Name of Sub-Committee:	Research & Innovation Sub-Committee
Chair of Sub-Committee:	Professor Philip Kloer, Medical Director/Deputy Chief Executive
Reporting Period:	Meeting held on 14th March 2022

Key Decisions and Matters Considered by the Sub-Committee:

The Research & Innovation Sub-Committee (R&ISC) last met on 14th March 2022. The purpose of this report is to provide the People, Organisational Development and Culture Committee (PODCC) with a summary of the key points against the agenda items.

- **R&ISC Terms of Reference (ToR)** (**version11) 2022-2023** were submitted for approval.
  - Changes to the ToR include
    - **A request from the Chair to move the meeting sequence back to quarterly from bi-monthly** - it was felt that although bi-monthly meetings had been useful to gain momentum for the new Sub-Committee, the group had matured enough to be able to provide assurance on a quarterly basis. Any gaps in assurance for PODCC caused by the mis-match in meeting dates will be covered by a brief update report from the R&I senior team covering research & development (R&D) activity, innovation activity, any quality and safety issues, and a financial position for both teams.
    - **The addition of the Sponsorship Review Panel as a formal Group reporting to the R&ISC** - the Sponsorship Review Panel (SRP) reviews internal research study proposals and will make the decision on behalf of Hywel Dda University Health Board (HDdUHB) whether it will sponsor the study. The sponsor is "the individual organisation or partnership that takes on overall responsibility for proportionate, effective arrangement being in place to set up, run and report a research project" (HRA 2021) . The sponsor also assumes responsibility for ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project. The SRP will provide assurance on this to R&ISC.
    - **TriTech Management Group -** the addition of the TriTech Management Group as a formal Group of the R&ISC. The TriTech Management Group oversees the performance and governance of the initiative and reviews proposals for commercially funded clinical investigations and evaluations of new technologies. It will make decisions on behalf of Hywel Dda University Health Board (HDdUHB) about whether it has the capacity and capability to undertake such clinical investigations and evaluations. In taking on an investigation, HDdUHB also assumes responsibility for ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the clinical investigation. The TriTech Management Group will provide assurance on this to R&ISC.
  - The revised R&ISC Terms of Reference (version 11) were approved and are submitted to PODCC for ratification (Appendix 1).
- **R&ISC Annual Report 2021-22**
  - The Annual Report was noted and approved for submission to PODCC on 14th March 2022 (Included as part of agenda item 7.2).

- **R&ISC Work Plan**
    - Work plans for 2021/22 and 2022/23 were noted and accepted.
- **Strategy Action Plan – Verbal report**
    - Year 1 of the action plan is being reviewed and actions closed as complete, or carried forward to Year 2. The Year 2 action plan is currently being prepared.

Research & Development (R&D)

- **R&D Team Report –** the R&D Team report was noted and accepted.
    - 8 portfolio studies have been opened across the sites in the past 2 months, increasing the number of portfolio studies opened this year to 36. This is on track to correspond with the previous pre-COVID-19 year.
    - Recruitment into studies continues well. HDdUHB is the highest recruiter into the CONSCOP2 (bowel cancer) study across the United Kingdom (UK), with a total of 123 patients recruited to date.
    - 18 applications for innovation funding have been supported and were submitted in early March 2022.
    - Phase 1 of the commissioned BioBank feasibility work is due to report at the end of March 2022.
    - The Limbus database project for the management of human tissue samples is completing trials and is due for sign off in June/July 2022.
    - The Power BI Dashboard completed by Health and Care Research Wales (HCRW) that presents real time data on the set up and recruitment of portfolio studies in HDdUHB was demonstrated to the R&ISC.
- **R&D Department Risk Register - report noted and accepted**
    - Risk 1160 is the only directorate risk and is related to the requirement for additional Principal Investigators. Further progress against the actions in place to mitigate the risk has been achieved and is detailed below under the Risks/Matters of Concern section.
    - Risk 1035 (Bronglais facilities) score has reduced from 16 to 12 due to the previous R&D clinical room on the hospital site being returned to the Team, thus enabling them to more easily recruit patients into studies again.
- **Governance Report from Research Quality Management Group (RQMG) – report noted and accepted**
    - A completed Corrective Action Preventive Action (CAPA) for the Good Clinical Practice breach reported to the last PODCC meeting was submitted to R&ISC for information.
    - Updated ToR for the RQMG 2022/23 were noted and approved by R&ISC
    - The RQMG annual report for 2021-22 was noted and approved, and has been submitted to PODCC with the R&ISC Annual Report as agenda item 7.2.
- **R&D Financial Report – report noted and accepted**
    - The financial position at the end of 2021-22 is set to breakeven.
- **R&D National Developments – verbal report**
    - The R&ISC received a verbal update from the Director of Research, Innovation and University Partnerships. This referred to the managed process that is ongoing across the UK to rebuild the clinical research portfolio following the COVID-19 pandemic. Questions have been raised about the effectiveness of this process, which is being reviewed at a UK level. The revised process, which will potentially

include closing certain studies, may result in implications for HDdUHB's financial allocation and the replacement of staff.

- **R&D Local Performance Framework – verbal report**
  - Work is continuing with R&D, Finance and Informatics to produce a Power BI dashboard to display progress in metrics related to the strategy.
- **R&D Local Facilities Update – verbal report**
  - The new Clinical Research Centre at Glangwili General Hospital (GGH) was officially opened by the HDdUHB Chair and Chief Executive on 9th March 2022.
  - Bronglais General Hospital's (BGH's) plans for a clinical research facility on the Penglais Campus of Aberystwyth University continue.
  - The Medical Director and the Director of Research, Innovation and University Partnerships will be meeting the Withybush General Hospital (WGH) management team to discuss options for clinical research space at this site.

Presentations

Two presentations were made to the R&ISC:

1. **Regional Oncology Research Presentation** – Dr Mark Davies

   Dr Mark Davies, Oncologist, Swansea Bay UHB attended the meeting and talked about his work in oncology and his role championing oncology research in HDdUHB.

2. **RECOVERY trial results to date** – Sandra Griffiths

   Sandra Griffiths, Lead Pharmacist for Research & Development in HDdUHB attended the meeting to provide a presentation on the RECOVERY trial which was set up in 2020 to identify treatments for COVID-19. Through the trial, three treatments have been found to be effective and are now part of normal practice, whilst many more treatments were found to be ineffective.

Innovation

- **TriTech Team Report – report noted and accepted.**
  - Significant progress has been made on the Quality Management System, which is due to be ready by the end of April 2022.
  - A Technology Scientific Review Panel (ThoRP) has been established to ensure that all technology innovation proposals receive rigorous methodological review.
  - Work is ongoing on a large grant opportunity with Amgen to develop a learning lab' for cardiovascular population risk prediction and high intensity intervention in a controlled health system, to target better outcomes.
  - **TriTech Risk Register -** Risk 1144 has been updated to reflect the recent internal audit report.
  - **Tritech Finance Update -** the finance report was produced with Month 10 figures. The financial position is set to breakeven. The Director of Finance identified that because of the way TriTech self-funds, this is a risk which requires monitoring, however was content with the current positive position.
  - **TriTech Business Plan -** the Head of Clinical Engineering has commenced working on a 12 month plan with the marketing company SBW. SBW has also been awarded the contract to develop a 3-5 year business plan. It is expected that the 12 month plan will be completed by the end of April 2022.
- **Technology Scientific Review Panel Terms of Reference – not approved**

  The inaugural Terms of Reference for the Technology Scientific Review Panel (ThoRP) were submitted to the R&ISC for approval. Following discussion it was felt that amendments would be required prior to approval.

University Partnerships – proposal agreed

- A new format for the university partnerships part of the R&ISC agenda was proposed. This would involve a rotation system, where each partner provides a more detailed overview at one in every three meetings.
    - University of Wales Trinity Saint David: June 2022.
    - Swansea University: September 2022.
    - Aberystwyth University: December 2022.

Matters Requiring People, Organisational Development & Culture Committee Level Consideration or Approval:

The R&ISC Terms of Reference (version 11) 2022-23.

Risks / Matters of Concern:

RISK 1160 (Directorate Risk)

TOPIC	CAUSE	SCORE	ACTIONS
There is a risk of a decreasing research portfolio, both in amount as well as diversity	This is caused by a lack of research leadership across HDdUHB (staff able to act as Principal Investigators)	12	A competitive process has been concluded that has led to the appointment of three new clinical leads for research. (Oncology, Women's Health, and the GGH site). The arrangements will be tested over the next 6 months before deciding whether to extend to other sites and specialities. Review 4/5/22.
			A colorectal cancer surgeon has two sessions protected for research, initially supported by a grant (Moondance Cancer Initiative), however with HDdUHB commitment to continue to support if successful. A research midwife with three days a week for developing the midwifery research portfolio, funded by R&D. Review 4/5/22.

Planned Sub-Committee Business for the Next Reporting Period:

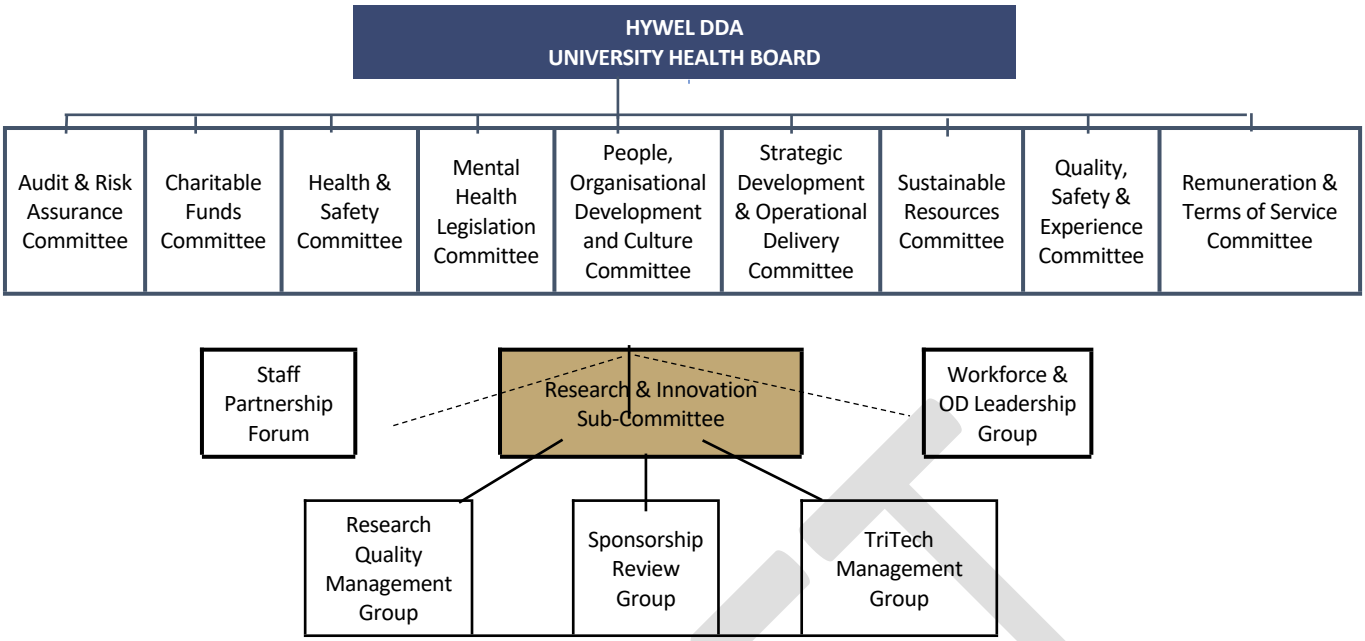
Future Reporting:

In addition to routine business, the R&ISC will receive reports on:

1. Strategy Action Plan Year 1 and Year 2.
2. The TriTech Business Plan.
3. A Standard Operating Procedure (SOP), “Management and Escalation of Monitoring and Audit Findings, Errors and Near Misses in Research”, to include a ‘Consequences Framework’.
4. Updates on progress surrounding the research facilities in BGH and WGH.
5. A draft Power BI dashboard for R&D development, quality assurance, and finance metrics.
6. Further information on future HCRW funding.

Date of Next Meeting:

Monday, 13th June 2022



TERMS OF REFERENCE

RESEARCH & INNOVATION SUB-COMMITTEE

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	Approved
V10.0	Research & Innovation Sub-Committee	08.03.2021	Approved
V10.0	Quality, Safety & Experience Assurance Committee	13.04.2021	Approved
V11.0	Research & Innovation Sub-Committee	14.03.2022	Approved
V11	People, Organisational Development and Culture Committee	04.04.2022	For Approval

RESEARCH & INNOVATION SUB-COMMITTEE

1. Constitution

1.1. The Research & Innovation Sub-Committee (RISC) was established as a Sub-Committee of the People, Organisational Development and Culture Committee (PODCC) and constituted from 1st August 2021.

2. Purpose

2.1. The purpose of the Research & Innovation Sub-Committee is to assure the Board, via the People, Organisational Development and Culture Committee, that it is discharging its functions and meeting its responsibilities with regards to the quality and safety of research, development and innovation activity carried out within the organisation.

The guiding principles will be:

2.1.1 a clear strategy;
2.1.2 clear governance and performance management
2.1.3 working within budget constraints.

2.2. The Research & Innovation Sub-Committee 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.

2.3. The Research & Innovation 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.

3. Key Responsibilities

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

3.2. Assure the Board, through the PODCC, that the sponsorship of research studies by Hywel Dda University Health Board follows a robust scientific review and complies with all relevant regulations.

3.3. Assure the Board, through the PODCC, that the arrangements for undertaking real world evaluations of medical devices are robust and comply with all relevant regulations.

3.4. Assure the Board, through the PODCC, that the ring-fenced funding is being spent according to Welsh Government requirements.

3.5. Receive assurance on the management of operational risks that have been aligned to the Sub-Committee, and provide assurance to the People, Organisational Development and Culture Committee that risks are being managed effectively and report any areas of concern, e.g. where risk tolerance is exceeded, lack of timely action.

3.6. Receive assurance on the progress of UHB sponsored research studies

3.7. Receive assurance on the progress of real-world evaluations of medical devices taking place in the UHB

3.8. Receive and comment on financial, performance management and data reports from the research and innovation operational team.

3.9. Oversee the development of the Health Board's Research & Innovation Strategy.

3.10. Oversee the development and approval of research and innovation written control documents (policies, plans, Standard Operating Procedures, etc) within the scope of the Sub-Committee, obtaining ratification as and where appropriate.

3.11. 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.

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

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

3.14. 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

3.15. Report on research and innovation activity to relevant health community committees and the Health Board via the Director of Research, Innovation and University Partnerships, or a nominated deputy.

3.16. Agree issues to be escalated to the People, Organisational Development and Culture Committee, with recommendations for action.

4. Membership

4.1 The membership of the Research & Innovation Sub-Committee shall comprise:

Title
Medical Director & Deputy Chief Executive (Chair)
Director Research, Innovation & University Partnerships (Vice Chair)
Independent Member
Clinical Director Research & Development
Head of Research & Development

Head of TriTech
Research & Innovation Finance Business Partner
Research active representatives – acute sector, primary care, mental health
Director of Finance
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
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

4.2 The membership of the Sub-Committee will be reviewed on an annual basis.

5. Quorum and Attendance

5.1 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.

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

5.3 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.

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

5.5 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.

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

5.7 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.

6. Agenda and Papers

6.1 The Sub-Committee Secretary is to hold an agenda setting meeting with the Chair and the Sub-Committee Lead 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 Director of Research, Innovation and University Partnerships.

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 quarterly and shall agree an annual schedule of meetings. Additional meetings will be arranged as determined by the Chair of the Sub-Committee in discussion with the Director of Research, Innovation and University Partnerships.

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 People, Organisational Development and Culture 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:

9.1.1 Joint planning and co-ordination of Board and Committee business;
9.1.2 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 on its behalf specific aspects of Sub-Committee business. The Sub-Committee will receive updates following each meeting, detailing the business undertaken on its behalf. The following management groups have been or will be established:

- Research Quality Management Group
- Sponsorship Review Group
- TriTech 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 People, Organisational Development and Culture 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 People, Organisational Development and Culture 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 Director of Research, Innovation and University Partnerships.

11. Review Date

11.1 These terms of reference shall be reviewed on at least an annual basis by the Sub-Committee for approval by the People, Organisational Development and Culture Committee.