GIG CYMRU NHS WALES
Cyd-bwyllgor Comisiynu
Joint Commissioning Committee

Clinical Trials (all ages): (i)Assessment for participation; (ii) Excess Treatment Costs and (iii) Funding after Completion of a Clinical Trial

Commissioning Policy: CP164

Policy Update

Document Information	
Document Name	Clinical Trials (all ages): (i) assessment for participation; (ii) excess treatment costs and (iii) funding after completion of a clinical trial
Document No	CP164
Document Purpose	Commissioning Policy
Publication Date	March 2026
Version No	3.0
Commissioning Team Author	Medical Directorate
Target Audience	Chief Executives, Medical Directors, Directors of Finance, Principal and Chief Investigators for Clinical Trials, Chief Pharmacists
Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
Document Update Information	This document has been updated to reflect research costing guidelines and funding mechanisms in Wales and confirms that NWJCC **will not** routinely provide funding to support clinical trials.

Contents

Abbreviations

AcoRD	Attributing the costs of health and social care Research and Development
ETC	Excess Treatment Costs
IPFR	Individual Patient Funding Request
NWJCC	NHS Wales Joint Commissioning Committee
SoECAT	Schedule of Events Cost Attribution Tool

Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission a range of items to support the participation of people resident in Wales in clinical trials (that fall within a specialised service commissioned by NWJCC) in accordance with the criteria outlined in this document.

In creating this document NWJCC has reviewed all relevant national policies and has consulted widely with healthcare professionals across Wales.

Welsh Language

NWJCC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the Welsh Language (Wales) Measure 2011 and the Welsh Language Standards (No.7) Regulations 2018.

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this, NWJCC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

NWJCC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the NWJCC commitment.

Disclaimer

NWJCC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the

circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

NWJCC disclaims any responsibility for damages arising out of the use or non-use of this policy.

1. Introduction

This policy has been developed to provide guidance to NHS Wales on a range of funding decisions related to the provision of clinical trials for people of all ages resident in Wales.

This document only relates to clinical trials that fall within services commissioned by the NHS Wales Joint Commissioning Committee (NWJCC) and applies to residents of all seven Health Boards in Wales.

Information about the support for clinical trials that fall outside the responsibility of NWJCC is available from Health and Care Research Wales)[1].

1.1 Aims and Objectives

This policy aims to define the commissioning position of NWJCC with regard to funding decisions related to clinical trials.

The objectives of this policy are to:

- describe the circumstances under which patients can be referred for assessment of their suitability for participation in a clinical trial
- provide guidance on applying for Excess Treatment Costs (ETCs) of externally funded non-commercial clinical trials
- describe the circumstances in which NWJCC may provide funding for a treatment once a clinical trial is completed.

1.2 Background

Clinical Trials

As new treatments develop, or as new applications of existing treatments are identified, the potential benefits and risks of the treatment are often tested through clinical trials. Trials are often conducted in usual NHS care settings according to strict protocols and with the full consent of the individual patient, parent or carer.

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related intervention to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes and preventive care.

[1] Homepage | Health Care Research Wales

Clinical trials can be divided into two categories:

- **Commercially-funded trials:** Commercially funded trials are those trials in which the costs of the treatment under investigation are fully funded by a commercial company, and where the NHS does not have responsibility for any costs of the specific intervention either during the trial period, or upon its closure.
- **Non-commercially funded trials:** Non-commercially funded trials can be funded through a range of sources. Often, they are funded by research bodies such as the National Institute for Health Research[2] (NIHR), the Medical Research Council[3] (MRC), registered charities or they may be funded by NHS bodies including NHS Wales (Health and Care Research Wales[4]).

Trial sponsor

The sponsor of a trial is the individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management, indemnity and financing (or arranging the financing) of the research.

Funding clinical trials

Health and Care Research Wales support the referral of patients for clinical trials where appropriate and there is no need to involve NWJCC in that process, nor request funding from NWJCC for any trial-related activity.

NWJCC in some situations may continue to fund the intervention after the trial for those patients that were already receiving it, if clear benefit and evidence support this.

NWJCC **will not** routinely provide funding to support any commercially-funded trial.

Funding for the costs of non-commercial research is met from a number of sources. Researchers wishing to access funding for their research must therefore attribute the costs across three categories:

- **Research Costs:** These are the costs of the research itself, incurred to carry out the trial and answer the clinical question. These costs are met by the research funder.
- **Support Costs:** These are the additional patient care costs associated with the research, which would end once the study in question had stopped.
- **NHS Treatment Costs:** The care costs, which would continue to be incurred if the care service in question continued to be provided after the study had stopped. These costs are funded by the NHS through normal commissioning arrangements for

[2] NIHR | National Institute for Health Research
[3] Home - Medical Research Council
[4] Homepage | Health Care Research Wales

patient care. The types of activities that are attributed to **NHS Treatment Costs** include:

- supplying and administering the medicine/device/therapy being studied
- supplying and administering any active comparators – including medicines, devices or therapies, but not placebo or sham treatments
- training of NHS staff to deliver the treatments
- investigations and tests which would continue to be incurred if the new treatment/service in question continued to be provided after the R&D study has stopped
- patient follow-up where this is required as part of the clinical management of a patient and will be part of the treatment if the intervention being tested becomes part of standard care.

Excess Treatment Costs (ETCs)

A research study may result in care that differs from standard treatment or is delivered in a different location from where it would normally be given. The associated NHS treatment costs may be less, or may be greater, than the cost of standard treatment. If greater, the difference between the NHS treatment costs and the cost of the standard treatment is referred to as the Excess Treatment Cost (ETC).

Health and Care Research Wales provide ETC funding for studies that fall within the commissioning responsibility of NWJCC. Further information on ETCs supported by Health and Care Research Wales is available on their web site[5].

Funding clinical research in Wales (including clinical trials)

In Wales, Health and Care Research Wales[6] run a number of schemes designed to stimulate excellence and support capacity building in health and social care research. It does this by funding high-quality research projects in primary and secondary care that will provide robust evidence with clear relevance to patients, service users, and carers.

Information is also available from Health and Care Research Wales on the Schedule of Events Cost Attribution Tool (SoECAT) [7] which will need to be completed for some clinical research grants from eligible funders. The SoECAT allows funders to receive reassurance that the cost activities within the study have been attributed correctly in line with AcoRD

[5] Make arrangements for support costs and excess treatment costs (ETCs) in the NHS and social care | Health Care Research Wales
[6] Funding schemes | Health Care Research Wales
[7] Schedule of events cost attribution tool (SoECAT) | Health Care Research Wales

guidance 'Attributing the costs of Health and Social Care Research and Development (AcoRD)' [8].

The AcoRD guidance provides specific examples of these costs (see Annex A of the AcoRD document for the relevant extract) and provides detailed guidance on how to attribute all the costs of health and social care research including ETCs for non-commercial research.

1.3 Relationship with other documents

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - NHS Excess Treatment Costs, guidance for secondary care. Health and Care Research Wales (2017).
  - Delivery Framework - Funding and Performance Management of Local Support and Delivery Funding 2021/22. Health and Care Research Wales/Welsh Government.
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR)
  - NHS Research and Development Finance Policy 2026 (WHC/2026/008)

- **Relevant NHS England policies**
  - Continuing funding after the completion of a clinical trial. NHS England Commissioning Policy (September 2017).
  - Funding and support of excess treatment costs. National Institute for Health Research (2018)
  - Attributing the costs of Health and Social Care Research and Development (AcoRD). Department of Health and Social Care research Wales (April 2024).

[8] Identify study costs in the NHS and social care | Health Care Research Wales

2. Criteria for Commissioning

Health and Care Research Wales approve funding of a range of items to support the participation of people resident in Wales in clinical trials including those that fall within a specialised service commissioned by NWJCC.

2.1 NHS assessments of suitability for clinical trial

No Prior Approval request, or Individual Patient Funding Request (IPFR) application is required if the purpose of the referral is clinical trial related, i.e. if a patient wishes to participate (or explore potential participation) in an 'interventional' research study outside of Wales, i.e. studies where the research protocol includes a treatment or intervention not otherwise available to the patient outside of a trial. There should be no barrier to a patient being seen by the trial site for this purpose, and no funding needs to be exchanged or be provided for the site to accept the referral.

The UK Policy Framework for Health and Social Care Research[9] is that costs associated with the referral are a research cost and as such must be met by the trial site (via the study grant for non-commercial studies, or by the commercial Sponsor for industry funded studies). This includes visits to the trial site at pre-screening stages prior to commitment or recruitment to the trial being confirmed, including where referrals that are more speculative for a range of potential trials open at the provider site, and includes the consultation costs and associated travel costs. The referring clinician will need assure themselves that the patient at least broadly meets (or has potential through further screening/assessment to meet) the eligibility criteria for one or more trials that are open to recruitment at the provider organisation before a referral is made.

Note: The above can be shared with the receiving hospital if the referring organisation/clinicians encounters any delay or indication of a different interpretation. If any support is required to expedite the referral, or if provider site requires more information on the UK position, please escalate to Health and Care Research Wales via Research-FundingSupport@wales.nhs.uk

2.2 Funding Excess Treatment Costs

NHS Treatment costs associated with non-commercial research studies are the responsibility of the NHS and Health and Care Research Wales. It is important, therefore, to identify early on the commissioning route for treatments delivered as part of a research study.

[9] UK Policy Framework for Health and Social Care Research - Health Research Authority

Excess Treatment Costs (ETCs) should be identified at an early stage of a study preferably prior to an application for research funding being submitted. Researchers should seek to minimise these through study design and management of costs. Cost attribution must be in line with "Attributing the costs of health and social care Research & Development" (AcoRD) principles, See the AcoRD[10] and SoECAT[11] guidance for more information on identifying non-commercial study costs.

The funding to cover ETCs is accessed via Health and Care Research Wales. Full information on the process for identifying ETCs and applying for funding can be found on the Health and Care Research Wales website[12] More information can be found at Attributing the costs of health and social care Research & Development (AcoRD) (healthandcareresearchwales.org)

ETCs will not be covered for:

- commercial research undertaken on behalf of pharmaceutical or other companies, or for the researcher's own personal commercial interests (except where a commercial company provides a contribution to the NHS costs of the research, for example by free provision of a drug, and the majority of the research costs are met by one of the research funders covered in section 1.2 above)
- research where the R&D costs are funded by NHS Health Boards and Trusts, or Trustee or other charitable funds held by or on behalf of one or more of the above, whether directly or through a separate charity or university, and
- costs associated with services to private patients undertaken by NHS Providers.

Applications for an ETC cannot be submitted for costs incurred prior to the submission of the application.

For people who are not resident in Wales but are participating in a Wales-led study (either in a centre in Wales or elsewhere in the UK) there are separate arrangements in place for applying for an Excess Treatment Cost in England[13], Scotland[14] and Northern Ireland[15].

[10] Identify study costs in the NHS and social care | Health Care Research Wales
[11] Schedule of events cost attribution tool (SoECAT) | Health Care Research Wales
[12] Make arrangements for support costs and excess treatment costs (ETCs) in the NHS and social care | Health Care Research Wales
[13] https://www.england.nhs.uk/wp-content/uploads/2021/09/B0355-excess-treatment-costs-guidance.pdf
[14] http://www.nhsresearchscotland.org.uk/education-and-funding/funding-for-nhs-research-infrastructure/excess-treatment-costs-for-research
[15] Funding the costs of research (AcoRD principles) | Public Health Agency - Research & Development in Northern Ireland

NHS organisations or researchers via the appropriate NHS R&D office can apply for ETC funding whilst undertaking other Research Support and Governance processes such as processing R&D permissions.

The Application Process

- The ETC Application should be completed by the Chief Investigator or Principal Investigator in collaboration with the NHS R&D office It is acknowledged that Clinical Trials Units are also involved in costing studies and will also be involved in attributing and costing studies as part of grant application development.
- The details given on the application are used to evidence the need for the funding of the ETC. Applicants must be clear and concise in what is being requested and importantly, realistic regarding recruitment rates and spending times scales.

ETC applications will only be considered once research grant funding has been awarded.

In order to decide whether a study has treatment costs and potentially ETCs, you should refer to the AcoRD guidance[16].

2.3 Continuing funding after completion of a clinical trial

2.3.1 Post-trial funding arrangements must be determined before the trial begins

NWJCC expects that all research organisations planning a trial, regardless of how they are funded or where the trial is located, must define and agree the arrangements for funding the treatment after the trial, for those patients where the trial has shown a clinical benefit. This is in line with the ethical approval requirements of the Health Research Authority (HRA) for clinical trials[17].

For those patients and clinicians wishing to access medicines offered to NHS Wales as free of charge should refer to the All Wales free of charge medicine supply policy.

2.3.2 Informing patients of post-trial funding arrangements prior to giving consent

Patients participating in a trial ***must*** be made fully aware of the arrangements for when the trial concludes as part of the process of giving their consent to participate in the trial. This includes making patients aware of the process for continuing to receive treatment after the end of the trial and in what circumstances they can expect this to continue.

[16] https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research
[17] https://www.hra.nhs.uk/

Clinicians should refer to the HRA Guidance[18] which sets out the information that should be provided to participants regarding the arrangements for funding care after a trial, including whether participants will have continued access to any benefits or intervention that they may have obtained during their participation in the trial once it stops.

The provider of the trial treatment and the clinician should take care to ensure that they do not make any statements or take any actions which might lead any participant in a trial to assume that NWJCC will or might fund ongoing treatment once the trial has completed, unless NWJCC has given a written commitment to provide such funding which would apply to that participant.

HRA guidance is explicit that the trial sponsor's plans must be made clear to potential participants before consent is sought. Where a commitment is made to provide continued treatment, review bodies will seek assurance that agreement has been reached on funding responsibilities.

Prior agreement to fund costs related to the clinical trial do not represent a policy decision by NWJCC to routinely commission the continuation of treatment once the trial has ended.

2.3.3 Post-trial funding arrangements for commercially funded trials

NWJCC's position is that where a clinical trial of a treatment has been initiated and sponsored by a manufacturer of pharmaceuticals or medical devices, or by some other commercial organisation, responsibility for funding on-going access to the treatment rests with those parties.

Commercial organisations sponsoring trials are responsible for putting in place the funding arrangements of post-trial treatment, in advance of the trial commencing, for those patients for whom the trial has shown a clinical benefit.

2.3.4 Post-trial funding arrangements for non-commercially funded trials

NWJCC will consider funding on-going access to the treatment given in a trial in circumstances where:

- the clinical trial is to be wholly funded by non-commercial bodies and on the Health and Care Research Wales Portfolio[19], and
- There is a clear clinical or evidence basis for doing so

[18] https://www.hra.nhs.uk/
[19] https://healthandcareresearchwales.org/researchers-support-and-guidance-researchers-what-research-directory-and-portfolio/what-portfolio

In these circumstances, the responsible clinician is able to apply for funding via the IPFR policy process.

Please refer to the IPFR policy for further information on this process:
Individual Patient Funding Requests

Treatment will be funded only for as long as the patient's supervising clinician agrees that the treatment is clinically appropriate, and that the treatment is meeting the identified clinical outcomes.

Any agreement by NWJCC to continue to fund a treatment following an IPFR for a non-commercial trial participant, does not represent a policy decision by NWJCC to routinely commission that treatment for other patients who were not part of the clinical trial.

2.4 Funding individuals' participation in existing trials, and funding experimental and unproved treatments

There may be some limited situations where the NHS may fund a patient's participation in an existing clinical trial, both commercially-funded and non-commercially funded. This may arise where a treatment is currently being evaluated in a commercial trial which is outside the NHS, for example in another country or healthcare system.

There are also some very rare circumstances where establishing the potential benefits of a treatment for an individual may not be possible through a formal trial, for example because the number of people affected is so small or because the individual concerned has an unusual clinical presentation. There may also be unusual clinical situations where the commissioner agrees that trials of an experimental treatment will be impossible to carry out.

Requests for on-going funding following any experimental or unproven treatment will only be considered following approval of an IPFR by NWJCC. IPFR requests may be made prior to commencing in the trial, during the study period, following the trial or when appropriate to prevent discontinuation of care The treatment provider and the clinician should ensure that patients do not assume that NWJCC will fund ongoing treatment once the initial funding period has ended.

2.5 Responsibilities

Prior to participation/enrolment, referrers/clinicians should:

- ensure the appropriate regulatory approvals are in place including approvals from Health and Care Research Wales for ETCs

- inform the patient and/or their parent or guardian that they are being referred to be part of a research trial and how this differs from standard care
-

Following a trial, clinicians considering continued treatment for patients should:

- discuss all alternative treatments with the patient and/or their parent or guardian;
- discuss with NWJCC
- submit an IPFR request

3. Evidence

NWJCC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

3.1 Date of Review

This document is scheduled for review every three years, unless information is received which indicates that the policy requires revision.

If an update is carried out the policy will remain extant until the revised policy is published.

4. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable NHS Wales Joint Commissioning Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

5. Putting Things Right:

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to NWJCC.

Annex i Glossary

Excess Treatment Costs (ETC)

Excess Treatment Costs (ETCs) are the difference between the costs of the treatment being studied and that of the standard treatment.

NHS Treatment Costs include the costs of:

- supplying and administering the medicine/device/therapy being studied
- supplying and administering any active comparators – including medicines, devices or therapies, but not placebo or sham treatments
- training of NHS staff to deliver the treatments
- investigations and tests which would continue to be incurred if the new treatment/service in question continued to be provided after the R&D study has stopped
- patient follow-up where this is required as part of the clinical management of a patient and will be part of the treatment if the intervention being tested becomes part of standard care.

Health and Care Research Wales

Health and Care Research Wales promotes research into diseases, treatments and services which can improve and save people's lives.

Individual Patient Funding Request (IPFR)

An IPFR is a request to NHS Wales Joint Commissioning Committee (NWJCC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

NHS Wales Joint Commissioning Committee (NWJCC)

NWJCC is a joint committee of the seven local health boards in Wales. The purpose of NWJCC is to ensure that the population of Wales has fair and equitable access to the full range of Tertiary Services. NWJCC ensures that services within our portfolio are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.

Contact Us

If you have a question related to this document you can contact us using one of the methods outlined below.

If you would like this document in an alternative format and/or language, please contact us for assistance.

Email:

NWJCC consultation mailbox – NWJCC.consultation@wales.nhs.uk

Telephone:

General Enquiries – 01443 433112

Website:

Contact us - NHS Wales Joint Commissioning Committee

Writing:

If you wish to contact the NHS Wales Joint Commissioning Committee, you can write to us at one of our locations below, we welcome correspondence in Welsh or English:

South Wales Offices
Unit 1, Charnwood Court, Heol Billingsley, Nantgarw, CF15 7QZ
Unit G1 The Willowford, Main Avenue, Treforest Industrial Estate, Pontypridd, CF37 5YL

North Wales Offices
Unit 3, Media Point - Unit 3, Mold Business Park, Mold, CH7 1XY
Preswylfa, Hendy Road, Mold, CH7 1PZ