Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

PWYLLGOR DIWYLLIANT, POBL A DATBLYGU SEFYDLIADOL
PEOPLE, ORGANISATIONAL DEVELOPMENT & CULTURE COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	04 April 2022
TEITL YR ADRODDIAD: TITLE OF REPORT:	Research & Innovation Sub-Committee Annual Report
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Professor Philip Kloer, Medical Director/ Deputy Chief Executive
SWYDDOG ADRODD: REPORTING OFFICER:	Dr Leighton Phillips, Director for Research, Innovation and University Partnerships

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

ADRODDIAD SCAA
SBAR REPORT

Sefyllfa / Situation

The purpose of this report is to present the Research & Innovation Sub-Committee (R&ISC) (previously known as the Research & Development Sub-Committee) Annual Report 2021/22 to the People, Organisational Development & Culture Committee (PODCC).

The R&ISC Annual Report provides assurances in respect of the work that has been undertaken during 2021/22, and that the Terms of Reference (ToR) as set by the Committee are being appropriately discharged.

Cefndir / Background

Hywel Dda University Health Board's (HDdUHB) Standing Orders and the Terms of Reference for the R&ISC require the submission of an Annual Report to the PODCC 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 R&ISC, as expressed in its Terms of Reference, is to assure the Board, via PODCC, 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.

This includes:

- a clear strategy;
- clear governance and performance management;
- working within budget constraints.

The R&ISC will promote and support involvement in high quality, multi-disciplinary and multi-agency healthcare research, development and innovation, promote evidence-based healthcare, build research and innovation capacity and foster a research and innovation culture, including patient/public involvement where appropriate.

The R&ISC will facilitate collaboration with the Research and Academic community to maximise outcome and impact for HDdUHB and the patients it serves.

Asesiad / Assessment

The R&ISC has been established under Committee delegation with the Quality, Safety & Experience Committee (the previous host Committee to the People, Organisational Development & Culture Committee) approving Terms of Reference for the Sub-Committee at its meeting on 13th April 2021.

This Annual Report outlines how the R&ISC has complied with the duties set through its Terms of Reference, and also identifies key actions to address developments.

Constitution

There is a core membership of the Sub-Committee which is comprised of:

- Medical Director/Deputy Chief Executive (Chair);
- Director for Research, Innovation & University Partnerships (Vice Chair);
- Independent Member;
- Clinical Director, Research & Development;
- Senior R&D Operations Manager;
- Head of Clinical Engineering;
- Assistant Director of Nursing (with a responsibility for research);
- Assistant Director of Therapies and Health Science (with a responsibility for research);
- A representative from Aberystwyth University;
- A representative from Swansea University;
- A representative from the University of Wales Trinity Saint David;
- Director of Finance;
- Head of Medical Education and Knowledge;
- Representative from the Division for Social Care and Health Research (DSCHR) Welsh Government - Health and Care Research Wales Workforce;
- Representative from 3rd Sector Organisation;
- Head of Research, Innovation & Improvement, Regional Partnership Board.

Meetings

During 2021/22, R&ISC meetings were held on a bi-monthly basis.

As the R&ISC is directly accountable to PODCC for its performance, it provides an assurance to the Committee through a formal written update report which is received at the subsequent Committee meeting. A full set of the papers for each Committee meeting is routinely made available on HDdUHB's website. During 2021/22, the R&ISC was initially accountable to the Quality, Safety & Experience Committee (May 2021).

During 2021/22, the R&ISC met on the following occasions and was quorate at each:

- 10th May 2021 (the report from this meeting was submitted to the Quality, Safety & Experience Committee);
- 12th July 2021;
- 13th September 2021;
- 8th November 2021
- 10th January 2022
- 14th March 2022

Areas of Responsibility

In discharging its duties, the R&ISC has undertaken work during 2021/22 against the following areas of responsibility in relation to its Terms of Reference:

- **Governance**

  - **TriTech – Management Team Meeting and Risks:** The R&ISC noted the Terms of Reference for the TriTech Management Group and gained assurance from the overview of risks and the proposed management approach on 12th July 2021.

  - **R&ISC ToR:** An updated ToR for 2022/23 was submitted for approval on 14th March 2022. The updated ToR included two main changes; the addition of the Sponsorship Review Panel as a Group, and a change of frequency of R&ISC meetings from bi-monthly to quarterly. A discussion ensued about adding the TriTech Management Group as a formal Group of the R&ISC. This was agreed and the ToR will be amended accordingly. The ToR was approved subject to this addition.

  - **Research Quality Management Group (RQMG) ToR:** An updated ToR was submitted for approval on 14th March 2022. The ToR were approved.

- **Discussion Items**

  - **Grants funding review:** A report outlining the grant application process and the success rates was presented to the R&ISC meeting on 12th July 2021. The R&ISC was asked to discuss/examine and consider the implications of the matter. The Director of Finance commended the Grants Team for the (albeit unsuccessful) Health Foundation application. Statistical support for grant applications continues to prove difficult to source. Grant applications are now expanding to include opportunities for artificial intelligence (AI) and technological advances.

  - **HDdUHB Research & Innovation Peer Review:** Presented to the R&ISC on 10th May 2021 to inform of the plans for the departmental peer review, one of the actions within the Research & Innovation Strategy 2021-2024. The R&ISC was requested to note the plans for the peer review; advise of further individuals that should be consulted as part of the process; and agree the correct forum for dissemination. The plans were agreed, and the peer review subsequently took place on 11th August 2021.

  - **Development of a Performance Framework:** The report presented to the R&ISC on 8th November 2021 introduced a proposed performance framework aligning to the recently published Research and Innovation Strategy. This had been requested in order to capture a more complete picture of performance, as the current performance metrics are solely focused on the performance of the Delivery Team. The R&ISC was requested to consider the proposed indicators and offer feedback on other indicators that should be considered. The proposed indicators were agreed, and the management team were requested to further review the frequency of reporting.

  - **Management Response to Peer Review Report:** The report was submitted to the R&ISC on 10th January 2022, setting out the management response to the external peer review report received by HDdUHB at the beginning of November 2021. The R&ISC was asked to consider the implications of the recommendations and examine the proposed / actual actions, approving where appropriate. It was agreed to incorporate recommendations from the peer review report, into the Strategy Work Plan.

  - **Plan for Introducing Commercial Studies to Bronglais General Hospital (BGH) and Glangwili General Hospital (GGH):** The report presented to the R&ISC on 10th January 2022 proposed a plan to manage the start-up of commercial research activity in GGH and BGH, ensuring that it will remain a sustainable option moving forward, whilst minimising

any associated risk. The R&ISC was requested to review and comment on these plans. The plan was commended, and funding for a research nurse has been requested from Health and Care Research Wales.

- **Assurance Items**

- **R&D Operational Teams Report:** Reports were presented to every meeting, providing an update on the activities taking place across all key areas in research & development operations. The R&ISC was requested to note each report and gain assurance that the Research & Development operational teams are continuing to make progress against expectations. The R&ISC received assurance from the reports presented to each meeting.

- **R&D Risk Register:** A report was presented to each meeting of the R&ISC, providing an update on the departmental risks. The R&ISC was requested to review the identified risks and associated action plans, and gain assurance from the report that the department risks are being managed appropriately. Assurance was received from the reports presented to each meeting.

- **Research Quality Management Group** – A report was presented to each meeting of the R&ISC from the Research Quality Management Group (RQMG) highlighting the key areas of work undertaken. These reports identified key risks, issues and matters of concern and assurance was received from the reports presented to each meeting.

- **TriTech Decision Making:** A report was presented to the R&ISC on 13th September 2021 explaining the TriTech decision making process regarding the projects it will advance. The R&ISC was requested to gain assurance from the decision-making processes subject to them being kept under ongoing review as the new team and associated functions mature. The R&ISC received assurance from the report.

- **TriTech Institute Report:** A report was presented to each meeting of the R&ISC from November 2021 onwards. The reports provided an update on the activities undertaken across all key areas in TriTech operations. The R&ISC was requested to note the reports and to receive assurance that the TriTech team is continuing to make progress against expectations. Assurance was received from the reports presented.

- **Progress Against the Strategy Work Plan:** A report was presented to the R&ISC on 10th January 2022, concerning the progress against the Research & Innovation Strategy work plan. The R&ISC was recommended to gain assurance that the majority of the action plan to support the strategy is set to deliver to time and target, and that where delays have occurred, steps have been taken to minimise any adverse impact and actions have been taken to recover the position. The R&ISC received assurance from the report.

- **Clinical Leadership Across R&D:** The Research and Development Department's risk register (Risk 1160) identifies the lack of research leadership (staff able to act as principal investigators) across HDdUHB as presenting an impediment to the Research & Development strategy. In recognition of this risk and the HDdUHB's University status, there has been a recent increase in plans and resources to support clinical staff engagement in research. The progress made by the Research & Development leadership group, as well as future plans were summarised in this report to the Sub-Committee on 10th January 2022. The R&ISC received assurance from the report.

- **Information Items**

  - **TriTech Business Case and Plan:** On 8th November 2021, the R&ISC received a presentation and several updates on the establishment of TriTech, covering the rationale for its establishment, key risks, and the Terms of Reference for its Management Group. The R&ISC was requested to note the business case, progress, and plans to develop a business plan and associated performance dashboard.

  - **Finance Reports:** Reports were presented to each meeting to inform the R&ISC of the current financial position for both Research & Development and TriTech. The R&ISC was requested to note the information provided.

- **Decision Items**

  - **Research Quality Management Group (RQMG) Annual Report 2020/21:** The Research Quality Management Group Annual Report 2020/21 was presented for approval on 10th May 2021, to be included as Appendix 1 of the Research & Innovation Sub-Committee's Annual Report 2020/21 to the Quality, Safety & Experience Committee. The R&ISC endorsed the Research Quality Management Group Annual Report 2020/21.

  - **Biobank Briefing Report on an Options Appraisal:** A report was submitted to the R&ISC on 19th July 2021, outlining the potential options to be included in the commissioning brief for a feasibility assessment of the Biobank. This piece of work was required as Health and Care Research Wales financial support for the Biobank had been removed. The R&ISC was requested to make a decision on which options should be included in the commissioning brief. It was agreed that the following options should be considered in the appraisal:

    Option 1: Stop running Hywel Dda UHB's Biobank.
    Option 3: Do minimum. Marginally increase the R&D/Pathology staffing complement, support more studies, generate an income to meet staffing complement, service and licence costs.
    Option 4: Do maximum. Run an independent Biobank Access Committee, increase R&D/Pathology staffing level, enhance facilities, and support more studies.
    Option 5: Hywel Dda UHB becomes a satellite for one of the other Welsh Biobanks e.g. Wales Cancer Bank (WCB) / Cardiff University (CU) Biobank.

  - **Research Facilities:** A report was presented to R&ISC on 8th November 2021 to provide an overview of the plans that have been developed to ensure the provision of suitable space for research. This issue is captured on the Department's risk register (Risk 1035 & Risk 1036). The R&ISC was requested to consider escalating these risks to PODCC. The R&ISC was also requested to consider escalating this to a directorate risk level, as the Research & Development Department alone has very limited ability to facilitate access to any clinical space within the hospital for research activity. The R&ISC agreed to escalate the risks to PODCC, which it did in its update report in December 2021.

  - **Revised Performance Framework:** A report was presented to the R&ISC on 10th January 2022, updating the proposed performance framework (mentioned above) aligned to the recently published Research and Innovation Strategy. The R&ISC was requested to approve the indicators and reporting frequency, and to note the intention to incorporate as much as possible of this into Power BI reporting. Health and Care Research Wales have created a live Power BI dashboard to demonstrate HDdUHB delivery performance. Research & Development, Finance and Informatics staff are working together to produce

a Power BI dashboard to capture the other agreed performance indicators. A draft will be completed by March 2022.

- **Research and Innovation Facilities at Pentre Awel:** A report was presented to the R&ISC on 10th January 2022, setting out HDdUHB's proposed Research and Innovation facility requirements at the Pentre Awel site, incorporating space for the Prince Phillip Hospital Clinical Engineering laboratory. It was noted that confirmation of these requirements would inform the heads of terms and subsequent lease negotiations with the scheme's proprietor, Carmarthenshire County Council. The R&ISC was requested to agree the Research and Innovation Department's space requirements at the Pentre Awel Scheme, subject to the financial implications and lease negotiations being progressed corporately by HDdUHB. The R&ISC was content with the scope of the proposal.

- **University Partnerships:** A paper was submitted to the R&ISC on 14th March 2022 outlining the need to optimise the time available to ensure that university partners are gaining value from the meeting. A new format for the university partnerships section of the R&ISC agenda was proposed. This would involve a rotation system, where each partner presents a more detailed overview at one in every three meetings. The R&ISC approved the proposed changes.

- **Research & Innovation Sub-Committee Annual Report 2021/22:** The R&ISC Annual Report 2021/22 was presented for approval on 14th March 2022. The report was approved, subject to information from the meeting on the 14th March being added.

- **Research Quality Management Group (RQMG) Annual Report 2021/22:** The Research Quality Management Group Annual Report 2021/22 was presented for approval on 14th March 2022. The R&ISC approved the report (see attached).

Key Risks and Issues/Matters of Concern Raised by the R&ISC to QSEC / PODCC during 2021/22 included:

- **Research & Innovation Strategy 2021-2024**
  - The Research & Innovation Strategy 2021-2024 has reached the final stage. The wording in the document has been finalised and it has been translated into Welsh.
  - A graphic design company has been commissioned to produce the final document.
  - The strategy was approved by the Research & Development Sub-Committee at its meeting on 8th March 2021, and was presented to the Quality, Safety & Experience Committee for ratification.
  - A formal launch of the strategy is being planned with HDdUHB's Communications Team.

- **University Status Review**
  - The Quality, Safety & Experience Committee was asked to note that the current pressures on all services would mean that the submission for the triennial University Status review could not be as comprehensive as in the past, however it would still meet the criteria set by Welsh Government.

- **Risk 1160 – Lack of research leadership**
  - Risk 1160 has been identified as a directorate risk. As such, an update on progress has been provided at each PODCC meeting.

- **Lack of Health and Care Research Wales (HCRW) funding for the Development Team**:
    - HCRW have withdrawn funding from the Development Team (circa £120k) from April 2021, with the expectation that they will cost-recover.
    - Whilst there are sufficient funds within the Research & Development account to cover any shortfall during 2021, this is not guaranteed moving forward. The Development Team lead has advised that current potential work would bring in the relevant costs, however the team's capacity to follow this through is required to be finalised.
    - The Medical Director highlighted the importance of the Development Team to the future ambitions of research, development and innovation within HDdUHB, therefore guaranteed funding is essential.

- **Clinical Research Facilities on the Bronglais Hospital (BGH) and Withybush Hospital (WGH) Sites.**
  The R&ISC raised the issue of a lack of clinical facilities on both the BGH and WGH sites. These issues have been a part of the risk register since 2016. Whilst recognising the challenges in the hospitals at present, the R&ISC highlighted the consequences of this lack of space, recognising the importance of understanding that the research teams in the acute hospital sites are clinical teams, and will be recruiting patients from wards, out-patients and the community, and have remained in the hospital sites throughout the COVID-19 pandemic.
    - **BGH** (Risk 1035)
      The Research Team in BGH previously had a dedicated clinical room within the hospital, however this was handed over during the first wave of COVID-19 and had not been returned. The team had received no support from hospital management in terms of securing their allocated space back or finding an alternative. This is now having an impact on the amount of research that can be undertaken in BGH, and out-patients eligible to be recruited into studies are not being given the opportunity as there is not a facility where the team can liaise with the patients and receive informed consent. When the new off-site facility is operational, there will still be a requirement for a clinical space within the hospital.
    - **WGH** (Risk 1036)
      The research team in WGH are currently utilising a waiting room as an office following the requirement to move out of their previous office due to COVID-19. The office is confined and restricted, and there is inadequate space for the whole team. The team does also have a small laboratory in another part of the hospital and is able to access some clinical space in the Pembrokeshire Haematology & Oncology Day Unit (PHODU) for patients in oncology trials. It also has a weekly afternoon session booked in outpatients. However, the lack of suitable space is having a detrimental effect on the ability to open commercial studies.

Matters Requiring Committee Consideration or Approval

- The R&ISC's revised Terms of Reference (2021/22) following their presentation to the Committee on 13/04/21.
- The R&ISC's revised Terms of Reference (2022/23) will be presented to PODCC on 04/04/22.
- The Research & Innovation Sub-Committee Annual Report 2021/22 will be presented to PODCC on 04/04/22.
- The Research Quality Management Group Annual Report 2021/22 will be presented to PODCC on 04/04/22.

Argymhelliad / Recommendation

The People, Organisational Development & Culture Committee is asked to endorse the Research & Innovation Sub-Committee's Annual Report 2021/22.

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 Committee on the Sub Committee's activities. This includes the submission of a Sub 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
Amcanion Strategol y BIP: UHB Strategic Objectives:	Not Applicable
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Statement	Not Applicable

Gwybodaeth Ychwanegol: **Further Information:**	
Ar sail tystiolaeth: Evidence Base:	Agendas, papers and minutes of the R&ISC meetings 2021/22.
Rhestr Termau: Glossary of Terms:	Included within the body of the report.
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Diwylliant, Pobl a Datblygu Sylfaenol: Parties / Committees consulted prior to the People, Organisational Development and Culture Committee:	R&ISC.

Effaith: (rhaid cwblhau) **Impact: (must be completed)**	
Ariannol / Gwerth am Arian: **Financial / Service:**	A sound system of internal control, as evidenced in the R&ISC'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&ISC'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&ISC's Terms of Reference, requires the submission of an Annual Report to the Quality, Safety & Experience Committee.
Enw Da: **Reputational:**	Not Applicable.
Gyfrinachedd: **Privacy:**	Not Applicable.
Cydraddoldeb: **Equality:**	Not Applicable.

Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

IS-BWYLLGOR YMCHWIL A DATBLYGU
RESEARCH AND INNOVATION SUB-COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	14 March 2022
TEITL YR ADRODDIAD: TITLE OF REPORT:	Research Quality Management Group (RQMG) Annual Report 2021/22
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Dr Sam Rice, Clinical Director of Research and Development and RQMG Chair
SWYDDOG ADRODD: REPORTING OFFICER:	Dr Lisa Seale, Senior R&D Manager, Research Quality Assurance Lead and RQMG Vice Chair

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 Quality Management Group Annual Report 2021/22.

The Research Quality Management Group Annual Report provides assurance in respect of the work that has been undertaken by the Group during 2021/22, and that the Terms of Reference as set by the Sub-Committee are being appropriately discharged.

Cefndir / Background

Hywel Dda University Health Board's Standing Orders and the Terms of Reference for the Research Quality Management Group require the submission of an Annual Report to the Sub Committee to summarise the work of the Group and to identify how it has fulfilled the duties required of it.

The purpose of the Research Quality Management Group as expressed in its Terms of Reference is to assure the Research and Innovation Sub-Committee (RISC), via the People, Organisational Development and Culture Committee (PODCC), and, where appropriate, the Quality, Safety and Experience Committee (QSEC), 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 on behalf of the Health Board.

This includes:

- Promoting and supporting involvement in high quality healthcare research, ensuring compliance with research quality standards and legislation and providing systems and processes to escalate and resolve issues where there is non-compliance.
- Identifying solutions where issues are discovered during routine monitoring visits or during routine or triggered (for cause) audits of research studies and clinical trials being sponsored or hosted by the Health Board.
- Identifying solutions where issues of non-compliance are brought to its attention by other means (e.g. via research delivery teams, whistle blowing, staff raising concerns).

- Reviewing the issues raised and advising on the Corrective And Preventative Action (CAPA) plans to ensure a fair and timely resolution of issues and authorising CAPA completion.
- Ensuring that common findings and non-compliance issues are shared across the research communities of both the Health Board and its research partners, so that lessons are learned.
- Promoting continuous improvement in research practice across the Health Board, thus ensuring the safety and wellbeing of the patients/subjects it serves where they agree to be involved in research.
- Assuring the Board that the conditions of the Health Board's Human Tissue Authority (HTA) License for Research are complied with.
- Where applicable, providing Research Governance oversight by receiving and reviewing a summary report of the independent Biobank Access Committee's activities, including authorisation of researchers' requests for human tissue samples from the HDdUHB Biobank, at each bi-monthly meeting.

Asesiad / Assessment

The Research Quality Management Group has been established under Sub-Committee delegation with the Health Board approving Terms of Reference for the Group (V0.4) at its Sub-Committee meeting on 14th March 2022.

This Annual Report outlines how the Research Quality Management Group has complied with the duties set through its Terms of Reference, and also identifies key actions to address developments.

Constitution

There is a core membership of the Group which is comprised of:

- Clinical Director, Research and Development (Chair).
- Senior Research and Development Manager (Quality Assurance) (Vice Chair).
- Quality Assurance Officer (Research).
- Research Governance Officer.
- Research and Development Manager (Study Set-up/Data Quality).
- Lead Research Nurse(s).
- Advanced Biomedical Scientist (Research) – co-opted member as required.
- Clinical Trials Pharmacist – co-opted member as required.
- Independent (Lay) Member.
- Researcher Development Support Manager.

The following In Attendance Members have also been identified to serve on the Group:

- Healthcare Science Practitioner Specialist (Research).
- Research Support Officer.

Meetings

During 2021/22, Research Quality Management Group meetings were held on a bi-monthly basis.

As the Research Quality Management Group is directly accountable to the Sub Committee for its performance, it provides an assurance through a formal written update report which is received at the subsequent Sub Committee meeting.

During 2021/22, the Group met on the following occasions and was quorate at each:

- 15th April 2021 (SBAR report presented at RISC 10th May 2021).
- 17th June 2021 (SBAR report presented at RISC 12th July 2021).
- 19th August 2021 (SBAR report presented at RISC 13th September 2021).
- 21st October 2021 (SBAR report presented at RISC 08th November 2021).
- 16th December 2021 (SBAR report presented at RISC 10th January 2022).
- 17th February 2022 (SBAR report presented at RISC 14th March 2022).

Areas of Responsibility

In discharging its duties, the Research Quality Management Group has undertaken work during 2021/22 against the following areas of responsibility in relation to its Terms of Reference:

- **Governance**

  - Serious Adverse Event and Urgent Safety Measure reports.
  - Deviations from Protocol/Good Clinical Practice (GCP)/other issues brought to the attention of the Research Quality Assurance (QA) Team via research-related DATIX reports.
  - Protocol breach in the SIREN study (19/03/2021).
  - Summaries of three DATIX reports (Personal Identifiable Information from numerous participants in 3 different respiratory research studies sent outside HDdUHB) i.e. breach of GDPR.
  - Lessons to be learned (identified via Root Cause Analysis) to be discussed with the research team involved in multiple GDPR breaches.
  - CTEX-WG7 CPAP Trial Final CAPA (02/02/2022) for authorisation.

- **Discussion Items**

  - R&D Written Controlled Documentation and R&D Facilities/Research Laboratory SOPs for the Clinical Research Centre (CRC), PPH.
  - Independent Biobank Access Committee Terms of Reference.
  - New decision-making process for releasing human tissue samples from the Biobank to internal/external researchers via the Sponsorship Review Panel (following recommendations made by the Biobank Access Committee).
  - Risk based audit programme to resume post-COVID along with self-audits using the Research Audit and Monitoring Visit Checklist, RDC-04.
  - Research Delivery Teams to inform the Research QA Team when arranging hosted Site Initiation Visits as a member of the Research QA Team needs to attend SIV if the study risk is high/major.
  - Corporate Governance of HDdUHB's Biobank, feedback from R&D Strategic Management Team (16/06/2021), SBAR Report presented at R&I Sub-Committee (12/07/2021) to consider options for a Biobank Feasibility Study.
  - Options appraisal and feasibility assessment of HDdUHB's Biobank agreed at R&I Sub-Committee (12/07/2021), Commissioning Brief produced to issue Invitations To Quote to potential partners via Procurement.
  - Invitation To Quote for the HDdUHB Biobank feasibility assessment issued to potential partners (07/12/2021), deadline for receipt of quotes 10/01/2022.
  - Biobank Task & Finish Group (BTFG) set up with advice from the Head of Corporate and Partnership Governance, RQMG approved BTFG Terms of Reference (16/12/2021), Quotes received, assessed and contract awarded on 01/02/2022.

- Advised Research Delivery Team Leads/R&D Pathology Lead to produce generic R&D Facilities/Research Laboratory SOPs for the existing and pending CRCs across all four main hospital sites, with local modification as required (long-term objective).
- Research Quality Assurance Team Training Delivery Plan for discussion of training videos at the R&D Strategic Management Team (14/02/2022).
- A new Template/Form to record the process of removing research file/s from a Clinical Research Centre and subsequent return, and a Workplace Instruction outlining the Research Assistants' roles in managing restricted access to the CRCs, would be produced by the Research Delivery Teams.
- The following R&D Written Controlled Document was discussed and is no longer required: RDSOP-23: Use of Facilities in a Clinical Research Centre (generic SOP). The intention was for the SOP to be updated by the Research Delivery Team, PPH, with reference to RDC-02: Checklist for External Staff/Students Joining a Research Study Team via an Honorary Research Contract (HRC) or Letter of Access (LoA). The need for this SOP was discussed and it was agreed that the SOP is superseded as access to the CRCs is now more strictly controlled; the site Lead Research Nurse liaises with/will liaise with the R&D Manager to confirm the HRC/LoA status of any external staff requesting access to the CRC at their site.
- The following R&D Written Controlled Document would be further reviewed as follows: RDT-02: Research Participant Information Sheet/Informed Consent Form Template (Version 1.4, 19/08/2021). The Template was updated following review at the RQMG meeting on 19/08/2021 but further discussion with the Community Health Council (to confirm their role) meant that the CHC would be sent an amended version of RDT-02 for CHC management team review in January 2022. This follows clarification that whilst the CHC can provide general independent advice and facilitate research participants' concerns or complaints, any queries about the research study should be addressed by the research team.
- RDSOP-14: Sponsorship Review Panel (SRP) Procedure (Terms of Reference); Senior R&D Manager (Quality Assurance) identified at the SRP meeting (16/02/2022) the need to confirm the formal reporting structure for SRP (listed as a Sub-Group of the R&I Sub-Committee hence does not report to RQMG), and also advised that the document is not a SOP, thus the prefix RDSOP-14 would be removed and reassigned by RQA Team.
- Draft Terms of Reference for Research Groups (generic document for Research Groups in various clinical disciplines) will be managed by the Researcher Development Team, with review and feedback requested from RQMG members by 24/02/2022.

- **Assurance Items**

  - Research QA Team Performance Metrics/Dashboard.
  - New Key Performance Indicators for R&D Power BI Dashboard report to RISC.
  - Routine and Triggered Audit reports.
  - Final summary audit report for Oncotype DX study (21/10/2021) and Early Monitoring Visit Report for TIPTOP study (09/11/2021).
  - Routine Monitoring Visits including Site Initiation Visits.
  - Research Study Set-up/Data reports and progress updates of risk-based monitoring plans.
  - Internal Audit of the HDdUHB Biobank's compliance with the HTA Licence for Research, briefing for audit to be undertaken on 25/06/2021.

- The Research Quality Assurance Team Lead committed to finalising and circulating all core R&D WCDs by 31/07/2021, under the caveat that training may be required to enable GCP-compliant implementation (June 2021).
- R&D Core SOPs and plans for producing/updating/adopting further R&D Written Controlled Documentation (WCD) following a gap analysis (August 2021).

- **Information Items**

  - Routine Self-Audit Checklist (RDC-04: Research Audit and Monitoring Visit Checklist Draft 0.4) issued as Pilot in Use.
  - GCP and other Research Training delivery.
  - MHRA/HTA Inspection-Ready Training.
  - Biobank LiMBuS database development and Biobank Project Group.
  - Application to Research Ethics Committee (REC) for Generic permission for HDdUHB's Biobank.
  - List of approved updated R&D Written Controlled Documents to be issued as Pilot in Use (SOPs, Templates, Guidelines, Checklists, Forms).
  - List of R&D Written Controlled Documents due for review/updating or requested for early review/amendment (SOPs, Checklists, Forms).
  - The following R&D Written Controlled Document for the Sponsorship Review Panel was due to be produced and submitted for RQMG approval in April 2021, but was delayed until the Biobank Access Committee procedure was clarified: RDSOP-14: R&D Sponsorship Review Panel Procedure (Terms of Reference).
  - The outcome of the proposed Biobank Feasibility Assessment/Business Case would determine whether an independent Biobank Access Committee would need to be established; if so, RDSOP-14 will be produced and implemented.
  - Cumulative Lessons Learned and Risks Log (detailing potential consequences of quality lapses) presented at the monthly Operational Leadership Group meetings - feedback sought.
  - Internal Audit Report of HDdUHB Biobank's compliance with the HTA Licence for Research presented for information, recommendation for routine Biobank audits to be included in the Research QA Team audit programme.
  - Printouts to be produced to prove that Biobank Training has been delivered by the Biobank Lead and attended by research staff (Biobank Training Log).
  - Cumulative list of core R&D Standard Operating Procedures finalised and implemented (available on the HDdUHB intranet site).
  - Following a change of reporting structure, R&I Sub-Committee no longer reports to the Quality, Safety and Experience Assurance Committee (QSEAC). To reflect this change, the RQMG Terms of Reference would be updated by 31/03/2022.
  - Biobank database Version 2 (enhanced features) was tested by the Healthcare Science Practitioner Specialist (Research) by uploading data for human tissue samples for research, with oversight by the Advanced Biomedical Scientist (Research) and Biobank Lead. The Database would be implemented across all sites with training provided for Research Teams.
  - The final Biobank database was tested, training provided for the PPH Research Delivery Team and implemented by 31/12/2021; training for Research Delivery Teams at the other three main hospital sites and implementation of the database was completed by 31/01/2022.
  - Substantial revision of R&D Policy 466: Biobank Policy (to request Generic Research Ethics Committee approval for HDdUHB's Biobank) was pending the outcome of the Biobank feasibility assessment/possible Business Case.

- **R&D Written Controlled Documents for formal RQMG approval:**
  - RDT-09: Corrective And Preventative Action (CAPA) plan Template.
  - RDF-07: The 13 Principles of Good Clinical Practice Form.
  - RDSOP-06: Research Participant Recruitment and Intention to Enrol.
  - RDSOP-12: Research Training Records.
  - RDSOP-10: Application for Sponsorship and Authorisation of a Research Study.
  - RDSOP-11: Application for Authorisation of a Hosted Research Study.
  - RDC-04: Research Audit and Monitoring Visit Checklist.
  - RDT-02: Research Participant Information Sheet/Informed Consent Form.
  - RDC-03: Sponsorship Review Panel Checklist for Researchers.
  - RDG-06: Guidance on Applying for Funding for Dissemination Activities.
  - RDT-18: Sponsorship Review Panel Template for Reviewers.
  - RDT-19: Sponsorship Review Panel Template for Internal/External Peer Reviewers.
  - RDG-02: Guidance for Researchers being Audited or Inspected.
  - RDG-09: Common Questions at MHRA Good Clinical Practice Inspections.
  - RDC-01: Essential Documentation for Research.
  - RDT-27: Study Amendment Log.
  - RDT-31: Research Protocol Template.
  - RDC-08: Medical Records Checklist for Auditors.
  - RDT-03: Research Participant Enrolment Log (updated 24/01/2022).
  - RDT-04: Research Subject ID Code List (updated 24/01/2022).
  - RDT-15: Research Participant Screening Log (updated 24/01/2022).
  - RDSOP-02: Setting Up and Maintaining Research Site Files (updated 04/02/2022).

Key Risks and Issues/Matters of Concern raised by the Group to the Sub Committee during 2021/22 included:

- Breach of Good Clinical Practice: Declaration of the end of the HDdUHB-Sponsored Clinical Investigation of a non-CE-marked Medical Device, the COVID-19 CPAP CTEX-WG5 (WG7) Ventilator multi-site device investigation:
  - Covering emails and formal declaration reports were sent to the Oxford Research Ethics Committee (by the Trial Manager/Chief Investigator) and to the Medicines and Healthcare products Regulatory Agency (by the medical device manufacturer). The formal end of trial reports were incorrect and stated that no participants were recruited ('N/A') when nine were recruited (five with eligible data) out of the planned fifty participants. Trial Manager to correct the reports and send to the Research QA Team prior to resubmitting to REC and MHRA, in order for HDdUHB R&D Department to demonstrate appropriate Sponsor oversight to REC/MHRA (*status at July 2021*).
  - Corrected formal declaration of the end of trial reports produced by the Trial Manager/Chief Investigator (as advised by the Research QA Lead) were checked and approved to be re-issued to the MHRA and REC. This enabled HDdUHB's R&D Department to demonstrate appropriate due diligence and Sponsor oversight to both MHRA and REC (*status at September 2021*).
- Serious Breach of Good Clinical Practice: CTEX-WG7 CPAP Clinical Investigation of a Medical Device (HDdUHB-Sponsored MHRA regulated trial):
  - Trial Master File and Study Delegation Log missing, no records kept of trial Participant IDs (neither Participant Enrolment Log nor Research Subject ID Code List completed).
  - Trial Master File found and gaps addressed by PPH Research Assistants; missing Study Delegation Log reproduced from emailed scanned copies; 7 PPH trial Participants

identified and Research Subject ID Code List completed retrospectively. Serious breaches of GCP satisfactorily addressed, RQMG Chair authorised CAPA 17/02/2022.

Matters Requiring Sub Committee Consideration or Approval

- The Research Quality Management Sub-Group Annual Report 2020/21 (Version 0.1, 13/04/2021) was submitted to RISC on 10th May 2021 for formal ratification.
- The R&D Sub-Committee Annual Report 2020/21 and the RQMG Annual Report 2020/21 (as Appendix 1) were included in the QSEAC Annual Report 2020/21 for the Extra-ordinary Board meeting on 10th June 2021.
- The Research Quality Management Group's revised Terms of Reference (Version 0.4, 02/03/2022) would be submitted to RISC on 14th March 2022 for approval.

The Research Quality Management Group approved the RQMG Annual Report 2021/22.

Argymhelliad / Recommendation

The Research & Innovation Sub-Group is recommended to formally approve the Research Quality Management Group Annual Report 2021/22 at its meeting on 14/03/2022, to be included as an Appendix to the R&I Sub-Committee Annual Report 2021/22 for the People, Organisational Development and Culture Committee (PODCC).

Amcanion: (rhaid cwblhau) **Objectives: (must be completed)**	
Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	Report formally, regularly and on a timely basis to the Sub Committee on the Group's activities. This includes the submission of a Group 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):	3.3 Quality Improvement, Research and Innovation Choose an item. Choose an item. Choose an item.
Amcanion Strategol y BIP: UHB Strategic Objectives:	3. Striving to deliver and develop excellent services Choose an item. Choose an item. Choose an item.
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019	8. Transform our communities through collaboration with people, communities and partners Choose an item. Choose an item. Choose an item.

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	Agendas, papers and minutes of the Group meetings 2021/22.
Rhestr Termau: Glossary of Terms:	Included within the body of the report.
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Ceisiadau Gofal Sylfaenol: Parties / Committees consulted prior to R&I Sub-Committee:	Research Quality Management Group (16/12/2021). R&D Strategic Management Team (14/02/2022).

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: **Financial / Service:**	e.g. financial impact or capital requirements: (if yes, please complete relevant section of the integrated impact assessment template available via the link below) http://howis.wales.nhs.uk/sitesplus/862/opendoc/453906
Ansawdd / Gofal Claf: **Quality / Patient Care:**	e.g. adverse quality and/or patient care outcomes/impacts: (if yes, please complete relevant section of the integrated impact assessment template available via the link below) http://howis.wales.nhs.uk/sitesplus/862/opendoc/453906
Gweithlu: **Workforce:**	e.g. adverse existing or future staffing impacts: (if yes, please complete relevant section of the integrated impact assessment template available via the link below) http://howis.wales.nhs.uk/sitesplus/862/opendoc/453906
Risg: **Risk:**	e.g. risks identified and plans to mitigate risks: (if yes, please complete relevant section of the integrated impact assessment template available via the link below) http://howis.wales.nhs.uk/sitesplus/862/opendoc/453906
Cyfreithiol: **Legal:**	e.g. legal impacts or likelihood of legal challenge: (if yes, please complete relevant section of the integrated impact assessment template available via the link below) http://howis.wales.nhs.uk/sitesplus/862/opendoc/453906
Enw Da: **Reputational:**	e.g. potential for political or media interest or public opposition: (if yes, please complete relevant section of the integrated impact assessment template available via the link below) http://howis.wales.nhs.uk/sitesplus/862/opendoc/453906

Gyfrinachedd: **Privacy:**	e.g. 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, etc: (if yes, please complete relevant section of the integrated impact assessment template available via the link below) http://howis.wales.nhs.uk/sitesplus/862/opendoc/453906
Cydraddoldeb: **Equality:**	e.g. potential negative/positive impacts identified in the Equality Impact Assessment (EqIA) documentation – follow link below • Has EqIA screening been undertaken? Yes/No (if yes, please supply copy, if no please state reason) • Has a full EqIA been undertaken? Yes/No (if yes please supply copy, if no please state reason) http://howis.wales.nhs.uk/sitesplus/862/opendoc/453906