

Health and Social Care Portfolio - Eligibility Criteria

1. Introduction

The purpose of this paper is to set out the criteria governing the eligibility of studies for adoption onto the Health and Care Research Wales – Health and Social Care Portfolio. Details of the support available to adopted studies and how to access it are available on the Health and Care Research Wales website. A list of eligible funders and answers to frequently asked questions are provided in the Portfolio section together with a glossary of terms used.

2. What is the Health and Social Care Portfolio?

The Health and Social Care Portfolio is a database of health and social care research studies currently being undertaken in Wales which meet specific eligibility criteria. It is expected that all eligible high quality research that involves NHS patients or social care service users, and that is funded by Health and Care Research Wales and other eligible funders, will be included in the Portfolio.

The Portfolio is central to allocation of Health and Care Research Wales resources. Once a study is adopted onto the Portfolio researchers will be able to apply for Excess Treatment Costs, Primary and Emergency Care, and Public Health Wales Support Costs. People working on a portfolio study will also be eligible to access Health and Care Research Wales training courses, workshops and events.

3. Definition of ‘research study’

Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods¹. This excludes: audit; needs assessments; quality improvement and other local service evaluations. It also excludes routine banking of biological samples or data except where this activity is integral to a self-contained research project designed to test a clear hypothesis. NHS Research Ethics Committee approval and NHS permission are requirements for research to be supported by Health and Care Research Wales.

4. Which studies are eligible for the Health and Social Care Portfolio?

All studies must already have full research funding (funding to meet all research costs associated with the study). The source of funding is the principal determinant of a studies eligibility. Eligible studies must meet the eligibility criteria outlined in Box 1.

¹ Research Governance Framework for Health and Social Care in Wales Second Edition 2009

Box 1. Eligibility criteria for adoption onto the Health and Social Care 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 Social Care Portfolio, the following definition of high-quality peer review will be used.

Peer review must be:

- a) **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.
- b) **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.
- c) **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.

5. How do we get studies onto the Portfolio?

- 5.1 Studies applying for NHS permission in Wales will be automatically assessed, eligibility will be confirmed via email by the Portfolio team.

Studies that do not require NHS permission can apply for adoption directly by completing the Portfolio Registration Form and sending it to portfolio@wales.nhs.uk

Studies funded by Health and Care Research Wales, other areas of central government, and registered eligible funders will be rapidly adopted onto the Portfolio. These eligible funders include all NIHR non-commercial partners as well as those organisations that have been identified by the Health and Care Research Wales Support Centre as meeting the funder eligibility criteria (Box 1).

- 5.2 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.
- 5.3 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).
- 5.4 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.
- 5.5 Studies eligible for the NIHR portfolio will be automatically adopted onto the Health and Social Care Portfolio in Wales.

6. Potentially eligible non-commercial studies

- 6.1 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.
 - a) **Investigator-initiated, commercial collaborative studies** are studies that are initiated by non-commercial investigators (e.g. University or NHS 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 Centre 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.

- b) **Non-commercial studies funded by overseas governments or overseas charities**
- c) **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.

7. NHS Costs

Once studies are adopted onto the Health and Social Care Portfolio, the Support Centre will further categorise studies by those incurring research related NHS Costs and those that do not.

Box 2. Health and Social Care Portfolio

i) Studies that incur research related NHS costs

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.

ii) Studies that do not incur research-related NHS costs

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. Examples include social care or public health studies in settings outside the NHS. 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 with grant funded research costs.