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:**	R&D Activity Report
CYFARWYDDWR ARWEINIOL: **LEAD DIRECTOR:**	Dr Philip Kloer, Executive Medical Director / Deputy CEO
SWYDDOG ADRODD: **REPORTING OFFICER:**	Dr Caroline Williams, Senior Operations Manager R&D

Pwrpas yr Adroddiad (dewiswch fel yn addas) **Purpose of the Report** (select as appropriate)
Ar Gyfer Trafodaeth/For Discussion

ADRODDIAD SCAA
SBAR REPORT

Sefyllfa / Situation

The current coronavirus pandemic has inevitably impacted on the research and development (R&D) department, with all routine trials being suspended and the delivery team being asked to spend their time advancing nationally prioritised COVID-19 trials. Due to the cancellation of the last quarterly R&D Sub-Committee meeting in April 2020, there is no exception report from that meeting. The performance measures applying to R&D have also been suspended during this period.

In the absence of an exception report to QSEAC, this report outlines the current research activity being advanced by Hywel Dda University Health Board (HDdUHB) to support the national and international drive towards tackling the COVID-19 disease.

Cefndir / Background

Undertaking research is one of the four pillars of the government's strategic response to COVID-19, and Hywel Dda UHB is participating in this response. The importance of COVID-19 research has been emphasised at various times throughout the pandemic via letters from the Chief Medical Officer, the Chief Nursing Officer, and the Welsh Government. There is no proven treatment for COVID-19, therefore taking part in clinical trials gives patients in West Wales the opportunity to receive treatment that is not available outside of the trial.

In addition to taking part in national studies, the R&D team are developing and supporting studies which are sponsored by the UHB; submitting a variety of grant applications to support this work, and participating in other ways to support the overall COVID-19 response.

Asesiad / Assessment

There is a single, UK process in place to identify the COVID-19 studies which hold the most potential for tackling the challenges. All potential research studies are reviewed by the National Institute for Health Research (NIHR) to ensure that the most urgent and the ones most likely to be beneficial are prioritised. They also ensure that a variety of studies are adopted. These

studies are identified as Urgent Public Health (UPH) studies and their passage through the normal approval systems is expedited.

The Health Board is currently taking part in ten different national/international COVID-19 studies, with a further four either in set-up or under consideration. This is in addition to collecting samples for the Hywel Dda Biobank. The Health Board's recruitment into the Clinical Characterisation Protocol (CCP-UK) study is amongst the best in Wales. Two of these studies have been sponsored by Hywel Dda; its very first medical devices trial to support a regionally produced breathing device and a unique study designed to understand the variable immune response to the virus.

A staff stress and burnout survey has been developed in-house by the grant and innovation team in R&D and this is currently being completed across the organisation. In addition, members of the team have been working with Professor Keir Lewis, Respiratory Consultant to host live educational web events to support COVID-19 education. These have been recorded and once approved will be uploaded to the intranet. Grant applications to support this and other work have also been taking place.

Undertaking this work has raised the profile of research within the UHB, particularly amongst staff looking after the in-patients who are the main source of recruitment. This is a different picture to normal, where most research participants are recruited as out-patients. Staff have been interested and enthusiastic, and without their help and support, undertaking the research would have been much more challenging. The R&D Department has enrolled some new medical staff as Principal Investigators (PI) and given some trainees the chance to be co-PIs, and the number of staff undertaking the Good Clinical Practice course on-line has also increased. Taking part in this work has required collaborating with a range of different partners and this bodes well for future work. The R&D Department has also shown that it can set up studies safely and accurately in half the time it would normally take with the support from our internal study set up team and the Quality Assurance (QA) team within R&D.

Appendix A lists the studies that are currently open, in set-up, or where an expression of interest has been made. It includes the studies where Hywel Dda is the sponsor, and information about the Biobank.

Appendix B lists the activities of the development team. These activities include research grant applications and internal researcher development work.

It is anticipated that as organisations recover from the first peak of coronavirus, some routine research and development activity will be able to take place and the University Health Board has been asked by Health and Care Research Wales to assess which studies would be safe to reopen as the four nations of the UK emerge from this period of lockdown. An update on this, alongside a comprehensive overview of how the R&D department plans to recover from this period, will be provided to the next R&D Sub-Committee meeting.

Argymhelliad / Recommendation

QSEAC is asked to note the current research activity being advanced by Hywel Dda University Health Board (HDdUHB) to support the national and international drive towards tackling the COVID-19 disease.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	4.6 Provide assurance that the organisation is discharging its functions and meeting its responsibilities with regards to the quality and safety of research activity carried out within the Health Board.
Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	N/A
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	3.3 Quality Improvement, Research and Innovation 7. Staff and Resources
Nodau Gwella Ansawdd: Quality Improvement Goal(s):	All Quality Improvement Goals Apply
Amcanion Strategol y BIP: UHB Strategic Objectives:	All Strategic Objectives are applicable
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019	4. Improve Population Health through prevention and early intervention, supporting people to live happy and healthy lives 6. Contribute to global well-being through developing international networks and sharing of expertise

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	See links to studies above.
Rhestr Termau: Glossary of Terms:	Contained within the body of the report
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Ansawdd, Diogelwch a Sicrhau Profiod: Parties / Committees consulted prior to Quality, Safety and Experience Assurance Committee:	Strategic Management Team R&D

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: Financial / Service:	Any financial impact arising from this report have been covered through the routine COVID-19 planning

	arrangements (e.g. research nurses working weekends to recruit patients to trials). There might be a positive impact on our financial position if we are successful in capturing grants.
Ansawdd / Gofal Claf: **Quality / Patient Care:**	No adverse quality or patient care outcomes/impacts
Gweithlu: **Workforce:**	No adverse existing or future staffing impacts:
Risg: **Risk:**	No risks identified
Cyfreithiol: **Legal:**	No known likelihood of a legal challenge:
Enw Da: **Reputational:**	Yes. Potential for local media interest in the research studies / educational package
Gyfrinachedd: **Privacy:**	Research data, human tissue samples etc. may be shared with other NHS organisations and with academic, third sector and commercial research partners. The R&D Department has protocols and systems in place to ensure that research information which is used or shared is anonymised (no patient identifiable information leaves the organisation).
Cydraddoldeb: **Equality:**	Equality of patient/participant access to take part in research studies and clinical trials across all HDdUHB hospital sites has been a challenge due to a variety of factors including availability of local expertise, a shortage of research nurses due to COVID-19 restrictions, and a lack of infrastructure to deal with human tissue samples on some sites.

APPENDIX A – RESEARCH IN HYWEL DDA

NATIONAL/INTERNATIONAL PORTFOLIO STUDIES OPEN IN HYWEL DDA	NO. OF PATIENTS RECRUITED INTO THE STUDY FROM HDUHB
RECOVERY - IRAS 281712 An platform randomised trial looking at the effectiveness of re-purposed drugs for patients with suspected or confirmed COVID-19 Drugs currently in the trial in HDdUHB • Hydroxychloroquine • Azithromycin Patients are randomised between one of the drug arms and normal treatment. Outcomes are measured at 28 days https://www.recoverytrial.net A paediatric arm has also just opened in Glangwili General Hospital (GGH). Over 9,000 patients have been recruited into this study across the UK, and the first outcomes are expected to be presented in June 2020.	14
CCP-UK Tier 0 - IRAS 126600 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. Data collection only on patients who test positive for COVID-19. Data collected on Day 1, Day 3, Day 6, Day 9 & outcome https://isaric4c.net Early results from this study have been released in a pre-publication paper.	181
GENOMICC - IRAS 269326 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 https://genomicc.org Study opened on 11.05.2020	1

REMAP-CAP – IRAS 237150 A Randomized, Embedded, Multifactorial Adaptive Platform trial (REMAP) to trial a variety of re-purposed drugs and new treatments. For ICU patients only, to identify the effect of a range of interventions to improve outcome as defined by all-cause mortality at 90 days The domains in the study include • Corticosteroids • Antibiotics • Antivirals • Immune modulation • Convalescent Plasma • Therapeutic anticoagulation https://remapcap.org To open in GGH only.	In Set up
PRINCIPLE – - IRAS: 281958 Platform Randomised trial of INterventions against COVID-19 In older people - A Primary Care study to evaluate the use of Hydroxychloroquine in community healthcare settings with the aim of reducing the need for hospital assessment. The study is being co-ordinated by Health and Care Research Wales (HCRW) https://www.phctrials.ox.ac.uk/principle-trial	Seven GP practices in HDdUHB are taking part • Meddygfa Emlyn (Newcastle Emlyn) • Meddygfa Teilo (Llandeilo) • Borth Medical Practice • Lampeter Medical Practice • The Robert Street Practice (Pembroke Dock) • Barlow House Surgery (Milford Haven) • Preseli Practice - Newport & Crymych Surgery
FLU-CAT - IRAS: 30029 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. 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 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. 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) www.rcpch.ac.uk/work-we-do/bpsu

UK Obstetric Surveillance System (UKOSS). IRAS: 112935 Opened in April 2020 to collect data on any viral pandemics. A national Surveillance study of women hospitalised with confirmed COVID-19 in pregnancy. 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 Registry of bronchiectasis patients open since 2015, now open with a COVID-19 arm.	Existing patients in the EMBARC study are being screened every week to see if they have a +ve COVID-19 swab.

HYWEL DDA SPONSORED STUDIES	
CTEX RG7 - IRAS: 282487 (HDUHB Sponsored multisite device study) 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. A patient is placed on trial machine for 12hrs, and a record of their observations for an hour either side of the change onto the trial machine is recorded.	1
Characterising the immune response in COVID19. IRAS: 283234 (HDUHB Sponsored study). To identify patterns of immune response in people with COVID-19 at different stages / severity of illness. Blood samples taken from patients admitted with COVID-19	Opening 01.06.20. in PPH only
Hywel Dda BioBank. IRAS: The Hywel Dda biobank stores various tissue types and information about patient's health which can be used to help further research. Patients are asked to give consent for any leftover blood or other tissue to be donated to the BioBank and used in other studies. Currently the Biobank is recruiting people who either have COVID-19 or who have recovered from COVID-19	20

NATIONAL/INTERNATIONAL POTENTIAL STUDIES
CROWN CORONATION – IRAS 282280 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

Randomization will be stratified by age (<50 and >50) and site. Participants will be healthcare workers at risk for contracting SARS-CoV-2. https://clinicaltrials.gov/ct2/show/NCT04333732 https://www.nihr.ac.uk/covid-studies/study-detail.htm?entryId=282280
PAN-COVID - Pregnancy and Neonatal Outcomes in COVID-19. - IRAS: 282655 To develop a global database detailing a number of outcomes (death of the baby or mother, stillbirth, miscarriage, pregnancy complications, gestational age at delivery, delivery method and testing the baby for SARS-CoV-2). The aim of this database is to understand the natural history of SARS-CoV-2 and COVID-19 and the impact on mothers and their babies to guide both treatment and prevention. PI identified. Awaiting the approval from Maternity. https://www.nihr.ac.uk/covid-studies/study-detail.htm?entryId=282655
PRIEST - IRAS: 101138 An A&E study looking at the initial assessment / triage of patients with COVID-19. The aim is to identify the key signs & symptoms that help to predict outcomes in patients with COVID-19. https://www.sheffield.ac.uk/scharr/sections/hsr/cure/priestpages/priest The Health Board is ready to go with this study however the sponsors have suspended any additional sites.

APPENDIX B – GRANT APPLICATIONS AND RESEARCHER DEVELOPMENT

- Two ‘Research for Patient and Public Benefit’ grant applications have progressed to next stage, comments were received on May 14th and a response is being prepared.

- 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. This had a 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 Research & Development Handbook is in preparation.

- A ‘Getting into Research’ webinar is scheduled for 1st June. This will be the first in a series of webinars designed to support staff develop their interest in research. 78 members of staff have so far applied for access to this.

- 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.

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 2018/19
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Dr Philip Kloer, Executive Medical Director and Deputy CEO
SWYDDOG ADRODD: REPORTING OFFICER:	Dr Caroline Williams, Senior Operations Manager R&D

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 2018/19 to the Quality, Safety & Experience Assurance Committee (QSEAC). The R&D Sub-Committee Annual Report provides assurances in respect of the work that was undertaken by the Sub-Committee during 2018/19 and outlines the main achievements which have contributed to robust integrated governance across the University Health Board (UHB).

This report from 2018/19 should have been submitted to the University Partnership Board in May 2019. This omission was identified in an Internal Audit (IA 1920-09 R&D Governance Review) in February 2020, with a requirement to submit the report.

With the University Partnership Board now disbanded and the R&D Sub-Committee instead reporting to QSEAC, this report is submitted to remedy the oversight.

Cefndir / Background

The UHB's Standing Orders and the terms of reference for the R&D Sub-Committee required the submission of an Annual Report to the University Partnership Board to summarise the work of the Sub-Committee and to identify how it has fulfilled the duties required of it. The University Partnership Board has been disbanded and the R&D function is now being overseen from an assurance perspective by QSEAC.

The fundamental purpose of the R&D Sub-Committee in 2018/19 was to assure the Board, via the University Partnership Board, that it was 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 (2018/19) 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 updated Terms of Reference for the University Partnership Board. The updated Terms of Reference of the Research and Development Sub-Committee were reviewed and approved at the meeting on 21st May 2018.

The Sub-Committee's purpose is to provide assurance to the University Partnership Board 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 University Partnership Board in respect of its provision of advice to the Board, and ensure the implementation and adherence to relevant research legislation and any requests for reports to Health and Care Research Wales, Welsh Government.

The Sub-Committee reported to the Board in 2018/19 via the University Partnership Board to:

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 General Data Protection Regulations (2018), which replaced the Data Protection Act (1998) on 25/05/18.
- International Conference for Harmonisation of Good Clinical Practice (ICH-GCP) standards (1996).
- Human Tissue Act (2004).
- The Medical Devices Regulations (2002) as amended

Consider the implications for the Board of the outcomes arising from relevant review, audit or inspection carried out by external regulatory authorities, 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 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 Policies
- R&D Standard Operating Procedures
- R&D Guidelines for Researchers

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

- University Links
- Health Education and Training Contribution
- Contribution to Quality Care
- Contribution to Health Research
- Contribution to other Health related activities

Provide general assurance to the Board by:

- Ensuring strong relationships and effective communication with associated Higher Education Institutions and other external organisations.
- Promote the dissemination of research findings in order to contribute to clinical effectiveness and evidence-based healthcare delivery.
- Agree issues to be escalated to the University Partnership Board with recommendations for action.
- Provide assurance to the Board that the ring fenced R&D Activity Based Funding is being spent according to Welsh Government requirements.
- Ensure R&D is appropriately resourced and that resources are channelled to local and national R&D priorities in the health community.
- Report to relevant agencies such as Health and Care Research Wales (HaCRW), Welsh Government, through the approval of the R&D Annual Return, Mid Year Return, Annual Plan and Spending Plan.
- Receive and comment on financial, performance management and data reports submitted to Health and Care Research Wales.
- Review new research applications pertaining to a member's specialist field / management responsibilities when requested by the R&D Manager.
- Promote increased staff involvement in research activity, including facilitating access to relevant training to enhance research capacity and capability.
- Encourage multi-disciplinary and multi-agency R&D, including patient/public involvement where appropriate.
- Report on R&D activity to relevant health community Committees and Health Board via the R&D Director or their nominated person.
- Ensure the implementation and adherence to relevant research legislation and any requests for reports to HaCRW.

Research and Development Sub-Committee Groups

The Sub-Groups reporting to the Research and Development Sub-Committee during 2018/19 were as follows:

Sponsor Review Panel (SRP) Group – established to consider whether, for in-house research proposals, the Health Board can/is willing to fulfil its responsibilities as Sponsor as laid out in the Research Governance Framework (RGF) for Health and Social Care in Wales 2nd Edition (Welsh Government 2009), or the UK Policy Framework for Health and Social Care Research (2017) from 01/02/18 (implementation date, superseding the RGF). To that extent the SRP will consider research proposals in terms of:

- Scientific quality and validity;
- Information use and dissemination/value of findings;
- Health and safety of researchers and participants;
- Finance, resource use and Intellectual Property

R&D Senior Team Group – established to oversee the strategic objectives of the R&D Department. Issues considered include:

- Change management/restructuring R&D Department to create an Innovation Hub in partnership with the Medical Directorate
- Staff management, prioritising and appointing to new posts and making temporary posts permanent
- Ensuring compliance with the NHS R&D Finance Procedure, and advising research community on the Terms and Conditions affecting management of their Investigator research accounts

R&D Research Quality Management Group was established (in April 2018) to provide an independent process for reviewing and addressing research quality assurance issues. 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 Research and Development Sub-Committee Annual Report 2018/19 is intended to outline how the Sub-Committee and its Groups have complied with the duties delegated by the University Partnership Board through the Terms of Reference 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 in 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 Manager
Clinical Trials Nurse representative
Medical Education and Knowledge representative
Workforce and Organisational Development representative
Representatives from Health and Care Research Wales
Representative from Swansea Trials Unit
Representative from Social Care (new)

Meetings

Quarterly Research and Development Sub-Committee meetings were held as follows:

21st May 2018
13th August 2018
12th November 2018
11th February 2019

During 2018/19 the Research and Development Sub-Committee was directly accountable to the University Partnership Board for its performance. Following each meeting it provided an

assurance to the Committee through a formal written update report which was received at the subsequent Committee meeting.

During 2018/19, the Sub-Committee met on 4 occasions and was quorate at all meetings.

Sub-Committee Terms of Reference and Principal Duties
In discharging its duties, the Research and Development Sub-Committee has undertaken work during 2018/19 against the following areas of responsibility in relation to its Terms of Reference:

Providing assurance that the ring-fenced NHS R&D Activity Based Funding is spent according to Welsh Government guidelines and requirements by:

- Ensuring R&D is appropriately resourced and that resources are channelled to local and national R&D priorities in the health community.
- Reporting to HaCRW, Welsh Government, through the approval of the R&D Annual Return, Mid Year Return, Annual Plan and Spending Plan.
- Receiving and commenting on financial, performance management and data reports submitted to HaCRW.
- R&D funding for 2019/20 has been reduced by £99,000 triggering an organisational change.

Overseeing the Research Governance arrangements for managing research activities across Hywel Dda:

- Number of Clinical Trials of Investigational Medicinal Products (CTIMPs) and non-CTIMPs reviewed and approved (HDdUHB Sponsored and Hosted).
- Total number of Commercial, non-Commercial, Clinical Research Portfolio and Pathway to Portfolio research studies reviewed and approved.
- Total number of research studies/clinical trials reviewed and approved.
- Number of approved studies categorised as High, Medium or Low risk, and summary of approved risk management plans for High risk studies.
- Research studies rejected and summary of reasons including lack of capacity, capability or infrastructure to support.
- Summary of research-related Adverse Events and Serious Adverse Events.
- Making recommendations on summary Research Quality Assurance reports following routine monitoring visits and triggered audits of research studies and clinical trials.

Reviewing and approving R&D Strategies, Policies, Procedures and Guidance:

- During 2018/2019 the following documents were reviewed and approved in line with the UHB's 190 - Written Control Documentation Policy:
  - 446 - BioBank Policy
  - 757 - Document Version Control for Research Standard Operating Procedure
  - 789 - Study set up - Trial Master File/Investigator Site file for Research Standard Operating Procedure
  - 803 - Receiving Informed Consent to Participate in Research Standard Operating Procedure

Ensure the Health Board maintains its University status by monitoring and driving improvement in relevant metrics.

- Fostering a culture of innovation through partnerships with Agor IP, Bevan Commission exemplars, and the West Wales Academic Health Collaborative
- Appointment of West Wales Academic Health Collaborative Administrator
- Number of research grants applied for and the number successful

- Approval of a joint post with Swansea University for a Deputy Director of Research & Innovation

Feedback from Groups:

Sponsor Review Panel Group (SRP) – The revised Sponsorship Review Panel process was approved by the R&D Sub-Committee in May 2018. Written update reports from the SRP Group have been received on four occasions by the R&D Sub-Committee during 2018/19.

- Over the course of the year the group considered eight studies for possible sponsorship by the Health Board, of which,, two were approved and the remaining six returned to the applicant with comments for review and possible resubmission.

R&D Senior Team Group – update reports from 12 meetings of the R&D Senior Team Sub-Group were received by the R&D sub-committee highlighting the key areas of work scrutinised and identifying key risks and issues and matters of concern,:

- Increased oversight of Investigator Research accounts to ensure robust financial governance, including new Guidelines for Researchers to implement the recommendations of the All Wales R&D Finance Policy issued by Welsh Government.
- Oversight of the R&D Department's financial reporting to HaCRW to demonstrate compliance with the 'Purpose and Use of NHS R&D Funding Guidelines'; Annual Spending Plan and Annual Work Plan, Mid-Year and Annual Financial Returns were submitted to Welsh Government. R&D delivered a break-even position at the end of the year April 2019. The Annual Return was verified and accepted as a true and fair reflection of the financial position.
- Outcome following the Performance Management Meeting with HaCRW
- Submitting research data reports to the University Partnership Board to demonstrate compliance with HaCRW Key Performance Indicators.

Research Quality Management Group

- A number of R&D Standard Operating Procedures (SOPs), Checklists, Templates and Forms have been completed.
- Internal processes for study audits/monitoring have been more rigorous during 2018/19 than previous years.
- The Quality Assurance Officer (QAO) has undertaken regular monitoring activity throughout the year. Summary outcomes and/or Corrective and Preventative Action plans (CAPAs) from routine/triggered monitoring/auditing visits have been reported in full to the R&D Research Quality Management Group (RQMG) and reported to R&D Sub-Committee for information.
- An ongoing routine audit programme has been agreed with the Research Quality Management Group (RQMG) and R&D Sub Committee.
- A proposed project between HDdUHB and Aberystwyth University to design a new database to track human tissue samples was discussed as the current software license was not fit for purpose.

Key Risks and Issues/Matters of Concern

During 2018/19, the following key risks were raised to the University Partnership Board:

- Certain KPI targets will be difficult to achieve in 2018/19, in particular recruitment to portfolio studies. This is due to some large studies closing, the target increasing 10% on last year, and a lack of Chief and Principal Investigators across HDdUHB
- There is a lack of dedicated research space for research activities and staff on all sites. This will lead to an impact/effect on NHS Research and Development (R&D) Activity Based Funding received from Welsh Government which could be reduced if there is a

downturn in research activity, and this could ultimately put Hywel Dda's 'University' Health Board status at risk.

Matters Escalated to University Partnership Board
During 2018/19, the following matters requiring University Partnership Board level consideration or approval were raised:

- May 2018 - R&D Sub-Committee revised Terms of Reference for endorsement
- November 2018 - The lack of dedicated research space, lack of CIs/PIs and lack of
- engagement from Consultants to start new studies
- February 2019 – The lack of input from Universities to RDSC

Research and Development Sub-Committee Developments for 2019/20
The following developments are planned for the Research and Development Sub-Committee during 2019/20:

- A further review of the Sub-Committee membership will be undertaken.
- Group annual reports to facilitate the Research and Development Sub-Committee annual reporting to the University Partnership Board.
- Membership and terms of reference for groups will be reviewed to more closely define the activities and reduce the number of meetings that each person attends.

Argymhelliad / Recommendation

To endorse, retrospectively, the R&D Sub-Committee Annual Report 2018/19.

Amcanion: (rhaid cwblhau) **Objectives: (must be completed)**	
Committee ToR Reference: 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: Datix Risk Register Reference and Score:	Not Applicable
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	Governance, Leadership and Accountability
Nodau Gwella Ansawdd: Quality Improvement Goal(s):	All Quality Improvement Goals Apply
Amcanion Strategol y BIP: UHB Strategic Objectives:	Not Applicable

Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019	10. Not Applicable

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	Agendas, papers and minutes of the R&D Sub-Committee meetings 2018/19
Rhestr Termau: Glossary of Terms:	Included within the body of the report.
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Ansawdd, Diogelwch a Sicrhau Profiod: Parties / Committees consulted prior to Quality, Safety and Experience Assurance Committee:	R&D Sub-Committee Chair and Lead Director

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: 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: Quality / Patient Care:	SBAR template in use for all relevant papers and reports.
Gweithlu: Workforce:	SBAR template in use for all relevant papers and reports.
Risg: Risk:	SBAR template in use for all relevant papers and reports.
Cyfreithiol: 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. 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 University Partnership Board.

Enw Da: **Reputational:**	Not Applicable
Gyfrinachedd: **Privacy:**	Not Applicable
Cydraddoldeb: **Equality:**	Not Applicable

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) **Objectives: (must be completed)**	
Committee ToR Reference: 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: Datix Risk Register Reference and Score:	Not Applicable
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	Governance, Leadership and Accountability
Nodau Gwella Ansawdd: Quality Improvement Goal(s):	All Quality Improvement Goals Apply
Amcanion Strategol y BIP: UHB Strategic Objectives:	Not Applicable
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019	10. Not Applicable

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	Agendas, papers and minutes of the XXX Sub-Committee meetings 2019/20
Rhestr Termau: Glossary of Terms:	Included within the body of the report.
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Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: 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: Quality / Patient Care:	SBAR template in use for all relevant papers and reports.

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Risg: **Risk:**	SBAR template in use for all relevant papers and reports.
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