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Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Llywodraeth Cymru
Welsh Government

Classification on the Health and Care Research Wales Directory and criteria governing eligibility for support

1. Overview

1.1 The Health and Care Research Wales Directory (the Research Directory) is a database of research studies, biobanks and research data registries active in Wales relating to health and social care. These activities can be funded by a range of funders - including Welsh Government, NIHR, research councils, life sciences industry, charities, central and overseas governments.

1.2 The purpose of the Research Directory is to have an accessible list of research being undertaken in Wales to facilitate providing this information to potential participants and researchers.

1.3 The purpose of this paper is to set out criteria to enable activities to be classified correctly on the Research Directory and to capture information on individuals/ teams who are involved in collating data and/or biological samples onto biobanks and research registries. The paper outlines whether these activities are eligible for Health and Care Research Wales support through one or more of the Support and Delivery funding streams.

1.4 The diagram below outlines the main categories within the Research Directory.

2. Definitions

2.1 **Research** can be defined as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods[1]. This definition includes studies that aim to generate hypotheses as well as studies that aim to test them. This excludes:

- Audit
- Service evaluation, quality improvement and other local service based work
- Needs assessments
- Routine bio-banking of biological samples or data[2]
- Routine collection of data for a registry[3].

2.2 The Study Sponsor (as defined by the *UK Policy Framework for Health and Social Care Research, 2017*) has the formal responsibility for confirming that a study is 'research'.

2.3 Welsh Government has developed a definition of social care research for determining eligibility for its social care funding schemes, which will also be used to distinguish studies as 'social care' or 'health'.

2.5 A **Biobank** can be defined as a type of biorepository that stores biological samples (usually human) for use in research. Biobanks have become an important resource in medical research, supporting research in particular relating to genomics and precision medicine. Biobanks give researchers access to data representing a large number of people. Samples in biobanks and the data derived from those samples are generally used by multiple researchers for a range of research studies and purposes.

2.6 A **Research Data Registry** can be defined as an organised system that uses observational study methods to collect uniform data (clinical, social or other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical or policy purpose[4]. A registry is used for the collection and maintenance of information on individuals who have a similar condition and who will consent to be being contacted for future studies or who have agreed to allow their data to be used for research studies in a specific area of research.

[1] UK Policy Framework for Health and Social Care Research, NHS Health Research Authority v3.3 07/11/17

[2] These will be captured on the relevant registries.

[3] These will be captured on the relevant registries.

[4] Gliklich R, Dreyer N. Registries for Evaluating Patient Outcomes: A User's Guide. Rockville, MD: Agency for Healthcare Research and Quality; 2010. AHRQ Publication No. 10-EHC049.

3 Health and Care Research Wales Portfolio

3.1 The Health and Care Research Wales Portfolio consists of

(a) High-quality non-commercial research
(b) Commercial research

(a) High-quality non-commercial research

3.2 There are defined eligibility criteria for adopting studies onto the Health and Care Research Wales Portfolio to ensure that all relevant high-quality non-commercial research studies undertaken in Wales are captured, and to enable Welsh Government's funding through the Health and Care Research Wales Support and Delivery Service to be prioritised.

3.3 Studies are assessed by the Health and Care Research Wales Support and Delivery Centre; those that meet the eligibility criteria **outlined in Box 1** will be rapidly adopted onto the Portfolio. Studies that do not meet the criteria will be subject to further scrutiny through the *non-commercial adoption process* to determine whether they are adopted or not.

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Box 1. Eligibility criteria for adoption onto the Health and Care Research Wales Portfolio

In order to have a study adopted, it must concern research that is funded through high quality, peer-reviewed, open competition. All of the following criteria must apply.

1. Source of funding

Studies that are funded by **eligible funders** are from organisations that:

i) Award research funds as a result of open competition across Wales/UK/EU/internationally with high-quality peer review;

ii) Fund research that is of clear value to the NHS and Social Care; and

iii) Take appropriate account of the priorities, needs and realities of the NHS and social care in making decisions about research they fund.

2. Open competition

Open competition ensures that the best range of researchers is able to apply for the funding. Open competition is defined by:

a) The competition being open to all appropriately qualified individuals, and

b) Knowledge of the competition being available to all appropriately qualified individuals, and

c) The research funder being completely independent of the recipient organisation.

3. High-quality peer review

For studies submitted for adoption onto the Health and Care Research Wales Portfolio, the following definition of high-quality peer review will be used.

Peer review must be:

independent - At least two individual experts: should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators' host institution/funding body and not involved in the study in any way, having no close and active working relationship with the investigators. Reviewers do not need to be anonymous.

expert - Reviewers should have the expertise to assess the methodological and statistical aspects of the study and knowledge of the relevant discipline to consider the clinical, social and/or service based aspects of the proposal.

proportionate - Peer review should be commensurate with the size and complexity of the study. Large multicentre studies should have higher-level review - more reviewers with broader expertise and often an independent review committee or board, and potentially international peer review.

3.4 The study's source of research funding is the principal determinant of whether the study can be adopted onto the Health and Care Research Wales Portfolio. This involves funder organisations and their associated research scheme meeting criteria set out in Box 1. Studies that are eligible for rapid adoption are those funded by Health and Care Research Wales research grant schemes, other areas of central government such as NIHR, and other non-commercial research funders. For the purpose of this policy, these organisations are called **eligible funders**.

3.5 The list of Health and Care Research Wales eligible funders and their associated funding schemes is updated regularly at https://www.healthandcareresearch.gov.wales/how-to-register-your-study/. This includes all NIHR non-commercial partners as well as those organisations that have been identified by the Health and Care Research Wales Support and Delivery Centre as meeting the funder eligibility criteria (Box 1)[5].

3.6 Individual studies funded as part of programme or centre/unit grants, or as part of research training awards, will be required to have undergone protocol peer review before they can be considered for adoption onto the portfolio (see definition of high quality peer review; Box 1). The study Sponsor should provide confirmation of appropriate peer review.

3.7 Studies that are supported by a funding competition that has multiple funding partners will have their adoption decision based on the processes of the organisation who has managed the funding competition (specifically the peer review process).

3.8 Studies where the funder providing the research costs is different from the organisation managing the funding competition (including the peer review process), will have their adoption decision based on the processes of the organisation who has managed the funding competition.

3.9 Wales' approach is compatible with the UK approach to portfolio study adoption. Studies eligible for the NIHR portfolio will be automatically adopted onto the Health and Care Research Wales Portfolio in Wales. If there are Welsh led studies that are on the Health and Care Research Wales Portfolio and require sites in other UK countries and access to resources, the NIHR will review the studies to confirm that they meet the relevant NIHR criteria.

[5] Please note that some schemes administered by eligible funders may not meet the criteria in Box 1 and therefore are not automatically eligible.

Potentially eligible non-commercial studies

3.10 Studies that do not meet the criteria described in Box 1 and are not rapidly adopted onto the Portfolio will be required to follow a separate process. Additional adoption checks will be required to ensure they reach the quality threshold that is required for rapidly adopted studies. This separate *non-commercial adoption process* involves presenting evidence in order to determine whether the criteria outlined in Box 1 are met. The following types of non-commercial studies are considered as requiring such adoption checks.

i. **Investigator-initiated, commercial collaborative studies** are studies that are initiated by non-commercial investigators (e.g. University, NHS or third sector staff) with the majority of the research funding being provided by a commercial organisation
(e.g. a pharmaceutical, biotechnology or devices company), specifically to support that study. Contracts for such studies should include provision for the investigator to take responsibility for analysis, interpretation and publication of findings. Investigator-initiated commercial collaborative research includes pilot studies and nested exploratory studies. It is recognised that commercial organisations do not usually award this funding by means of a structured competition which differentiates this from non-commercial research funding structures. Nevertheless, to be eligible for adoption onto the Portfolio, the potential field of researchers who could be awarded the funding must not have been restricted to specific Universities or NHS Trusts within UK.

Funders of investigator-initiated, commercial collaborative studies are required to provide the Support and Delivery Centre Portfolio team with written confirmation that the funding opportunity was open to all qualified researchers in the UK (or beyond).

It is also essential that all investigator-initiated commercial collaborative studies must have been subjected to high quality peer review before they can be adopted on to the portfolio. Peer review should be commensurate with the size and complexity of the study. The study Sponsor should provide confirmation of appropriate peer review.

ii. **Non-commercial studies funded by overseas governments or overseas charities**

iii. **Certain other high quality studies funded by any source of funding not mentioned above, but which awards research project funding.** This might include non-commercial studies funded by an organisation not captured on the list of Health and Care Wales eligible funders**.**

(b) Commercial Contract Research (Industry funded and industry sponsored)

3.11 Health and Care Research Wales is committed to creating a dynamic environment for the life sciences sector to undertake research and innovation in Wales; and to providing a supportive environment for greater collaboration between NHS Wales, social services, academia, and industry. Collecting information on commercially led studies will help the Welsh NHS and social care environments to meet the research needs of industry.

3.12 In order to be captured on the portfolio, studies taking place in the NHS must meet the definition of 'research' as defined in section 2.1. The study must receive NHS Research Ethics Committee favourable opinion, Health Research Authority/Health and Care Research Wales approval, and sites must also have confirmed their capacity and capability to deliver the study prior to initiation at that site. Pharmacovigilance studies and other post authorisation safety studies required by regulatory authorities that meet these criteria are in scope. Studies whose primary objective is to support product marketing will not be registered.

3.13 Commercial contract research studies receive full funding from industry, i.e. funding of the activities that are additional to treatment outside the context of the study, including funding for all research costs, NHS support costs and treatment costs.

4. Non-Portfolio Studies

4.1 Health and Care Research Wales is committed to ensuring that all research undertaken in Wales is visible. All studies that do not meet the portfolio criteria will be captured on this part of the directory.

4.2 This includes NHS studies developed through Pathway to Portfolio activities (defined as Health and Care Research Wales funded activities that are undertaken to inform the development of a portfolio study or a grant application for a portfolio study), commissioned studies, studies funded through non-competitive steams and studies commissioned locally.

4.3 Welsh Government R&D Division and Public Health Wales are undertaking a mapping exercise to better understand the public health research study landscape and will make further policy decisions on resource needs once this has been considered

5. Biobanks and Research Data Registries

5.1. Researchers are invited to register their involvement in biobanks and /or Research Data Registries on the Research Directory. This might include biobanks or registries led by individuals/teams in Wales, or their involvement in biobanks or registries led from outside Wales. The name of the Biobank and Registry including information on the nature of the data collection and/or nature of the biological samples, will be collected on a Biobank and Research Data Registries Register in order to raise awareness of the ongoing activity and feed into the development of Health and Care Research Wales genomic, precision medicine and other strategies and programmes of activities.

5.2. If the banking of biological samples or data is integral to a self-contained research project designed to test a clear hypothesis, this study should be considered for adoption onto the Health and Care Research Portfolio. Studies where the banking of samples or data is integral to the research project can also be registered as non-portfolio, where they do not meet the eligibility criteria outlined in Box 1.

6. Access to Support and Delivery funding and resources

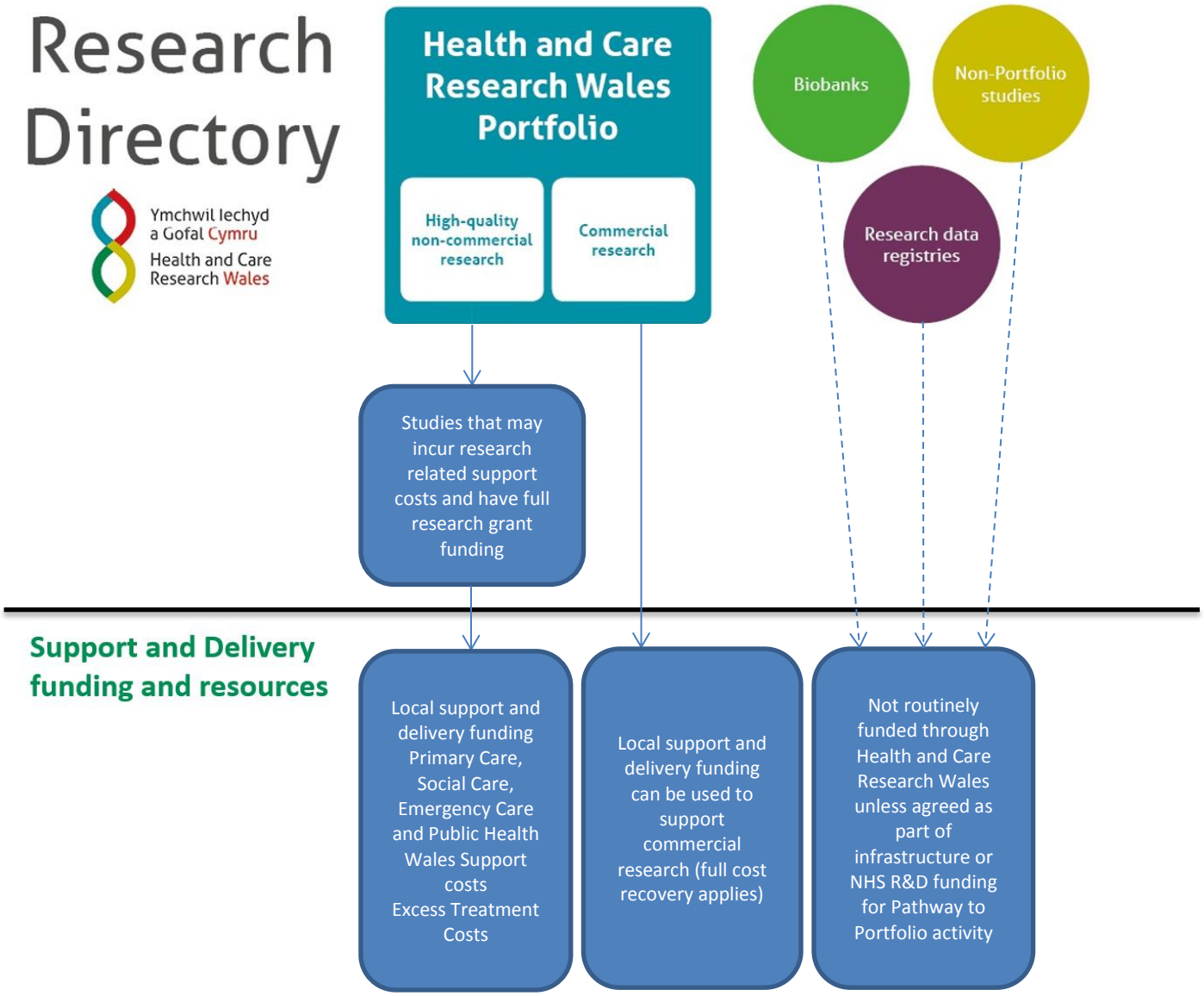
6.1 Capturing all high-quality studies that *incur research related NHS costs* is required in order to enable Welsh Government to distribute activity-based funding to NHS organisations. All studies must already have full research funding (in compliance with AcoRD guidance), and this will allow access to NHS Support Costs and Excess Treatment Costs resources.

6.2 Local Support and Delivery Funding may be used to fund research activities in non-NHS settings, equivalent to NHS support cost activities as defined in the AcoRD guidance. To be eligible, all studies must have full research funding. Social care studies on the portfolio will be eligible to claim the equivalent NHS support costs of studies taking place within the NHS. This includes social care studies in non-NHS settings.

6.3 Capturing all high quality studies that do *not incur research related NHS costs* is equally important in order to identify the breadth of studies undertaken by the R&D community in Wales and identify/determine relevant resources to support such studies. There may be research undertaken with no NHS research related funding implications. In these instances, all studies should be fully funded with arrangements made with relevant organisations (e.g. social care or education) to meet potential costs outwith grant funded research costs.

6.4 An overview of Health and Care Research Wales funding and resources available to support research activities across the Research Directory is

outlined in the diagram below. Studies on the Health and Care Research Wales Portfolio are given highest priority in terms of access to support and delivery funding and resources. There may be exceptional circumstances (e.g. flagship projects such as the 100,000 Genomes Project and HealthWise Wales that are captured on the Biobanks or Research Data Registries list) and these will be determined by Welsh Government.



Note: UK wide work is underway to better understand how adaptive and other innovative trials are captured on the portfolio in future.