## 2. Scope and Objectives

The overall objective of the review was to assess the adequacy of arrangements for the management of R&D in order to provide assurance to the Audit & Risk Assurance Committee that risks material to the achievement of systems objectives are managed appropriately. The scope of the review was to ensure that:

- There is an appropriate process that ensures that guidance is in place for R&D and that research is approved and of an appropriate quality and relevance to the Health Board; and
- The R&D department is appropriately managed and governed.

The main areas that the review sought to provide assurance on are:

- There are appropriate organisational arrangements in place for the management of research & development, including the structure for R&D within the Health Board, management of the R&D team, reporting and monitoring, also considering the links with HCRW;
- The Health Board produces appropriate guidance and training for the management of research & development studies/trials which is distributed appropriately throughout the Health Board;
- Approval processes ensure that research is of an appropriate quality, and relevant to the Health Board; and
- All R&D projects in the Health Board are appropriately peer and risk reviewed, approved, and comply with research governance standards and statutory requirements.

## 3. Associated Risks

The potential risk considered in the review was as follows:

- R&D does not deliver work aligned to the overall strategic objectives of the Health Board nor Health & Care Research Wales (HCRW);
- R&D is of poor quality;
- Patient harm due to poor management of trials/research; and
- Lack of governance and management of the R&D Department.

## OPINION AND KEY FINDINGS

### 4. Overall Assurance Opinion

We are required to provide an opinion as to the adequacy and effectiveness of the system of internal control under review. The opinion is based on the work performed as set out in the scope and objectives within this report. An overall assurance rating is provided describing the effectiveness of the system of internal control in place to manage the identified risks associated with the objectives covered in this review.

The level of assurance given as to the effectiveness of the system of internal control in place to manage the risks associated with the Research and Development Department Governance Review is **Limited** assurance.

| RATING | INDICATOR | DEFINITION |
|---|---|---|
| **Limited Assurance** |  | The Board can take **limited assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. More significant matters require management attention with **moderate impact on residual risk** exposure until resolved. |

The overall level of assurance that can be assigned to a review is dependent on the severity of the findings as applied against the specific review objectives and should therefore be considered in that context.

A review of the management and governance processes of the Research & Development (R&D) Department identified the establishment of a statutory sub-committee supported by local groups that review and manage the performance and development of research studies and grants. However, we identified a number of high priority findings that require addressing, including:

- The R&D Sub-Committee (RDSC) annual report for 2018/19 has not been submitted to the University Partnership Board meeting within six weeks of the end of the financial year.
- Quarterly investigation account reports, introduced in June 2019, were required to been submitted to Health & Care Research Wales (HCRW). However, the first set of quarterly reports were submitted in November 2019.
- No adequate arrangements were in place to ensure that invoices received from Swansea University in relation to the R&D Director were support by a breakdown of costs.

- No finance reports or updates have been submitted to the RDSC since February 2019.

We also noted a number of medium priority findings in relation to the publication of an unapproved R&D Strategy document, no R&D entries on the staff interests/ gifts/ hospitality/ sponsorship registers since 2017, lack of updates noted on the risk register, instances of non-compliance for the management of sickness absence and PADR objectives.

The appropriate guidance and training for the management of research and development studies and trials was evident through the suite of standard operating procedures. However, a medium priority finding was identified with 16 extant SOPs that have not yet been reviewed or submitted for approval.

Whilst we noted that research studies undertaken by the Health Board had been review and approved by the R&D Department and Ethics Committee prior to their commencement, a high priority finding was identified where the signatures of the grant applicant and R&D Director were not evident on retained documents provided to Internal Audit.

## 5. Assurance Summary

The summary of assurance given against the individual objectives is described in the table below:

| | | Assurance Summary* | | | |
|---|---|---|---|---|---|
| **Audit Objective** | |  |  |  |  |
| **1** | There are appropriate organisational arrangements in place for the management of research & development, including the structure for R&D within the Health Board, management of the R&D team, reporting and monitoring, also considering the links with HCRW | | ✓ | | |
| **2** | The Health Board produces appropriate guidance and training for the management of research and development studies/trials which is distributed | | | ✓ | |

| Audit Objective | | Assurance Summary* | | | |
|---|---|---|---|---|---|
| | |  |  |  |  |
| | appropriately throughout the Health Board | | | | |
| 3 | Approval processes ensure that research is of an appropriate quality and relevant to the Health Board | | | ✓ | |
| 4 | All R&D projects in the Health Board are appropriately peer and risk reviewed, approved, and comply with research governance standards and statutory requirements | | | | ✓ |

** The above ratings are not necessarily given equal weighting when generating the audit opinion.*

## Design of Systems/Controls

The findings from the review have highlighted **three** issues that are classified as weakness in the system control/design of governance arrangements within the Research and Development Department. These are identified in the Management Action Plan as (D).

## Operation of System/Controls

The findings from the review have highlighted **10** issues that are classified as weakness in the operation of the designed system/control of governance arrangements within the Research and Development Department. These are identified in the Management Action Plan as (O).

## 6. Summary of Audit Findings

The key findings are reported in the Management Action Plan at Appendix A.

**OBJECTIVE 1: There are appropriate organisational arrangements in place for the management of research & development, including the structure for R&D within the Health Board, management of the R&D team, reporting and monitoring, also considering the links with HCRW**

Strategy

The Health Board has a *Research and Development Strategy 2016-2020* in place that sets out the strategic direction for Research and Development (R&D) within the organisation. A 'version 3' copy of the strategy document was approved by the University Partnership Board (UPD) in April 2016 and was published on the R&D internet site. However, a 'version 4' had also been uploaded on the Health Board site. Concluding discussion with the Senior R&D Manager and Information Governance Manager, they were unaware of a 'version 4' strategy document; whilst there was no evidence of its approval in UPB minutes in May 2018.

**See Finding 6 in Appendix A.**

R&D Sub-Committee

The R&D Sub-Committee (RDSC) was established in 2015 as a sub-committee of the University Partnership Board (UPB) and can confirm that an approved term of reference was in place. The supporting groups of the RDSC are the Research Quality Management Group (RQMG) and the Sponsorship Review Panel (SRP). We can confirm reports from both supporting groups were submitted to the RDSC during 2019.

The RDSC is required to provide regular formal reports of the sub-committee's activities and an annual report to be submitted within six weeks of the end of the financial year to the UPB as outlined in the term of reference. Whilst we can confirm the RDSC regular reported to the UPB for the period April 2018 to September 2019, the annual report for 2018/19 had not been submitted to the UPB within six weeks of the end of the financial year (i.e. May 2019 meeting).

**See Finding 1 in Appendix A.**

Declaration of Interest, Gifts, Hospitality & Sponsorship

A review was undertaken to establish assurance that staff within the R&D Department were aware of the requirements of the declaration of interest, gifts and hospitality policy.

Whilst all R&D employees updated their Declaration of Interests forms in June 2019, a review of the organisational registers published on the Health Board's

website (including gifts, hospitality and sponsorship) noted that entries had not been updated since 2017.

**See Finding 7 at Appendix A.**

Risk Management

The R&D Department has an operational risk register in place. A review was undertaken of the operational risk register as at 17th December 2019. Concluding our review, we noted the following:

- One risk (Ref. 145) had not been updated since May 2018.
- One risk (Ref. 149) appears to have implemented satisfactory actions to mitigate the risk, yet the risk remains on the register.

We can confirm that the risk register was regularly submitted to the RDSC during 2019 and evidence of discussion and scrutiny of the listed risks were evident in the sub-committee minutes.

**See Finding 8 at Appendix A.**

Finance

In June 2019, a new dedicated finance team was established to support the R&D Department. The finance team, in conjunction with the Deputy Director for Research & Innovation, have undertaken work on establishing governance arrangements and internal controls in regard of R&D finances, including the identification of budget holders and a scheme of financial delegation in line with Standing Financial Instructions and Standing Orders.

The Finance Department are required to submit regular update reports to the RDSC. However, a review of the RDSC meetings for 2019 noted that a Finance report had not been submitted to the since February 2019.

The R&D Finance Team have established regular monthly meetings with the R&D Department to discuss and review the financial position and performance. In addition, the Senior R&D Manager also has access to the QlikView system to monitor finances.

A number of identified researchers are responsible for investigation accounts, with quarterly reports required to be submitted to Health & Care Research Wales via the Finance Department. The first set of reports were due to be submitted in June 2019. However, the first set of submissions were made in November 2019.

The R&D Director has an honorary contract with the Health Board as a Consultant within Respiratory Medicine in addition to the R&D role for one session. Payment of the R&D Director salary is made via regular invoices from Swansea University.

Following receipt of the invoice into the Finance Department, authorisation was sought from the Assistant General Manager (General Medicine) prior to processing the payment.

However, information of the R&D Director's financial breakdown in relation to work undertaken was unable to be provided with no reconciliatory checks undertaken to ensure submitted costs were accurate prior to approval of payment.

In December 2019, the R&D Director stood down from his role within the R&D Department. The R&D Department should ensure that payments for the role of R&D Director are not included in future invoices received from Swansea University.

**See Findings 2, 3 & 4 at Appendix A.**

Workforce

A sample of 10 periods of sickness were selected and tested to ensure appropriate actions had been taken and documented in line with the *NHS Wales Managing Attendance at Work Policy*. Of the 10 periods of sickness chosen within our sample, documentation relating to two periods of absence could not be located. However, we have noted that the Return to Work (RTW) forms have now been completed retrospectively. Of the eight periods of sickness where documents were retained on file, we noted:

- A sickness absence for one employee where the self-certificate was incomplete with no start or end dates of sickness recorded and no manager signature, whilst the return to work interview was undertaken 16 days after the employee returned to work.

- A sickness absence for one employee where self-certificate employee and manager signatures were dated incorrectly, whilst the RTW form employee signature was dated incorrectly.

Five employee personal appraisal development review (PADR) forms were tested to ensure personal objectives align with the Health Board's Policy referring to the use of SMART objectives. Of the five PADRs selected within our sample, 18 personal objectives had been created. We noted that some objectives were not measurable or timely, whilst an older version of the PADR form was evident for one individual. We also noted that one employee's PADR did not have any set personal objectives.

**See Findings 9 & 10 at Appendix A.**

Incident Reporting

Incidents involved in research studies will prompt a trigger audit by the R&D Department. A review of the Research Quality Management Group meetings for the period January – September 2019 noted that the reporting and scrutiny of triggered audits was evident.

Travel Claims

A sample of five employees with the highest travel claim costs were selected from a claims report obtained from the e-Expenses system for the period September 2018 to August 2019. Of the five employees tested, we were able to reconcile two employees travel claims to their personal electronic diaries. However, three employees were unable to be tested due to terminating employment with the Health Board or being on leave.

**See Finding 11 at Appendix A.**

## OBJECTIVE 2: The Health Board produces appropriate guidance and training for the management of research and development studies/ trials which is distributed appropriately throughout the Health Board

A review of research and development standard operating procedures (SOPs) was undertaken to ensure all had been approved and distributed throughout the Health Board. Concluding our review, we noted that three SOPs had recently been reviewed and distributed to R&D Sub-Committee members for review and feedback prior to their publication in January 2019 on the organisation's intranet site. However, due to the organisational constraints pending the outcome and approval of an Organisational Change Process and the prioritisation of audits within the R&D Department, 16 extant SOPs had not been reviewed.

**See Finding 12 at Appendix A.**

## OBJECTIVE 3: Approval processes ensure that research is of appropriate quality relevant to the Health Board

All research studies undertaken by the Health Board require review and approval from the R&D Department and Ethics Committee prior to their commencement. A sample of four research studies was selected from the Research Database Application (ReDA) active studies report.

We can confirm that approval by the R&D Department and relevant Ethics Committee was evident and that the appropriate steps in drawing up a study (sponsored and non-sponsored) were followed as per the Standard Operating Procedures for Research & Development. Whilst we noted that research study information was retained on the ReDA system, some Health Board documents such as the 'Research Application Checklist' were not always fully completed.

Concluding a review of four successfully applied grants for 2018/19, we identified two submissions, *Patient Involvement PtP* and *Research to Publication*, where the signatures of the grant applicant and R&D Director were not evident on retained documents provided to Internal Audit.

**See Findings 5 & 13 at Appendix A.**

### OBJECTIVE 4: All R&D projects in the Health Board are appropriately peer and risk reviewed, approved and comply with research governance standards and statutory requirements

All research projects are risk assessed by the R&D Department prior to the application submission. Of the four studies selected for testing, we can confirm that a risk assessment had been undertaken and captured on local R&D forms.

The Quality Assurance Officer (Research) is responsible for undertaking routine & triggered audits and monitoring visits for all successful research projects to ensure compliance with governance standards and statutory requirements. These audits and visits are captured on a local register and are prioritised on a risk-based approach. Of the four research studies tested, only LungCast had been audited to date. The three other studies within our sample were scheduled to be audited in 2020 due to their low risk assessment that was evident on retained local R&D forms.

**No matters arising.**

## 7. Summary of Recommendations

The audit findings and recommendations are detailed in Appendix A together with the management action plan and implementation timetable.

A summary of these recommendations by priority is outlined below.

| Priority | H | M | L | Total |
|---|---|---|---|---|
| **Number of recommendations** | **5** | **8** | **0** | **13** |

### Context to Management Response

At the last ARAC on 25th February, committee members asked for the findings of the audit report to be contextualised in view of recent changes to the structure and function of Research and Development in Hywel Dda University Health Board, in advance of providing a detailed response to each recommendation. The following two sections provide this context.

### 7.1 Research and Development in Hywel Dda University Health Board

The Research and Development Department in HDUHB performs three main functions, each supported by a team (members of each team work across all functions):

- Research Delivery – this team facilitates and supports the local set up and delivery of Health and Care Research Wales Portfolio studies and some commercial studies. The team is predominantly made up of research nurses and assistants but also includes some other staff essential to the conduct of research, including pharmacy and laboratory services. There is a research team at each of the Health Board's hospital sites;

- Core R&D functions (including governance) – this team deals with the local NHS Support and Management of R&D. This team deals with study set up, applications for regulatory approvals, ethical and NHS permissions. The governance team specifically deals with monitoring and auditing sponsored studies to ensure compliance, reporting to the MHRA on adverse events, breaches and urgent safety measures; and

- Researcher Development – this includes supporting researchers and supporting them to submit bids to grant funders, running pilot and feasibility studies, developing a greater number of principal and chief investigators within the organisation, and supporting the development of in-house research and evaluation.

The Research and Development Department receives the majority of its funding from Health and Care Research Wales (circa £1m per annum) to support the activities of these teams. In addition, it is encouraged to supplement this income by applying for research grants or entering agreements with commercial research funders (e.g. a drug company wishing to undertake a trial of a new medication). The benefits of generating high levels of research activity within the NHS are well documented to include improving care for patients, providing evidence on the efficacy of new healthcare treatments, supporting continuous improvement, assisting recruitment and retention and income generation. A high performing Research and Development function is critical to Hywel Dda University Health Board, as demonstrated by its significant recent contribution to the research endeavours associated with the Coronavirus, which has in several ways boosted research activity within the organisation. The context offered by the clinical services strategy also provides a significant and ongoing role for research.

The Research and Development Department has two reporting lines.
It is accountable to Health and Care Research Wales (HaCRW) and the Welsh Government for the way in spends the grant it receives on an annual basis and several research performance indicators. The key performance indicators include contributions towards:

- Number of applications to National Institute for Health Research (NIHR) Evaluation, Trials and Studies (NETS), (and any similar UK funding schemes in which Health and Care Research Wales participates);
- Commercial income generated;
- Number of papers published in journals;
- Number of Health and Care Research Wales PhD Studentships awarded;
- Number of Health and Care Research Wales Fellows obtaining Principal Investigator (PI) portfolio eligible grant funding within 3 years of completion of their award;
- Number of full NHS Ethics applications processed;
- Number of recruiting NHS Clinical Research Portfolio (CRP) studies;
- Number of NHS Clinical Research Portfolio and commercial studies receiving NHS Research Permissions;
- Number of participants recruited to NHS Clinical Research Portfolio studies;
- Number of recruiting NHS commercial sponsored studies;
- Number of studies on the social care portfolio;
- Number of samples in supported tissue banks; and
- Number of Health and Care Research Wales funded students or fellows in a mentorship scheme.
- Hywel Dda University Health Board is recognised nationally as having a very good Research and Development Department, which has received significant increases in the funding it is allocated over a 10 year period. It

strictly adheres to Health and Care Research Wales guidelines and the funding it receives is a direct reflection of the activity it generates.

The Research and Development Department is also accountable to Hywel Dda University Health Board, now through the Research and Development Sub Committee and the Quality, Safety and Experience Assurance Committee. The leadership and management of R&D is within the Medical Department. The Health Board's level of involvement in the governance and management of Research and Development increased from 1st October 2016, when the staff within the national research workforce were transferred into Health Boards and integrated team structures were established. The reality is that the Research and Department has to continuously look in two directions, as HaCRW also offer a number of advisory functions to the Health Board, offering specialist advice in respect of research matters, which the Health Board's corporate functions are not used to routinely dealing with. This might be, for example, ensuring a contract with a pharmaceutical company to enable the testing of a new and novel drug.

**Context to the Audit Report**

The overall audit opinion should be read in the context of a challenging period for the Research and Development Department. The fundamentals of the Department remain strong and many of the recommendations made by internal audit are straight forward to address. While a detailed response is offered to each of the recommendations in the usual format, Audit and Assurance Committee are asked to note that the root causes of the main issues raised have now been addressed, notably:

- The Department has concluded a restructure to ensure the size of the department and leadership structures are optimally configured to deliver high quality research while meeting the standards and expectations of the Health Board. The organisational change process guiding the res-structure was introduced in acknowledgement that the old arrangements were not fit for purpose in view of the substantial growth experienced by the R&D function. High levels of research activity place additional pressures on team members recruiting into trials and following up patients, study set up and governance. A key appointment as part of the restructure is a senior operational manager sitting across the three functions of the Department and ensure high management standards;

- Business continuity arrangements are significantly stronger. There have been significant gaps in the leadership structure, with staff leaving to take on new opportunities, maternity leave, and sickness absence. While some absence is to be expected in any team, unfortunately the absences have been lengthy and in key areas. There has also been insufficient succession planning and cover arrangements within the team. This has and will

continue to be addressed with succession planning and equipping more than one person in every team with the ability to cover the jobs of others being a key responsibility for all team members; and

- The fragility experienced in service delivery arrangements has also been felt in research, limiting the number of principle and chief investigators that are able to supervise research within the organisation. What's more, when services are stretched, time for research is usually the first thing that is compromised. While making such decisions might seem reasonable in the short term, in the medium to long term it could compromise the organisation's ability to retain talented clinical staff. It is also well documented that research active clinicians are often those who are at the top of their game in delivering high quality care. While acknowledging there is no easy fix to this, all parts of the Health Board must continue to acknowledge and support staff to become research active and in doing so the wider operations of the department will benefit. Most decisions regarding time for research sit outside of the core functions of the Research and Development Department.

In conclusion, while on the surface, the audit opinion is disappointing, nearly all the issues raised have been resolve in part due to wider developments in the R&D Department that were in motion in advance of the audit taking place. The one additional issue raised at ARAC on 25 February related to moving from the interim leadership arrangements to a substantive solution. The work to address this point has been delayed for two reasons. The first is a recently announced review of the role of Research and Development Directors, commissioned by HaCRW. As they fund all R&D Directors, it will be important to take account of their conclusions in the job description for the new role. Secondly, the R&D Department has prioritised its work on the COVID-19 research studies that have formed the third point of the Government's four point plan to address the awful disease (See appendix 1). A combination of these factors mean that the substantive solution will now not be in place until the autumn at the earliest. The interim arrangements have not in any way delayed the implementation of the recommendations.

| Finding 1 – RDSC Annual Report 2018/19 (O) | Risk |
|---|---|
| The RDSC annual report for 2018/19 has not been submitted to the UPB meeting within six weeks of the end of the financial year as explicitly noted in the RDSC TOR. | Lack of governance and management of the R&D Department. |
| **Recommendation 1** | **Priority level** |
| **The Research & Development Sub-Committee should ensure that the annual report for 2018/19 is submitted to the appropriate committee meeting and future reports should be submitted within six weeks of the end of the financial year.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| The report is complete and has been circulated to R&D Sub Committee Members and included in the QSEAC papers to note.<br><br>A formal and time bound process of producing end of year reports is now in place. The 2019/20 report, for example, is now complete. | Deputy Director, Research and Innovation.<br><br>31 March 2020. |

| Finding 2 – HCRW Financial Returns (O) | Risk |
|---|---|

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|---|---|
| A number of identified researchers are responsible for investigation accounts, with quarterly reports required to be submitted to Health & Care Research Wales via the Finance Department. The first set of reports were due to be submitted in June 2019. However, the first set of submissions were made in November 2019. | Lack of governance and management of the R&D Department. |
| **Recommendation 2** | **Priority level** |
| **R&D Management should ensure individual researchers assigned investigation accounts promptly complete and submit their quarterly returns to Health & Care Research Wales via the Finance Department.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| While there has always been a clear policy in place, Investigators have been slow to submit their spending plans. The finance department has therefore introduced a process of consolidating any funds for which there is not a spending plan into a central capacity building account, for which there is a robust spending plan in place. No account now exists for which there is not an associated spending plan and there is no risk of this problem arising in the future. | Deputy Director for Research and Innovation<br><br>31 March 2020 |

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| **Finding 3 – R&D Director Payments (D)** | **Risk** |

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|---|---|
| The former R&D Director has an honorary contract with the Health Board as a Consultant within Respiratory Medicine in addition to the R&D role for one session. Payment of the R&D Director salary is made via regular invoices from Swansea University. However, no supplementary information is provided to validate the R&D Director's financial breakdown in relation to work undertaken. In December 2019, the R&D Director stood down from his post within the R&D Department. The R&D Department should ensure that payments for the role of R&D Director are not included in future invoices received from Swansea University. | Lack of governance and management of the R&D Department. |
| **Recommendation 3** | **Priority level** |
| **The R&D, General Medicine and Finance Departments should come together and establish a reconciliation arrangement to ensure invoices received from Swansea University for the tenure of the former R&D Director are accurate and correct prior to payment by the Health Board.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| The former R&D director is not paid directly by R&D. Invoices from Swansea University are received by Unscheduled Care and 0.2 sessions were recharged to R&D for the work that he did in supporting R&D. R&D have no input into invoicing arrangements with Swansea University. Finance have ensured that the recharges have dropped to 0.1 now that the former director has dropped his sessions, and if he steps back fully from R&D we will ensure that the recharges stop. This is all managed internally within finance. Part of the ongoing control of this will also be the monthly finance file which is sent out to the Senior Research & Development Operations Manager and Deputy Director | Director of Finance<br><br>28 February 2020 |

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|---|---|
| for Research & Innovation which will enable us to identify anyone who is being paid inappropriately. | |

| **Finding 4 – Finance Update Reports (O)** | **Risk** |
|---|---|
| A review of the R&D Sub-Committee 2019 meeting agendas and papers noted that a Finance report/update had not been submitted since February 2019. | Lack of governance and management of the R&D Department. |
| **Recommendation 4** | **Priority level** |
| **The Finance Department should ensure that an R&D financial position update should be reported to the R&D Sub-Committee on a regular basis.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| A change in Finance Team and reporting arrangement resulted in this finding. With a new team and system in place, this has now been resolved and written reports now being sent to every R&D Sub-Committee meeting. Financial reports against a spending plan are also routinely submitted to HaCRW. | Director of Finance<br><br>30 April 2020 |

| **Finding 5 – Grant Submissions (O)** | **Risk** |
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| Testing was undertaken on a sample of four grant submissions to ensure appropriate approval was evident. Concluding a review of the grant documents, we identified two submissions where the signatures of the grant applicant and R&D Director were not evident on retained documents provided to Internal Audit. | Patient harm due to poor management of trials/research. |
| **Recommendation 5** | **Priority level** |
| **Management should ensure that signed and dated copies of all grant submission documents are retained on file.** | **HIGH** |
| **Management Response** | **Responsible Officer/ Deadline** |
| This is accepted. Management will ensure the documentation for all 'awarded grants' and live studies is held on file. All signed documents will be stored electronically and hard copies within a study specific Trial Master File or Grants Log. | Deputy Director, Research and Innovation<br><br>1st April 2020 |

| **Finding 6 – R&D Strategy Document (D)** | **Risk** |
|---|---|
| The Health Board's internet site has uploaded the *Research and Development Strategy 2016-2020* (version 4). However, no evidence to support its submission or approval was evident at the University Partnership Board (UPB) in May 2018 nor by the Senior R&D Manager or Information Governance Manager. Approval by the UPB was evident for *Research and Development Strategy 2016-2020* (version 3). | R&D does not deliver work aligned to the overall strategic objectives of the UHB nor Health and Care Research Wales (HCRW). |

| Recommendation 6 | Priority level |
|---|---|
| **Management should ensure that only a formally approved Research & Development Strategy document is uploaded onto the Health Board's internet page.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| There was an error in the document coversheet. The correct and UPB approved version of the strategy (V4) is now on the Internet Site. | Deputy Director, Research and Innovation<br><br>28 February 2020 |

| Finding 7 – Declarations on Corporate Registers (O) | Risk |
|---|---|
| A review was also undertaken to establish whether R&D Department staff had registered any interests, gifts or hospitality/ sponsorship in line with the Health Board's Standing Orders. Whilst all R&D employees updated their Declaration of Interests forms in June 2019, a review of the organisational registers published on the Health Board's website (including gifts, hospitality and sponsorship) noted that entries had not been updated since 2017. | Lack of governance and management of the R&D Department. |
| **Recommendation 7** | **Priority level** |
| **R&D Management should ensure the Health Board registers of gifts, sponsorship and hospitality are accurate and up-to-date, with staff** | **MEDIUM** |

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|---|---|
| **reminded of their requirement to comply with the Standards of Behaviour Policy.** | |
| **Management Response** | **Responsible Officer/ Deadline** |
| A process for routinely updating registers through the R&D SMT and management structures across research and development has been introduced. In addition, the question will be added to the start of every meeting agenda to ensure it is a routine part of R&D business. | Deputy Director, Research and Innovation<br><br>28 February 2020 |

| **Finding 8 – Risk Register (O)** | **Risk** |
|---|---|
| A review of the R&D risk register, as at 17th December 2019, noted that one risk (Ref. 145) had not been updated since May 2018, whilst another risk (Ref. 149) appears to have implemented actions, yet the risk remains on the register rather than accepting the mitigating risk. | Lack of governance and management of the R&D Department. |
| **Recommendation 8** | **Priority level** |
| **R&D Management should review the risk register to ensure all actions are updated on a regular basis and the application of risk treatment is accurate and correct.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| A strengthened process of risk management has now been introduced. Management of individual risks have been re-assigned to ensure they are | Deputy Director, Research and Innovation |

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|---|---|
| 'owned' by a named person. Risks and associated action plans to mitigate the risks will be reviewed monthly by the Senior Management Team, with escalation to the R&D sub-committee where necessary, and removal of the risk where appropriate. | 28th February 2020 |

| **Finding 9 – Sickness Absence (O)** | **Risk** |
|---|---|
| Of the 10 periods of sickness reviewed, documentation relating to two sickness absences could not be located. However, we noted that the Return to Work forms have now been completed retrospectively. Of the eight periods of sickness tested, we noted:<br><br>• A sickness absence for one employee where the self-certificate was incomplete with no start or end dates of sickness recorded and no manager signature, whilst the return to work interview was undertaken 16 days after the employee returned to work.<br>• A sickness absence for one employee where self-certificate employee and manager signatures were dated incorrectly, whilst the RTW form employee signature was dated incorrectly. | Lack of governance and management of the R&D Department. |
| **Recommendation 9** | **Priority level** |
| **Department managers and leads should ensure that the management of all periods of sickness complies with the NHS Wales Managing Attendance at Work Policy.** | **MEDIUM** |

| Management Response | Responsible Officer/ Deadline |
|---|---|
| Management arrangements have been strengthened through an OCP and management gaps have been addressed. A team based structure is now in place with each team leader managing a maximum of 6 staff. An email has been sent to all team leaders reminding them of the NHS Wales Managing Attendance at Work Policy and requesting that they attend an update. This will be checked in their next 1:1s. | Deputy Director, Research and Innovation<br><br>1st April 2020 |

| Finding 10 – PADR Form (O) | Risk |
|---|---|
| Of the 18 personal objectives reviewed, the majority of objectives were specific, measurable, achievable, realistic and timely. However, we noted that one employee did not have any objectives set out in their PADR form, whilst three objectives were not measurable or timely. In addition, the PADR forms used to capture employee's appraisals did not match the latest approved PADR forms. | Lack of governance and management of the R&D Department. |
| **Recommendation 10** | **Priority level** |
| **R&D Department management should ensure all objectives recorded in employee PADRs are consistent with the SMART principle set out in the Performance Appraisal and Personal Development Plan Policy, and are captured on the latest approved PADR proforma.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |

| | |
|---|---|
| PADRs are undertaken on a regular basis throughout the year. Figures from team leaders suggest that upwards of 90% of staff have a current PADR. Those PADRs which are out of date are planned.<br><br>There are a number of new team leaders within the R&D department. A workshop on writing SMART objectives is planned for March. Line-managers will ensure that everyone has been on the Health Board PADR training session and this will be reviewed in 1:1s. Staff will be reminded to download the most up-to-date version of the PADR form when preparing for their next PADR. | Deputy Director, Research and Innovation<br><br>1st April 2020 |

| **Finding 11 – Travel Claims (D)** | **Risk** |
|---|---|
| Travel claims were unable to be reconciled for three employees due to the unavailability of their diaries to line managers in their absence due to terminating their employment or being on leave. | Lack of governance and management of the R&D Department. |
| **Recommendation 11** | **Priority level** |
| **Management should ensure all R&D employees accurately maintain their diaries to enable line mangers to reconcile submitted travel claims.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| All managers routinely check and reconcile claims but a reminder of the requirement to make sure calendars can be accessed by others has been issued. This will continue to be checked in 1:1s. | Deputy Director, Research and Innovation |

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|---|---|
| | 1st April 2020 |

| **Finding 12 – Standard Operating Procedures (O)** | **Risk** |
|---|---|
| There are currently 16 extant SOPs that require reviewing. However, due to the organisational constraints pending the outcome and approval of an Organisational Change Process and prioritisation of audits, this has delayed the drafting of these documents. | R&D is of poor quality. |
| **Recommendation 12** | **Priority level** |
| **Management should ensure that all extant Research & Development standard operating procedures are reviewed, submitted for approval and published on the organisation's intranet site.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| A timeline for the review of SOPs has been prepared for discussion in the SMT on 17.2.20. This will ensure that all SOPs are reviewed on a rolling programme. All 16 outstanding SOPs will be reviewed, approved and published by January 2021. | Deputy Director, Research and Innovation<br><br>31st January 2021 |

| **Finding 13 – Research Application Checklist (O)** | **Risk** |
|---|---|

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|---|---|
| 'Research Application Checklist' documents were evident for the four research studies sampled. However, we noted that some forms were partially completed (e.g. IDEAL-2). This was raised at the time of testing with the R&D Manager who informed us that the information would be on saved the ReDA system. | Patient harm due to poor management of trials/research. |
| **Recommendation 13** | **Priority level** |
| **Management should assess the need to maintain the research application documents and checklists given that evidence is captured and retained on the IRAS system.** | **MEDIUM** |
| **Management Response** | **Responsible Officer/ Deadline** |
| As described in the 'finding' section above, all the information is captured electronically in ReDA, ie ReDA Cymru and in more recent months in ReDA3 (LPMS).<br><br>The office checklist is not a requirement for good management of trials/research - it is in addition as an aide memoir for staff working on study set-up on a day to day basis to easily refer to when queries come in, therefore only limited information is completed e.g. outstanding issues, acronyms etc.<br><br>In recent weeks, the Study Set Up Manager, as part of a task and finish group in HCRW has developed a new checklist for in-office assistance to be used as required (in paper or electronic format). It is not mandated, nor is there a need for it to be fully completed as the ReDA3/LPMS system is used for this purpose (our current data completeness is recorded as 100% in LPMS). | Deputy Director, Research and Innovation<br><br>28th February 2020. |

## Appendix B - Assurance Opinion and Action Plan Risk Rating

### 2019/20 Audit Assurance Ratings

 **Substantial Assurance** - The Board can take **substantial assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Few matters require attention and are compliance or advisory in nature with **low impact on residual risk** exposure.

 **Reasonable Assurance** - The Board can take **reasonable assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Some matters require management attention in control design or compliance with **low to moderate impact on residual risk** exposure until resolved.

 **Limited Assurance -** The Board can take **limited assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. More significant matters require management attention with **moderate impact on residual risk** exposure until resolved.

 **No Assurance** - The Board has **no assurance** arrangements in place to secure governance, risk management and internal control, within those areas under review, which are suitably designed and applied effectively. Action is required to address the whole control framework in this area with **high impact on residual risk** exposure until resolved.

### Prioritisation of Recommendations

In order to assist management in using our reports, we categorise our recommendations according to their level of priority as follows.

| Priority Level | Explanation | Management action |
|---|---|---|
| **High** | Poor key control design OR widespread non-compliance with key controls.<br>PLUS<br>Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement. | Immediate* |
| **Medium** | Minor weakness in control design OR limited non-compliance with established controls.<br>PLUS<br>Some risk to achievement of a system objective. | Within One Month* |
| **Low** | Potential to enhance system design to improve efficiency or effectiveness of controls.<br>These are generally issues of good practice for management consideration. | Within Three Months* |

* Unless a more appropriate timescale is identified/agreed at the assignment.

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