

**South East Coast Policy Recommendation Committee
Policy Recommendation**

Policy:	PR 2010-02: NHS Pick up of trial funding
Issue Date:	June 2010
Review Date:	June 2012
<p>The South East Coast (SEC) Policy Recommendation Committee (PRC) has considered international and national guidance and legislation, and the views and opinions of local stakeholders. Taking these into account, the Policy Recommendation Committee recommends that:</p> <p>SEC PCTs will not pick up the ongoing funding of treatments for patients who have completed clinical trials unless either:</p> <ul style="list-style-type: none"> • The PCT has agreed through normal commissioning processes prior to the trial commencing with the trial funder that the PCT will provide funding for the trial participants' ongoing treatment once they have left the trial. This agreement will be documented through normal commissioning processes and according to the Trust's governance procedures. In that event, the NHS organisation hosting the clinical trial is required to document the agreed exit strategy in the trial protocol and state the PCT will provide funding for the trial participants' ongoing treatment once they have left the trial and provide detail as is appropriate to each individual study; or • A PCT has agreed to fund the treatment as a service development for all patients in the clinical category of those patients leaving the clinical trial; or • The PCT's IFR Panel has considered and approved a request to provide individual funding for a patient. However, if such a request is made the fact that the patient has been involved in a clinical trial shall not amount to an exceptional clinical circumstance or be used by the IFR Panel to justify a finding of exceptionality. <p>It is the consenting clinician's responsibility to ensure that patients are fully informed of and agree to their management plan at the end of the trial. This includes making patients aware of this commissioning policy and, where relevant, any successful or unsuccessful request for post-trial funding. Their consent should be documented.</p> <p>PCTs in NHS South East Coast will always consider appropriate individual funding requests (IFRs) through their IFR process.</p>	

Supporting documents

- South East Coast Health Policy Support Unit (2010) NHS Pick up of trial funding. Online: www.sehealthpolicysupportunit.nhs.uk
- Equality Impact Assessment

Key findings and rationale

Why are clinical trials important?

The conduct of clinical trials is an integral part of NHS business and such trials make an important contribution not only to advancing knowledge and improving healthcare, but also to an important sector of the UK economy (National Specialised Commissioning Group 2008).

What is “pick up” of trial funding?

NHS pick up of trial funding refers to situations where an NHS patient has been entered into a clinical trial and where continued treatment is being requested after the trial has ended or when a patient has left a clinical trial and is requesting treatment outside of the standard NHS pathway of care for that patient group.

Why is “pick up” of trial funding an issue for PCTs?

PCTs are regularly asked to pick up ongoing funding of treatments for patients who have participated in clinical trials. The pick up of ongoing funding has an impact on the PCT resources. Healthcare resources are finite and each PCT has a statutory duty not to exceed their Revenue and Capital Resource Limits and an administrative duty not to exceed their cash limit (NHS Act 2006). PCTs will always be faced with difficult and sensitive decisions about apportioning healthcare resources. They have to draw the line between what will be funded and what will not.

How are PCT funds allocated?

In general decisions made about the funding of medicines and treatments will be taken on a population basis by PCTs; with cooperation with provider trusts and stakeholders. The PCT does not offer treatment to a named individual that would not be offered to all patients with equal clinical need. No external body can commit the resources of PCTs without their agreement.

Who is responsible for the “pick up” of trial funding?

The Declaration of Helsinki does not bind any specific organisation, body or individual to fund the treatment of patients post-trial. Nor does it follow that, given a failure of others to meet this cost, the responsibility to do so should sit with PCTs. PCTs should interpret the Declaration of Helsinki in a way which is consistent with the principles they have adopted for priority setting.

How do patients know what will happen after a trial has finished?

An exit strategy should be stated in the research protocol for all medicinal trials and the plans should be clear to potential participants before consent is sought (The Medicines for Human Use (Clinical Trials) Regulation 2004 (statutory instrument 2004/1031). An exit strategy details the treatment plan for patients once a trial is finished.

It is the consenting clinician's responsibility to ensure that patients are fully informed of and agree to their management plan at the end of the trial. This includes making patients aware of the exit strategy in the research protocol, this commissioning policy and, where relevant, any unsuccessful request for post-trial funding. Their consent should be documented.