4.3 Research & Development (R&D) Sub-Committee Update Report and RDSC Terms of Reference

*Presenter: Dr Philip Kloer*

Item 4.3 RD Sub-Committee Report

Apendix 1 RDSC ToR v0.9

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| **Enw'r Pwyllgor: Name of Sub-Committee:** | Exception Report from Research & Development Sub-Committee |
| **Cadeirydd y Pwyllgor: Chair of Sub-Committee:** | Dr Philip Kloer, Medical Director and Deputy CEO |
| **Cyfnod Adrodd: Reporting Period:** | 14th September 2020 |

**Materion Ansawdd, Diogelwch a Phrofiad: Quality, Safety & Experience Matters:**

As all Health Board Sub-Committee meetings were stood down in March 2020 due to the COVID-19 Pandemic, the first meeting of the Research & Development Sub-Committee (RDSC) since January 2020 was held on 14th September 2020.

**1. Terms of Reference**

The RDSC Terms of Reference (ToR) (Appendix 1) were presented for review. The Sub-Committee agreed to amend the frequency of R&DSC meetings from quarterly to bi-monthly, to bring it in line with the frequency of QSEACs meetings and prevent any gaps in assurance. They also approved the ToRs for onward ratification by the Quality, Safety and Experience Assurance Committee (QSEAC).

**2. R&D Operational Team Performance**

The Sub-Committee received a report from the R&D operational manager on R&D operations across the University Health Board (UHB), with the following noted:

- Recovery from the impact of COVID-19 is continuing.
- The lack of research facilities in Bronglais and Glangwili General Hospitals is hindering their ability to open new portfolio studies.
- The sponsorship review panel has seen six studies this year to date, already a 100% increase on the previous year.
- A pathway to portfolio grant programme has been set up by R&D. This initiative will run quarterly, with 1 award made to date.
- Progress continues on the written control documents
- An update to internal audit had been received (see section below)

**3. Research Quality Management Group Report**

The Sub-Committee received a report from the Research Quality Management Group (RQMG). The RQMG provides assurance to the R&DSC that all research and development activities in Hywel Dda University Health Board comply with the UK Policy Framework for Health and Social Care Research and other applicable research legislation, and also meet the International Conference for Harmonisation of Good Clinical Practice (GCP) standards for research. The RQMG has met in March and August in 2020, with the following noted from the August 2020 meeting:

- Oncotype Dx trial handover facilitated by Quality Assurance Officer (Research) before the current Study Coordinator left their post;
- Fourier Transform Infrared (FTIR) spectroscopy study triggered audit report approved by RQMG Chair's action and submitted to Wales Research Ethics Committee 7 on 17th July 2020;

- Approved the FTIR study human tissue sample destruction in compliance with the Biobank Policy (466) and HDdUHB's Human Tissue Authority License for Research;
- Progress update for HDdUHB's Biobank Database project;
- Discussion relating to establishing a Biobank Access Committee to consider requests for, and oversee the release of, human tissue samples from HDdUHB's Biobank;
- Developing Guidance for R&D staff and the research community on Statutory Inspections by the Medicines and Healthcare products Regulatory Agency / Human Tissue Authority (MHRA/HTA)

In addition, 14 items from the outstanding suite of written control documents were presented to RQMG for approval. All documents were approved.

**4. Financial Report**

The Sub-Committee received the financial report , with the following noted:

- R&D is on track to break even for 2020/21 with no risk to the Health Board.
- Commercial trial income has reduced due to decrease in commercial research. A commercial approach will be included as part of the strategy development process.

**5. Items for ratification**

Three documents from the suite of written control documents were approved. These documents related to Research-Related Adverse Event / Serious Adverse Event Reporting. The documents received interim approval for 6 months on 9th April 2020 by the RQMG Chair and the R&D Strategic Management Team Chair, with a requirement to receive full approval.

**6. R&D Strategy**

The current R&D strategy comes to an end in March 2021, therefore work is progressing to develop a new 3-5 year R&D strategy.

- The strategy will cover innovation as well as research.
- A discussion took place with active involvement of the three University representatives.
- A work plan to support the strategy development is being produced

**7. University Partners**

The Sub-Committee received an update from the University Partners on their current and planned work with Hywel Dda R&D.

**Risgiau:**
**Risks (include Reference to Risk Register reference):**

There are nine active risks for R&D on the Risk Register, with three risks added to the register during August 2020 (see further details below). Whilst the Sub-Committee received assurance on the management of the risks, it agreed to escalate the following risk to the QSEAC:

**The lack of dedicated research space on the acute hospital sites** – this links to Risk 148 described below. This issue is also related to Risks 556 (Failure to increase research studies – a KPI); 557 (Failure to increase opportunity for people to participate in research – a KPI); 915 & 916 (Unsafe working environments in the research lab in (Prince Philip Hospital (PPH) / lab space in Glangwili General Hospital (GGH); 952 (Lower than expected income).

- PPH has a dedicated clinical research centre with clinical space and a laboratory that is currently being upgraded to a CL2 standard (to address risk 915).
- Withybush General Hospital (WGH) has use of lab space, and use of clinical rooms in the chemotherapy day unit.
- Bronglais General Hospital (BGH) has no lab space, and currently no clinical space
- GGH has no clinical space and the space that was being used to process samples has recently been condemned (risk 916), so the activity has ceased.

The lack of dedicated research space (research laboratory to process samples, and a clinical room to see patients) is significantly hindering the ability of GGH and BGH to open any research studies beyond simple observational trials. This impacts on the team's ability to achieve the KPIs that have been set by Health and Care Research Wales. A failure to achieve the KPIs means a reduction in income for research the following year.

If offering the best quality care is to offer the opportunity for patients to receive access to new and novel therapies, often through trial, then without addressing the space issue, we will be suboptimal.

The issue is most acute in GGH. It has been on the R&D risk register since May 2016, and it is something that R&D cannot solve by themselves. Meetings have been held between R&D, the GGH management team, and estates, and a potential space has been identified. The area in question is ripe for improvement, the fabric and services have not been attended to for some time, and the electrical circuitry cannot be extended in its present state. The area will also need alteration to make it suitable for R&D needs. Estates have produced some drawings and an estimate of costs, however the estimate is high and reducing the scope has not had a significant impact on the cost. The Director of Estates has kindly agreed to re-visit. Although R&D can contribute to the costs we are not able to fully fund the current estimate. Unless we can identify an option that works within the available budget, then more complicated observational and interventional research at GGH will not be able to take place.

**Gwella Ansawdd:**
**Quality Improvement:**

**Internal Audit**

Between September 2019 and January 2020, the R&D department was subject to an internal audit. The objective of the review was to assess the adequacy of arrangements for the management of R&D in order to provide assurance to the Audit & Risk Assurance Committee (ARAC) that risks material to the achievement of systems objectives were being managed appropriately.

In January 2020, the overall decision of the auditors was that the Board could only take **limited assurance** that arrangements to secure governance, risk management and internal control were suitably designed and applied effectively, resulting in a moderate impact on residual risk to exposure until the recommendations were implemented.

A management response was prepared and submitted to ARAC and a re-audit was planned. In the interim, work took place across the R&D department to address the recommendations.

Re-Audit – report available on 28th August

The re-audit took place between 13th-27th August 2020, to establish the progress made by

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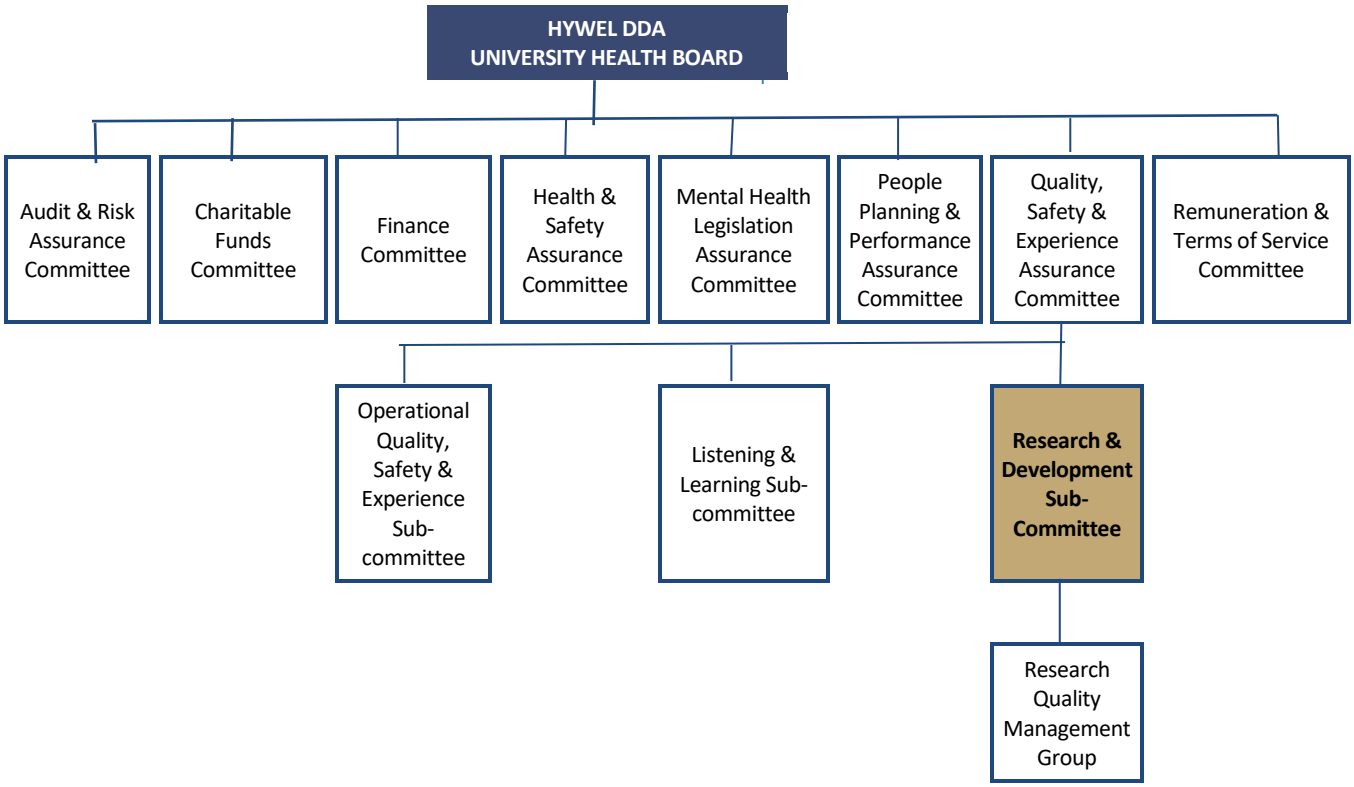
| management team in implementing the agreed actions. The outcome of the re-audit being that the level of assurance as to the effectiveness of the system of internal control in place is **Reasonable** A**ssurance**. A full report is being prepared for ARAC on 20th October 2020. |
| **Argymhelliad:**<br>**Recommendation:** |
| QSEAC is asked to note the content of this report and ratify the revised R&DSC Terms of Reference (Appendix 1). |
| **Dyddiad y Cyfarfod Pwyllgor Nesaf:**<br>**Date of Next Sub- Committee Meeting:** |
| Monday 9th November 2020 |




# RESEARCH & DEVELOPMENT SUB-COMMITTEE

## TERMS OF REFERENCE

| Version | Issued to: | Date | Comments |
|---|---|---|---|
| V0.2 | Research & Development Committee | 07.10.2013 | Approved |
| V0.3 | Research & Development Committee | 24.10.2014 | Approved |
| V0.4 | University Partnership Board | 16.11.2015 | Approved |
| V0.5 | Research & Development Sub-Committee | 27.11.2015 | Approved |
| V0.6 | Research & Development Sub-Committee | 22.02.2016 | Approved |
| V0.7 | Research & Development Sub-Committee | 13.02.2017 | Approved |
| V0.8 | Research & Development Sub-Committee | 21.05.2018 | Approved |
| V0.9 | Research & Development Sub-Committee | 14.09.2020 | Approved |
| V0.9 | Quality, Safety & Experience Assurance Committee | 06.10.2020 | |

# RESEARCH & DEVELOPMENT SUB-COMMITTEE

## 1. Constitution

1.1 The Research & Development Sub-Committee has been established as a Sub-Committee of the Quality, Safety, and Experience Assurance Committee (QSEAC) from 1st December 2019.

## 2. Membership

2.1 The membership of the Sub-Committee will comprise the following:

| Title |
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| Medical Director & Deputy Chief Executive (Chair) |
| Deputy Director Research & Innovation (Vice Chair) |
| R&D Director |
| Deputy R&D Director |
| Senior R&D Operations Manager |
| Independent Member |
| Assistant Director of Nursing (with a responsibility for research) |
| Assistant Director of Therapies and Health Science (with a responsibility for research) |
| Research active representatives – acute sector, primary care, mental health |
| A representative from Aberystwyth University |
| A representative from Swansea University |
| A representative from the University of Wales Trinity Saint David |
| Director of Finance or deputy |
| Head of Clinical Engineering |
| 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 |

2.2 Membership of the Sub-Committee will be reviewed on an annual basis.

## 3. Quorum and Attendance

3.1 A quorum shall consist of no less than a third of the membership, and must include as a minimum the Chair or Vice-Chair of the Sub-Committee, and a research active clinician.

3.2 An Independent Member shall attend the meeting in a scrutiny capacity.

3.3 Any senior officer of the UHB or partner organisation may, where appropriate, be invited to attend, for either all or part of a meeting, to assist with discussions on a particular matter.

3.4 The Sub-Committee may also co-opt additional independent external “experts” from outside the organisation to provide specialist skills.

3.5 Should any member be unavailable to attend, they may nominate a fully briefed deputy to attend in their place, subject to the agreement of the Chair.

3.6 The Chair of the Research & Development Sub-Committee shall have reasonable access to Executive Directors and other relevant senior staff.

3.7 The Sub-Committee may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

## 4. Purpose

4.1 The purpose of the Research & Development Sub-Committee will be to assure the Board, via the Quality, Safety and Experience Assurance Committee (QSEAC), 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 guiding principles will be:
4.1.1 a clear strategy;
4.1.2 clear governance and performance management; and
4.1.3 working within budget constraints.

4.2 The Research & Development Sub-Committee will promote and support involvement in high quality, multi-disciplinary and multi-agency healthcare research, promote evidence-based healthcare, build research capacity and foster a research culture, including patient/public involvement where appropriate.

4.3 The Research & Development Sub-Committee will facilitate collaboration with the Research and Academic community to maximise outcome and impact for the Health Board and the patients it serves.

## 5. Key Responsibilities

5.1 Assure the Board, through the QSEAC, in relation to arrangements for ensuring compliance with all relevant frameworks, UK Clinical Trials and other Regulations (transposed into UK law from European Union Directives) and reporting requirements.

5.2 Consider the implications for the Health Board of the outcomes arising from relevant review, audit or inspection carried out by external regulatory authorities, review progress with resulting Corrective and Preventative Action plans (CAPAs) and authorising their completion.

5.3 Oversee the development of the Health Board's Research and Development (R&D) Strategy, R&D Policies, Standard Operating Procedures and other relevant written control documents in line with local and national priorities and guidance.

5.4 Approve R&D written control documents (policies, plans, Standard Operating Procedures, etc) within the scope of the Sub-Committee, obtaining ratification as and where appropriate.

5.5 Provide assurance to the Board, through the QSEAC that the ring fenced R&D funding is being spent according to Welsh Government requirements.

5.6 Receive and comment on financial, performance management and data reports from the R&D operational team.

5.7 Ensure strong relationships and effective communication with associated Higher Education Institutions and other external organisations.

5.8 Support Universities with their research agenda, including undergraduate /postgraduate work, research impact, and their Research Excellence Framework submission.

5.9 Ensure the UHB 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

5.10 Seek assurance on the management of operational risks that have been aligned to the Sub-Committee, and provide assurance to the Quality, Safety and Experience Assurance Committee that risks are being managed effectively and report any areas of concern, eg where risk tolerance is exceeded, lack of timely action.

5.11 Report on R&D activity to relevant health community committees and the Health Board via the R&D Director or a nominated deputy.

5.12 Agree issues to be escalated to the Quality, Safety and Experience Assurance Committee, with recommendations for action.

## 6. Agenda and Papers

6.1 The Sub-Committee Secretary is to hold an agenda setting meeting with the Chair and/or the Vice Chair and the R&D Director, at least **six** weeks before the meeting date.

6.2 The agenda will be based around the Sub-Committee work plan, identified risks, matters arising from previous meetings, issues emerging throughout the year and requests from Sub-Committee members. Following approval, the agenda and timetable for papers will be circulated to all Sub-Committee members.

6.3 All papers must be approved by the Deputy Director, Research & Innovation.

6.4 The agenda and papers for meetings will be distributed **seven** days in advance of the meeting.

6.5 The minutes and action log will be circulated to members within **ten** days to check the accuracy.

6.6 Members must forward amendments to the Sub-Committee Secretary within the next **seven** days. The Sub-Committee Secretary will then forward the final version to the Sub-Committee Chair for approval.

## 7. Frequency of Meetings

7.1 The Sub-Committee will meet bi-monthly and shall agree an annual schedule of meetings. Any additional meetings will be arranged as determined by the Chair of the Sub-Committee in discussion with the R&D Director.

7.2 The Chair of the Sub-Committee, in discussion with the Sub-Committee Secretary, shall determine the time and the place of meetings of the Sub-Committee and procedures of such meetings.

## 8. Accountability, Responsibility and Authority

8.1 The Sub-Committee will be accountable to the Quality, Safety and Experience Assurance Committee for its performance in exercising the functions set out in these Terms of Reference.

8.2 The Sub-Committee shall embed the UHB's vision, corporate standards, priorities and requirements, e.g. equality and human rights, through the conduct of its business.

8.3 The requirements for the conduct of business as set out in the UHB's Standing Orders are equally applicable to the operation of the Sub-Committee.

## 9. Reporting

9.1 The Sub-Committee, through its Chair and members, shall work closely with the Board's other committees, including joint / sub committees and groups to provide advice and assurance to the Board through the:
10.1.1 joint planning and co-ordination of Board and Committee business;
10.1.2 sharing of information.

9.2 In doing so, the Sub-Committee shall contribute to the integration of good governance across the organisation, ensuring that all sources of assurance are incorporated into the Board's overall risk and assurance framework.

9.3 The Sub-Committee may establish groups or task and finish groups to carry out specific aspects of Sub-Committee business on its behalf. The Sub-Committee will receive updates from each Group detailing the business undertaken on its behalf. The following management groups have been or will be established:
10.3.1 Research Quality Management Group;

9.4 The Sub-Committee Chair, supported by the Sub-Committee Secretary, shall:
9.4.1 Report formally, regularly and on a timely basis to the Quality, Safety and Experience Assurance Committee on the Sub-Committee's activities. This includes the submission of a Sub-Committee update report for information after every meeting, as well as the presentation of an Annual Report within 6 weeks of the end of the financial year;
9.4.2 Bring to the Quality, Safety and Experience Assurance Committee's specific attention any significant matters under consideration by the Sub-Committee;
9.4.3 Ensure appropriate escalation arrangements are in place to alert the UHB Chair, Chief Executive, or Chair of other relevant Committees, of any urgent/critical matters that may compromise patient care and affect the operation and/or reputation of the UHB.

## 10. Secretarial Support

10.1 The Sub-Committee Secretary shall be determined by the Deputy Director, Research & Innovation.

## 11. Review Date

11.1 These Terms of Reference and operating arrangements shall be reviewed on at least an annual basis by the Sub-Committee for approval by the Quality, Safety and Experience Assurance Committee.