

Southampton Clinical Research Institute (SCRI)
SCRI Information Sheet No. 19
Guidance on Research Costs, Service Support Costs and Treatment Costs
for Grant Applications
V1.1 23-07-08

Introduction

- This guidance is for use with non-commercial research studies only.
- The aim of this guidance is to assist researchers at Southampton University Hospitals Trust and the University of Southampton to identify and classify the costs associated with research in accordance with Department of Health requirements.
- This guidance provides examples but is not an exhaustive list.
- Additional information is available in the Department of Health publication Attributing revenue costs of externally funded non-commercial research in the NHS (ARCO). December 2005, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4125282.pdf

Basic principles

The costs of R&D in the NHS are split into three categories:

- Research Costs
- Service Support Costs
- Treatment Costs

Who meets which costs?

- Research Costs will be met by the research funder(s)
- Service Support Costs will be met by the NHS through the CLRNs
- Treatment Costs will normally be met through commissioning arrangements for patient care.

Research Costs

Research Costs are the costs of the R&D itself¹.

Examples of research costs:

Costs associated with:

- Data collection (people/paper/computer/software)
- Analysis (people/paper/computer/software)
- Activities needed to answer the research question that are not required for clinical care AND the results of which will not inform clinical care
 - For example:
 - Blood tests, not required for clinical purposes or informing clinical care
 - X-rays, not required for clinical purposes or informing clinical care
- Salaries of research staff employed specifically for research project
- Indirect staff costs
- Trial registration fees
- MHRA fees
- Costs for making results accessible
- Costs of external training (trainer/venue/catering/expenses)
- Cost of placebo(s)
- For study drugs, where not done on NHS premises, costs of formulating, disguising, storing, distributing.
- If not required for clinical purposes, cost of follow-up visits (people/space/IT etc.).
- Costs of sponsorship, R&D Management and Administration
- Cost of Pharmacovigilance / safety reporting
- Provision of GCP training if provided by the NHS (if external this is a research cost)
- Cost of study management (minimum trial manager, maximum full service from Clinical Trials Unit, refer to CTU for costs).
- MHRA Inspections

Service Support Costs

NHS Support Costs include the additional patient-related costs associated with the research, *which would end once the R&D activity in question had stopped*, even if the patient care service involved continued to be provided¹.

Examples of service support costs are:

¹Attributing revenue costs of externally funded non-commercial research in the NHS (ARCO).
December 2005,

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4125282.pdf

- Extra patient tests where the results may be used to inform clinical care if clinical significant
- Extra nursing attention provided by staff that are not employed specifically for research project
- Extra time from NHS staff not employed specifically for research project for identifying patients eligible to participate, explaining the study to participants, obtaining informed consent
- Time spent managing a portfolio of research (e.g. NHS Divisional R&D Leads, R&D Support Network, Programme Leads, R&D management staff).
- Time of NHS staff engaged in research activities alongside clinical activities (NB note that clinical activities includes activities performed for research but also meet clinical need or contribute to clinical care of patient).
 - For example:
 - Pharmacists
 - Radiologists
 - Radiographers
 - Pathologists
 - Clinical Scientists
 - Nurses
 - Doctors
- Location costs, cost of clinic time, bed space, chair space etc.
- Attending GCP training.
- Provision of training in new intervention if required to provide clinical care.
- Attendance of training in new intervention if required to provide clinical care.
- For study drugs, costs of formulating, disguising, storing, distributing, where done on NHS premises – BUT if expensive, maybe considered a Research Cost.
- Costs associated with preparing grants, protocols, applications to various bodies, study-set up.

Treatment Costs

Treatment Costs are the patient care costs ***which would continue to be incurred if the patient care service in question continued to be provided after the R&D activity had stopped***. Where patient care is provided that is either an experimental treatment or a service in a different location from where it would normally be given and it differs from the normal, standard treatment for that condition, the difference between the total Treatment Costs and the costs of the standard treatment (if any) is called Excess Treatment Costs. These costs are nonetheless part of the Treatment Costs, not an NHS Support or Research Cost. The term Treatment Costs covers all types of patient care services, including diagnostic, preventive, continuing-care and rehabilitative-care services, and health promotion.

Examples of Treatment Costs are:

- Cost of clinical care that would normally be provided if the research was not taking place
- Cost of clinical care that would be introduced as a result of the research and continue after the research had stopped.