GIG CYMRU NHS WALES

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)

Welsh Health Specialised Services Committee (WHSSC)

Specialised Services Commissioning Policy: CP164

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

December 2019

Version 1.0

Document information	
Document purpose	Policy
Document name	Clinical Trials (all ages): Excess Treatment Costs and Funding after completion of a Clinical Trial
Author	Welsh Health Specialised Services Committee
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Commissioning Team	Medical Directorate
Target audience	Chief Executives, Medical Directors, Directors of Finance, Principle 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 No	CP164
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Contents

Policy Statement

Welsh Health Specialised Services Committee (WHSSC) 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 WHSSC) in accordance with the criteria outlined in this document.

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

Disclaimer

WHSSC 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.

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

1. Introduction

The purpose of this document is 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 Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

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

1.1 Aims and Objectives

This policy aims to define the commissioning position of WHSSC with regards 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 to WHSSC for funding to cover Excess Treatment Costs (ETCs) of externally funded non-commercial clinical trials.
- Describe the circumstances in which WHSSC 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] https://www.healthandcareresearch.gov.wales/funding/

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

The circumstances in which WHSSC will provide funding for a non-commercial trial may include funding of Excess Treatment Costs (ETC) and continued funding of the intervention after the trial for those patients that were already receiving it.

WHSSC **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:

1. **Research Costs:** These are the research development costs incurred to carry out the trial and answer the clinical question. These costs are met by the research funder.
2. **Support Costs:** These are the additional patient care costs associated with the research (for example Excess Treatment Costs), which would end once the study in question had stopped. Support costs would be contingent upon adherence to the application process described within this policy.
3. **NHS Treatment Costs:** These costs are funded by the NHS through normal commissioning arrangements for patient care.

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

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 (ETC)

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).

HCRW do not provide ETC for studies that fall within the commissioning responsibility of WHSSC. Further information on ETC supported by HCRW is available on their web site[5].

Funding clinical research in Wales (including clinical trials)

In Wales, Health and Care Research Wales (HCRW)[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 HCRW on the Schedule of Events Cost Attribution Tool (SoECAT) 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 guidance 'Attributing the costs of Health and Social Care Research and Development (AcoRD)'[7].

[5] https://www.healthandcareresearch.gov.wales/news/soecat-what-it-is-and-what-it-means-to-you/
[6] www.healthandcareresearch.gov.wales/funding
[7] https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

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 2019/20. Health and Care Research Wales/Welsh Government.
  - Attributing the costs of Health and Social Care Research and Development (AcoRD). Department of Health and Social Care research Wales (June 2015).
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR)
  - NHS Research and Development Finance Policy. Welsh Health Circular, WHC (2018) 005.

- **Relevant NHS England policies**
  - Guidance on Excess Treatment Costs. NHS England (November 2015).
  - 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)

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee (WHSSC) approve funding of a range of items to support the participation of people resident in Wales in clinical trials (that fall within a specialised service commissioned by WHSSC) in-line with the criteria identified in the policy.

2.1 NHS assessments of suitability for clinical trial

If additional tests are required to determine eligibility for a clinical trial, referrals for assessment of suitability (within a specialised service commissioned by WHSSC) requires prior approval of funding by WHSSC. The assessment usually includes an outpatient appointment and any relevant bloods test or imaging. WHSSC will not reimburse any travel or accommodation costs.

An IPFR request for funding must be completed by the referring clinician and submitted to WHSSC with a copy of the referral letter.

Please refer to the IPFR policy for further information on this process: http://www.whssc.wales.nhs.uk/individual-patient-funding-requests

Funding will only be considered for the assessment and, if the patient is deemed suitable for the clinical trial, any related Excess Treatment Costs must be requested separately (see section 2.2 below).

2.2 Funding Excess Treatment Costs

NHS Treatment costs associated with non-commercial research studies are the responsibility of the NHS and should be funded through the normal commissioning process. It is important, therefore, to identify early on the commissioning route for treatments delivered as part of a research study.

Excess Treatment Costs (ETC) 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.

The funding to cover ETC for specialised services should be accessed through a centrally managed process in WHSSC using the standard application form (Appendix 1).

Neither the NHS organisation (for example WHSSC or the Health Boards) nor HCRW will fund non-NHS treatment costs i.e. the cost of interventions that if put into practice at the end of the study would be met from non-NHS funding bodies such as social care or education.

For practitioners in secondary care there is centrally managed funding process which is the responsibility of the Health and Care Research Wales

Support Centre[8]. It provides an infrastructure to support and increase capacity in R&D, runs a range of responsive funding schemes and manages the Support and Delivery centralised funding allocation.

ETC 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 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[9], Scotland[10] and Northern Ireland[11].

NHS organisations or researchers via the appropriate NHS R&D office can apply for an ETC 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.

[8] https://www.healthandcareresearch.gov.wales
[9] https://www.england.nhs.uk/commissioning/supporting-commissioners/research/etc/
[10] http://www.nhsresearchscotland.org.uk/education-and-funding/funding-for-nhs-research-infrastructure/excess-treatment-costs-for-research
[11] http://www.research.hscni.net/research-costs-acord-guidance

- All applications for ETC from WHSSC should be made on the application form (Appendix 1).

ETC applications will only be considered once research grant funding has been awarded. WHSSC does not provide an offer of ETC funding (even a letter in principle) prior to grant award.

In order to decide whether a study has treatment costs and potentially ETCs, you should refer to the AcoRD guidance[12].

2.3 Continuing funding after completion of a clinical trial

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

WHSSC 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[13].

These arrangements must be agreed before the trial commences, and should state the agreed level of proven benefit that will result in ongoing funding being given, and the criteria for stopping the treatment.

WHSSC does not fund the continuation of any treatment started as part of a clinical trial unless there is a prior documented agreement to do so between the trial organisers and WHSSC, i.e. agreement reached before the trial commences. No assumption can be made that funding responsibility would be transferred to WHSSC without WHSSC's explicit written approval prior to commencement of the trial.

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 whether or in what circumstances they can expect to continue to receive treatment after the end of the trial.

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

Clinicians should refer to the HRA Guidance[14] 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 WHSSC will or might fund ongoing treatment once the trial has completed, unless WHSSC 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 WHSSC to routinely commission the continuation of treatment once the trial has ended.

2.3.3 Post-trial funding arrangements for commercially funded trials

WHSSC'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

WHSSC 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 is sanctioned by the NIHR[15], and
- when the request is made *before* the clinical trial commences.

[14] https://www.hra.nhs.uk/
[15] https://www.nihr.ac.uk/

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:
http://www.whssc.wales.nhs.uk/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 WHSSC to continue to fund a treatment for a patient, following a non-commercial trial, does not represent a policy decision by WHSSC 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 are some circumstances where WHSSC may agree to fund treatments for individual patients. In these circumstances, the responsible clinician is able to apply for funding via the Individual Patient Funding Request (IPFR) policy process.

Please refer to the IPFR policy for further information on this process.
http://www.whssc.wales.nhs.uk/individual-patient-funding-requests

- 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 if the treatment was begun following approval of an IPFR by WHSSC. The treatment provider and the clinician should ensure that patients do not assume that WHSSC will fund ongoing treatment once the initial funding period has ended.

2.5 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an IPFR can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at:
http://www.whssc.wales.nhs.uk/individual-patient-funding-requests

2.6 Responsibilities

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinician considering treatment should:

- discuss all the alternative treatment with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

3. 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 Welsh Health Specialised Services 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.

4. Putting Things Right: Raising a Concern

4.1 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 WHSSC.

4.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

Appendix 1. Application Form

NHS Excess Treatment Cost Application Form
WHSSC Commissioned Specialised Services

Important: Please refer to WHSSC Commissioning Policy CP164 before completing this form.

Study acronym	
Funding Amount requested	£
Study contact name	
Study contact email	
Study contact telephone number	

Please send a scanned signed copy to:

Andrew.Champion@wales.nhs.uk

Or complete and forward to:

Assistant Director, Evidence Evaluation and Effectiveness
Welsh Health Specialised Services
Unit G1, The Willowford
Treforest Industrial Estate
Pontypridd,
CF37 5YL

Section 1 - Study Information

Full study name
Sponsor
CPMS portfolio number or IRAS reference number
Grant funder
Grant award date
Total grant award
£

Please give details on where the study will take place

Section 2 - Study Team Information

Chief Investigator		
Title:		Address:
Name:		
Employing organisation:		
Post:		
E-mail:		
Telephone:		

Principal Investigator/ lead Principal Investigator in Wales (if CI is not based in Wales)		
Title:		Address:
Name:		
Employing organisation:		
Post:		
E-mail:		
Telephone:		

Nominated study contact for any queries regarding the application		
Title:		Address:
Name:		
Employing organisation:		
Post:		
E-mail:		
Telephone:		

NHS Wales R&D Office Contact	
Name	
E-mail:	
Telephone:	

Section 3 - Study Details

Start date of whole study	**Overall end date of study**
Proposed date from which ETC's will be incurred	**Proposed end date when ETC's will cease to be incurred**
Study outline (word limit:300)	

Section 4 - Details of Excess Treatment Costs

Please provide comprehensive detail items or resources you need to purchase and any associated costs you are requesting funding for, including the following:

- Staff resources (medical, nursing, allied health professionals, admin)
- Drug and equipment costs
- Hospital and GP services (radiology and pathology)
- Any other additional resources/equipment

Detail included in this submission is what is used to assess the viability of your request. It is important that you add as much detail as possible to speed up the request process by reducing querying any unsubstantiated cost requests. Please ensure your request is in-line with the AcoRD guidance[16] for Wales and that the relevant NHS R&D Department have been consulted and signed the application form.

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

Section 5 - Declaration and Signatures

I declare that the information given on the form is complete and correct.

I agree to update figures, and update the Health and Care Research Wales Support Centre if any details are modified (e.g. number of sites or anticipated recruitment increases)

Lead Investigator

Signature: _____ Date: _____

Name: _____

NHS R&D Manager/Director

Signature: _____ Date: _____

Name: _____

Please send the following documents electronically to Andrew.Champion@wales.nhs.uk

1. Completed and signed ETC application form
2. Comprehensive details of costs required
3. Most recent approved study protocol
4. Patient Information Sheet (if available)
5. If applicable, a copy of any letters providing decisions on ETCs in England, Scotland, or Northern Ireland

To determine whether your study requires excess treatment costs, please refer to the AcoRD Guidance[17] for Wales.

If you have used a costing template, please attach this to your application

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