Hywel Dda University Health Board

Research & Development Department Governance Review

Final Internal Audit Report

February 2020

Private and Confidential

NHS Wales Shared Services Partnership

Audit and Assurance Services

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Review reference:	HDUHB-1920-09
Report status:	Final Internal Audit Report
Fieldwork commencement:	10th September 2019
Fieldwork completion:	29th January 2020
Draft report issued:	4th February 2020
Management response received:	10th February 2020
Final report issued:	11th February 2020
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Committee:	Audit & Risk Committee

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

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1. Introduction and Background

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

2. Scope and Objectives

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

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

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

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

3. Associated Risks

The potential risk considered in the review was as follows:

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

OPINION AND KEY FINDINGS

4. Overall Assurance Opinion

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

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

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

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

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

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

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

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

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

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

5. Assurance Summary

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

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

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

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

Design of Systems/Controls

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

Operation of System/Controls

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

6. Summary of Audit Findings

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

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

Strategy

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

See Finding 6 in Appendix A.

R&D Sub-Committee

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

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

See Finding 1 in Appendix A.

Declaration of Interest, Gifts, Hospitality & Sponsorship

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

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

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

See Finding 7 at Appendix A.

Risk Management

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

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

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

See Finding 8 at Appendix A.

Finance

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

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

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

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

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

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

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

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

See Findings 2, 3 & 4 at Appendix A.

Workforce

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

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

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

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

See Findings 9 & 10 at Appendix A.

Incident Reporting

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

Travel Claims

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

See Finding 11 at Appendix A.

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

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

See Finding 12 at Appendix A.

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

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

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

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

See Findings 5 & 13 at Appendix A.

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

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

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

No matters arising.

7. Summary of Recommendations

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

A summary of these recommendations by priority is outlined below.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix B - Assurance Opinion and Action Plan Risk Rating

2019/20 Audit Assurance Ratings

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

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

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

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

Prioritisation of Recommendations

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

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

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

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