Bundle Quality, Safety & Experience Assurance Committee 13 August 2020

4.3 Research & Development (R&D) Sub-Committee - Research & Development Restart Activity Report

Presenter: Dr Philip Kloer

Item 4.3 Research & Development Restart Activity Report

Appendix 1 - Request to Restart Suspended Study

Appendix 2 - Restart Scenario Table v2.0

Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

PWYLLGOR ANSAWDD, DIOGELWCH A SICRHAU PROFIOD
QUALITY, SAFETY AND EXPERIENCE ASSURANCE COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	13 August 2020
TEITL YR ADRODDIAD: TITLE OF REPORT:	Research & Development Restart Activity Report
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Dr Philip Kloer, Medical Director / Deputy CEO
SWYDDOG ADRODD: REPORTING OFFICER:	Dr Caroline Williams, Senior Operations Manager R&D

Pwrpas yr Adroddiad (dewiswch fel yn addas)
Purpose of the Report (select as appropriate)

Er Sicrwydd/For Assurance

ADRODDIAD SCAA
SBAR REPORT

Sefyllfa / Situation

Health and Care Research Wales (HaCRW) have asked that all Research and Development (R&D) Departments put in place an arrangement for restarting non COVID-19 research studies, in view of the marked decrease in patients with the disease and the requirement to ensure all patients and staff are able to benefit from research.

This report sets out the approach that Hywel Dda University Health Board's (HDdUHB) R&D Department is taking to re-starting studies, utilising a risk based scenario approach, and ensuring full compliance with local and national directives. As the next R&D Sub-Committee is not until 14th September 2020, this report is presented to the Quality, Safety & Experience Assurance Committee's attention for assurance.

Cefndir / Background

Research has and continues to be essential to finding effective responses to COVID-19. HDdUHB has been proactively involved in several studies as part of the international and national response. In line with HaCRW advice, this has meant reprioritising research delivery team resources towards the COVID-19 studies. With the number of COVID-19 patients in decline, HaCRW has asked that non COVID-19 studies now restart.

The restart of a currently paused study and the start-up of new studies is dependent on a number of preconditions being met. HaCRW has set out that it is the responsibility of the sponsor, the funder, the Chief Investigator (CI), the study site(s) legal entity, and, where applicable, the Principal Investigator (PI) at each site to assess that these are met before applying to restart/start. The principles that HDdUHB has been asked to follow in making decisions about restart are as follows:

Principle 1: Only research that is still viable should restart/start.

Principle 2: Research should only restart/start when safe to do so. Safety considerations in restarting research include:

- The risk of exposure to COVID-19.

- Government guidance on social distancing, restart of work, and travel.
- Local site policies in respect of COVID-19.

Principle 3: Capacity and site readiness

- The pace of restart and the commencement of new studies will be commensurate with capacity and readiness at each site in the Health Board.

Principle 4: Prioritisation. Three levels for prioritisation of studies that need delivery team support have been developed and will be applied according to study urgency (Level 1 is highest priority/urgency):

- Level 1: Essential studies providing evidence for pandemic management, i.e. nationally prioritised COVID-19 Urgent Public Health (UPH) research studies.
- Level 2: Studies where the research protocol includes an urgent treatment or intervention without which patients could come to harm. These might be studies that provide access to potentially life preserving or life-extending treatment not otherwise available to the patient.
- Level 3: All other studies (including new COVID-19 studies not in Level 1).

Asesiad / Assessment

To ensure these principles are followed in HDdUHB, the following approach is being taken:

Establishment of an Assessment and Prioritisation Panel

This panel meets virtually every Monday to consider all applications for restart. The panel consists of the R&D Director/Deputy R&D Director, Senior Operations Manager, Study Set Up Manager, Lead Clinical Research Nurses, Associate Director Medical Directorate. The panel ultimately decides whether studies can restart in line with the criteria set out by the subsequent sections.

Application of Prioritisation Criteria

The panel reviews the restart requests from Sponsors and Local PIs. Initial general prioritisation principles are applied to identify which studies are the most urgent to restart. Prioritisation of portfolio studies take into account the national discussions within Wales where a centralised decision has been taken to prioritise certain studies. For those identified studies, the local team review the capacity and capability of the Health Board and prioritise resource accordingly. A restart form has been specifically designed to allow a clear audit trail of the R&D Department's decision making process (Appendix 1).

Risk Assessment and Development of Management Plan

Appendix 2 sets out the four main types of research that the Health Board routinely undertakes and the typical research processes associated with each type. Importantly, it sets out the level of infection risk associated with each type of research. The R&D Department is categorising the research it restarts using these scenarios.

Practically, the categorisation of research studies in this way allows a risk assessment and associated management approach. In summary, when a study is categorised as:

Low Risk, it means that most aspects of the study can be conducted remotely, by telephone or internet calls. If interventions are required they are non-invasive, and there is

minimal infection risk. The R&D Department can only agree to the study starting/restarting following:

- an assessment of its priority (i.e. the three levels set out by HaCRW); and
- a site capability and capacity assessment (e.g. if the research is a low priority and would distract from COVID-19 studies, it would not be agreed for restart).

Medium Risk, it means patients have to attend sites or health board staff need to go to other premises where patients are present. Measurements and samples with a potentially low viral load e.g. blood & urine, need to be taken and/or treatments administered. No test or procedure is aerosol generating. The R&D Department can agree to the study starting/restarting providing that:

- site infection control has been consulted and there is a risk management plan in place;
- the guidelines of the site leadership team relating to the areas where the study will be undertaken are followed;
- an assessment of priority has taken place; and
- a site capacity and capability assessment has been conducted, which will include laboratory capacity.

High Risk, it means participants have to attend sites to meet research staff and measurements and samples need to be taken and/or treatments administered. Tests and procedures are aerosol generating or carry a potentially high viral load e.g. saliva & sputum. Starting/restarting the study will be determined by the R&D Department and the site management team on a study by study basis providing that:

- infection control has agreed, with a clear management plan in place; this will include taking place in designated facilities meeting specified infection control criteria;
- specific guidelines developed in partnership with the site leadership team are implemented;
- an assessment of priority has taken place; and
- a site capacity and capability assessment has been conducted, which will include laboratory capacity to process potentially high risk samples.

The implications of this report are that for low and medium risk studies, in the majority of circumstances, the R&D Department is able to approve the restart of studies. High risk studies can only be agreed on a study by study basis with the site leadership team(s) where the study is going to be carried out and dependent on laboratory capacity to process samples.

At present, all sites are able to support low risk studies. Under the Senior R&D Operations Manager, lead research nurses are undertaking assessments, and making adjustments, that should enable all sites to support medium risk studies. Some adjustments will be necessary and will require the support of operational management teams (e.g. providing a space within outpatients to consult with patients). The additional facilities required to undertake high risk studies (e.g. accessible laboratory space of appropriate categorisation) means that the Health Board will only be able to conduct them at one or two of its sites. No study will be restarted at sites where it is not safe and viable to do so. There are several adjustments and improvements to R&D facilities required at the various sites to ensure studies can be carried out safely and effectively. A failure to address these will have an impact on study recruitment (i.e. key performance targets and research income).

<u>Considering HDUHB Sponsored Studies</u>

The restarting of Health Board sponsored studies is being overseen by the Health Board Sponsor Review Panel (SRP), with the study CIs completing the restart checklist. The detail

received is reviewed by the SRP for assurances that all conditions have been met including assurances on specific COVID-19 safety requirements to be implemented. CIs holding major grants are being prioritised to assess their restart capabilities.

Re-issuing Capacity & Capability Assessment

Once the Assessment and Prioritisation panel consent to a study restarting, with any conditions being addressed, the study can only start recruiting when a formal statement of capacity and capability is re-issued through the study being green lighted. Any revisions to study targets or changes in the way the study is to be delivered locally are summarised in the capacity and capability confirmation email.

The consideration of new studies

The current priority is to restart paused activity and resources will initially be prioritised to this process. The Assessment & Review panel will monitor progress and identify timelines where it would be appropriate to fully re-open all new study applications, including student studies. It is anticipated this timeline will become naturally evident as the numbers of studies to restart become fewer.

Argymhelliad / Recommendation

QSEAC is asked to receive an assurance from the Research & Development Restart Activity Report.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	4.5 Provide assurance that the organisation, at all levels, has the right governance arrangements and strategy in place to ensure that the care planned or provided across the breadth of the organisation's functions, is based on sound evidence, clinically effective and meeting agreed standards.
Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	N/A
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	3.3 Quality Improvement, Research and Innovation 2.4 Infection Prevention and Control (IPC) and Decontamination

Effaith/Impact:	
Ariannol / Financial: **Ansawdd / Patient Care:** **Gweithlu / Workforce:** **Risg / Risk:**	Not Applicable

Cyfreithiol / Legal: **Enw Da / Reputational:** **Gyfrinachedd / Privacy:** **Cydraddoldeb / Equality:**	

Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

Request for restart of hosted research activity following COVID-19 pause

Team leads / PI

Project Title	
IRAS No	
Sponsor / CI	/
Summary / synopsis of the study.	
Locations (circle / delete)	WGH / PPH / GGH / BGH / Primary Care In-Patient / Out-Patient
PI/s	
Priority level (circle / delete) see appendix 1	1 2 3
Scenario (circle / delete) see appendix 2	1 2 3 4 If 3 or 4 state risk: Low / Medium / High
Has this scenario been agreed to locally?	Yes / No / na / In process
Were there any existing issues with the study prior to COVID? Eg poor recruitment?	
What are the risks to participants if we DO NOT restart the study?	
Planned re-start date	
Planned end of recruitment date	
Revised recruitment figure	
Sponsor agreed to restart?	Yes / No

Are there any additional requirements (beyond the agreed scenario) regarding:

Risk of exposure to COVID-19 for patients and staff.	Yes / No
Compliance with social distancing.	Yes / No
Supply of PPE.	Yes / No
Guidance on safety issues and precautions available to participants and staff.	Yes / No
Access to hospital / clinics for patients or staff.	Yes / No
Revised paperwork (consent, Info sheets etc)	Yes / No
Interventions / tests conducted.	Yes / No

If 'Yes' to any of the above, please complete the table below.

Management of infection risk (add rows if needed).

Requirement / intervention	Management of risk

Lead PI signature / date	/

R&D office

Funding in place.	Yes No n/a
Departmental leads aware	Yes No n/a
Regulatory approvals / amendments in place?	Yes No n/a
Contract in place	Yes No n/a
Support departments agreement - Pharmacy	Yes No n/a
Support departments agreement - Radiology	Yes No n/a
Support departments agreement – Pathology	Yes No n/a
Support departments agreement - Other	Yes No n/a

Re-start Panel

Agree to re-start?	Yes No Yes with conditions
If 'Yes with conditions' please list what is required before restarting here.	
Date	

Please return completed for to Chris.Tattersall@wales.nhs.uk . The information you have provided will be reviewed and considered for restart of your study. We will contact you once a decision has been made or if we have further queries.

	Patient location?	Consent	Low Risk Activity.	Medium Risk Activity.	High Risk Activity.	COVID Considerations.	Infection Control/ Estates Sign Off.
NON-INTERVENTIONAL GROUP STUDIES	Home	Remote	Nil	Nil	Nil	Nil	
OBSERVATIONAL STUDIES (without interventions).	Home	Remote	Nil	Nil	Nil	Nil	
	Ward	In person	Consenting process, completion of QOLS, taking of medical history. Vital signs, height & weight if required.	Nil	Nil	Follow current local/government guidance for general interactions with participants e.g. where possible follow 2 metre social distancing, hand hygiene & correct PPE for staff & participant depending on activity. Assess suitability of patient for approach i.e if they are in a vulnerable group consider deferral or use clinical judgement of benefit of research to the patient vs possible COVID risk.	
	Outpatients	In person	Consenting process, completion of QOLS, taking of medical history. Vital signs, height & weight if required.	Nil	Nil	Same as ward with addition of; Follow current local guidance for bringing patient into hospital for clinical research visit, e.g. outpatient policy such as patient temperature checks on arrival.	
	CRC	In person	Consenting process, completion of QOLS, taking of medical history. Vital signs, height & weight if required.	Nil	Nil	LOW RISK – Follow current local/government guidance for general interactions with participants e.g. where possible follow 2 metre social distancing, hand hygiene & correct PPE for staff & participant depending on activity. Guidance documents are available in the CRC that cover 1. Procedure for participant visits to CRC 2. Research participant instructions 3. Covid 19 Participant screening 4. Cleaning procedure for CRC	

OBSERVATIONAL STUDIES (with interventions)	Ward	In person	Consenting process, completion of QOLS, taking of medical history, vital signs, height & weight, ECG.	General medical examination, low viral load sample collection & storage e.g. blood, urine. Radiology tests if required.	High viral load sample collection, e.g. saliva, sputum. Aerosol generating procedures such as respiratory investigations e.g. spirometry. Sample processing	LOW RISK - Follow current local policy/government guidance for general interactions with participants e.g. where possible follow 2 metre social distancing, hand hygiene & **correct PPE for staff & participant depending on activity**. Assess suitability of patient for approach i.e if they are in a vulnerable group consider deferral or use clinical judgement of benefit of research to the patient vs possible COVID risk. MEDIUM RISK – as above but please be aware guidance/PPE needed may alter dependent on the intervention required and is not consistent across all procedures. e.g the policy and requirements for recording height and weight may differ to that required for collecting a blood sample. Please ensure that local policies and guidelines are checked and adhered to for each individual intervention required. HIGH RISK – as above but also need to vacate room for 1 hour after collecting sample. Currently cannot process samples on all sites unless additional appropriate laboratory space is made available.	
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	CRC	In person	Consenting process, completion of QOLS, taking of medical history, vital signs,	General medical examination, low viral load sample collection & storage e.g. blood, urine.	High viral load sample collection, e.g. saliva, sputum.	LOW RISK – Follow current local/government guidance for general interactions with participants e.g. where possible follow 2 metre social distancing, hand hygiene & correct PPE for staff & participant depending on activity. Guidance documents are available in the CRC that cover	

			height & weight, ECG.	Radiology tests if required.	Aerosol generating procedures such as respiratory investigations e.g. spirometry. Sample processing	1. Procedure for participant visits to CRC 2. Research participant instructions 3. Covid 19 Participant screening 4. Cleaning procedure for CRC MEDIUM RISK – as above but please be aware guidance/PPE needed may alter dependent on the intervention required and is not consistent across all procedures. e.g the policy and requirements for recording height and weight may differ to that required for collecting a blood sample. Please ensure that local policies and guidelines are checked and adhered to for each individual intervention required. HIGH RISK – as above but also need to vacate room for 1 hour after collecting sample. Processing of samples to be done in CL2 histology Lab. under MSC, Mon-Fri 11-2pm until CRC research Lab. facilities have CL2 status. Work is currently underway to achieve this.	
INTERVENTIONAL/ CTIMP STUDIES	Ward	In person	Consenting process, completion of QOLS, taking of medical history, vital signs, height & weight, ECG, dispensing of CTIMP and collection of remaining CTIMP or empty containers.	General medical examination, low viral load sample collection & storage e.g. blood, urine. Radiology tests if required.	High viral load sample collection, e.g. saliva, sputum. Aerosol generating procedures such as respiratory investigations e.g. spirometry. Sample processing	LOW RISK - Follow current local policy/government guidance for general interactions with participants e.g. where possible follow 2 metre social distancing, hand hygiene & **correct PPE for staff & participant depending on activity**. Assess suitability of patient for approach i.e if they are in a vulnerable group consider deferral or use clinical judgement of benefit of research to the patient vs possible COVID risk. MEDIUM RISK – as above but please be aware guidance/PPE needed may alter dependent on the intervention required and is not consistent across all procedures. e.g the policy and requirements for recording height and weight may differ to that required for collecting a blood sample. Please ensure that local policies and guidelines are checked and adhered to for each individual intervention required. HIGH RISK – as above but also need to vacate room for 1 hour after collecting sample. Currently cannot process samples on all sites unless additional appropriate laboratory space is made available.	
	Outpatients	In person	Consenting process, completion of QOLS, taking of medical history, vital signs, height & weight,	General medical examination, low viral load sample collection & storage e.g. blood, urine.	High viral load sample collection, e.g. saliva, sputum. Aerosol generating	LOW RISK - Follow current local policy/government guidance for general interactions with participants e.g. where possible follow 2 metre social distancing, hand hygiene & **correct PPE for staff & participant depending on activity**. Assess suitability of patient for approach i.e if they are in a vulnerable group consider deferral or use clinical judgement of benefit of research to the patient vs possible COVID risk.	

			ECG, dispensing of CTIMP and collection of remaining CTIMP or empty containers.	Radiology tests if required.	procedures such as respiratory investigations e.g. spirometry. Sample processing	MEDIUM RISK – as above but please be aware guidance/PPE needed may alter dependent on the intervention required and is not consistent across all procedures. e.g the policy and requirements for recording height and weight may differ to that required for collecting a blood sample. Please ensure that local policies and guidelines are checked and adhered to for each individual intervention required. HIGH RISK – as above but also need to vacate room for 1 hour after collecting sample. Currently cannot process samples on all sites unless additional appropriate laboratory space is made available.	
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