Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS

Executive summary

Part J - General Responsibilities

i. Research and Development (R&D) is a routine and necessary part of the work of the NHS. General allocations to NHS Commissioners (Health Authorities and GP Fundholders) are not intended to pay for R&D activity itself. They are, however, intended to cover patient care services which may be associated with it.

ii. NHS Commissioners and NHS Trusts must continue to ensure that patient care services associated with R&D are provided and funded efficiently through normal commissioning arrangements. This includes any “Excess Treatment costs”. Special arrangements, and separate costing of R&D-related costs, will only rarely be appropriate.

Part II - Externally Funded Non-Commercial R&D

iii. The NHS does not pay for, or carry out, the majority of the R&D from which it benefits. The Government is publishing a Statement of Partnership which specifies the circumstances under which the NHS will support non-commercial externally funded R&D by meeting associated patient care costs. A Concordat between the UK Health Departments and the Medical Research Council (MRC) explains arrangements between the NHS and MRC (with the Health Departments ensuring that the NHS meets legitimate service support and treatment costs associated with MRC funded research); there are similar agreements with other Research Councils.

iv. NHS Commissioners and NHS Trusts are required to ensure that the NHS’S obligations under this Statement of Partnership, the Concordat with the MRC and other similar agreements are met. R&D is a common good for the
NHS as a whole. It is **not** appropriate for individual parts of the NHS locally to
decide which externally funded R&D should and should not be supported. In
strictly limited circumstances the NHS Executive may make subventions
available to help meet some Excess Treatment Costs.

v. This guidance should be read alongside arrangements for R&D Support
Funding for NHS Providers. EL (97)7 refers.

**Action**

vi. In respect of R&D starting on or after 1 April 1998:

NHS Commissioners and NHS Trusts should:

- note the general responsibilities for funding patient care costs
  associated with R&D (Part I);

- note the specific expectations in respect of externally funded non-
  commercial R&D (Part II);

- facilitate and support R&D accordingly; and

- ensure that Treatment Costs continue to be met through normal
  processes for commissioning patient care.

In addition, NHS Providers should:

- obtain necessary Service Support funding from the NHS R&D Levy.
  The Invitation to Bid for R&D Support Funding for NHS Providers
  issued under cover of EL (97) 7 refers;

- note their specific role in notification arrangements for externally
  funded non-commercial R&D (Part II).

NHS Commissioners should:

- ensure that their contracts with non-NHS Providers require those
  Providers to follow these guidelines.

GPs and other Independent Family Health Services Providers are asked to
note these guidelines, and are strongly encouraged to operate within
them.

**Background**

vii. The arrangements set out in these Guidelines follow an extensive
consultation exercise launched in May 1996 with the publication of “Externally
Funded Non-Commercial R&D in the NHS: Consultation Document”. They
should be read alongside new arrangements for R&D Support Funding for NHS Providers (see EL(97)7). The NHS Executive will provide further details of these arrangements by Autumn 1997.

Addressees

For action:
NHS Trust Chief Executives
Health Authority Chief Executives

For information:
Regional Offices of NHS Executive
Regional Directors of Research & Development
Regional Managers of Research & Development
University Vice Chancellors
Deans of Medical and Dental Schools
Local Research Ethics Committee Chairs
Community Health Councils
Local Representative Committees (LMCs, LDCs, LOCs & LPCs)
Directors of Social Services
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PART I GENERAL RESPONSIBILITIES FOR FUNDING PATIENT CARE COSTS ASSOCIATED WITH RESEARCH AND DEVELOPMENT (R&D)

R&D in the NHS - Definition

1. Research and Development (R&D) is an essential element of the development of an increasingly evidence based service. For these purposes R&D means structured activity which is intended to provide new knowledge which is generalisable (i.e. of value to others in a similar situation) and intended for wider dissemination.

Patient Care Costs Associated with R&D

2. Much health and health services R&D is associated with patient care services. The R&D cannot proceed unless the patient care service is also
being provided. A distinction is drawn between the costs of the R&D itself (the “R&D cost”) - which are always paid for by the sponsor of the research, whether within or external to the NHS - and the associated patient care costs (“Service Support” and “Treatment Costs”).

3. **Service Support Costs** are the additional patient care costs associated with the research, which would end once the R&D activity in question had stopped, even if the same patient care service continued to be provided. This might cover things like extra blood tests, extra in-patient days, extra nursing attention.

4. **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 being provided which differs from the normal, standard, treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given) the difference between the total Treatment Costs and the costs of the “standard alternative” (if any) can be termed the *Excess Element of Treatment Costs* (or just “Excess Treatment Cost”), but is nonetheless part of the Treatment Cost, not a Service Support or R&D cost. Attached at Annex A is the table issued as part of the initial consultation document highlighting the distinction between the costs applied to a particular service provided to a patient.

5. As part of the implementation of the arrangements set out in this HSG, the NHS Executive will be issuing some operational guidance to help researchers, research funders and the NHS distinguish which costs are legitimately “patient care” costs and which are not.

Responsibilities for meeting patient care costs associated with R&D

6. Exact responsibilities for meeting patient care costs associated with R&D depend on the nature of the R&D:

7. **Commercial R&D** - where R&D is primarily for commercial purposes (eg studies of a new drug prior to licensing), NHS Trusts are expected to recover the full cost from the commercial company on whose behalf it is carried out. This includes both Service Support and Excess Treatment Costs. However,

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1 These are the standard terms now being used in NHS Executive guidance. Please note that both the terms and their definitions may differ from other usages with which you are familiar. In particular, the term “Service Support” is currently used in various different and sometimes contradictory senses. In NHS guidance it has only the meaning given here. Also, please note that the term “Excess Service Support” (which again has had various interpretations) is not now used in NHS Executive guidance, and should not be equated with Excess Treatment Costs.
please note that work is not automatically to be considered “commercial” simply because there is industrial funding. Commercial companies also support non-commercial work jointly with NHS bodies or non-NHS research funders. If the work is primarily for the public benefit, rather than the direct commercial benefit of the company concerned, it may be considered non-commercial.

8. **R&D Commissioned by Health Authorities and GP Fundholders** - the NHS Commissioners concerned should meet all the costs involved, including Service Support and Treatment Costs.

9. **All Other R&D** - Unless another party (eg industry or research charity) has agreed to meet all or part of the costs, the responsibility is shared between NHS Commissioners and Providers:

   It is NHS Providers’ responsibility to obtain funding from the NHS R&D Levy to meet Service Support Costs².

   It is the responsibility of NHS Commissioners and NHS Providers to continue to meet Treatment Costs (including any Excess Element) through normal patient care commissioning arrangements (see below).³

### Meeting Treatment Costs Through Normal Commissioning Arrangements

10. Commissioners and Trusts should follow their normal commissioning procedures to ensure that patient care associated with R&D is provided in an efficient manner and properly funded.

   - NHS Trusts should include all treatment costs in their proposed prices for patient care services. Separate arrangements for Excess Treatment Costs are not called for unless the NHS Executive has agreed a central subvention.

   - R&D related treatment costs normally make up only a small part of the overall costs of individual providers and are included in prices. Since R&D tends to be time limited and funding for it finite, when new activity starts other activity will generally have ended. While there may be material increases or decreases in Excess Treatment Costs between financial years, and Trusts should apprise commissioners of this, such changes do not provide a justification for changes in patterns of commissioning.

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² See EL(97)7, “R&D Support Funding for NHS Providers - An Introduction” and “R&D Support Funding for NHS Providers from 1998/99 - Invitation to Bid” (both NHS Executive, January 1997).

³ Slightly different arrangements apply in the Family Health Services. See paragraph 12 below.
Where a Trust is preparing to host a long term piece of R&D, and where there is any doubt about whether patient flows will support the work, longer term arrangements underpinning patient flows should be negotiated.

Treatment Costs should not be exempted from overall efficiency promoting disciplines. Within the arrangements for NHS support for externally funded R&D, NHS commissioners should continue to make decisions on the basis of overall cost effectiveness, where this is known, taking account of the fact that some increase in treatment cost may be an inevitable consequence of some research in the short term, but are expected to result in longer term cost effectiveness for the NHS as a whole.

R&D funding is itself generally competitive. NHS commissioners do not therefore need to - and should not - concern themselves with the scientific merit of the work which treatment costs will support.

Specific expectations apply to externally funded non-commercial R&D (see Part 11).

11. In addition, NHS Commissioners should ensure that their agreed protocols for elective Extra Contractual Referrals (ECRs) take account of referrals that may be appropriate for R&D purposes.

Family Health Services

12. Slightly different arrangements apply to family health services:

- practitioners can apply to the NHS R&D Levy for Service Support costs; and

- Treatment Costs will be generally met by standard Fees and Allowances etc; but it is anticipated that, practitioners/practices will be able to apply for Excess Treatment Costs which cannot reasonably be considered to be covered by existing fees and allowances.

Independent Sector Health Care Providers

13. Treatment Costs may sometimes arise in connection with NHS funded patient care services provided by the voluntary sector or under contract by other non-NHS providers (eg private hospitals, Universities). These should continue to be funded through normal arrangements.
14. In strictly limited cases, where the volume or concentration of Excess Treatment Costs associated with particular pieces of R&D would risk serious disruption to NHS services locally, the NHS Executive may make available subventions to cover part of the costs. This is explained more fully in Part II.
PART II SPECIFIC EXPECTATIONS IN RESPECT OF EXTERNALLY FUNDED NON-COMMERCIAL R&D

SUMMARY
National Statement of Partnership on Externally Funded Non-Commercial R&D - routine NHS support for Research Council, Research Charity, University and Government funded R&D

Researchers required to give NHS Providers advance notification of planned externally funded R&D.

NHS Providers to confirm their ability to host R&D, before researchers apply for R&D funding.

NHS Commissioners and Providers to fund and support externally funded R&D, in line with national Statement of Partnership

Central Subventions available from NHS Executive to NHS Providers in limited cases

Externally Funded Non-Commercial R&D

15. The NHS gains considerable benefit from R&D funded by external organisations.

16. There are already Concordats between the UK Health Departments and the Research Councils - particularly the Medical Research Council - which guarantee that the NHS's interests will be taken into account in their funding decisions. In return, the Government has undertaken that the NHS will always support the work they fund. Similar arrangements exist for Department of Health, Other Government Departments and European Union funded R&D.

17. Arrangements with Research Charities and Universities have until now been less formal. To clarify the position, the Government is issuing a Statement of Partnership (at Annex B). This Statement of Partnership guarantees NHS support for R&D funded by Research Charities and Universities, in all but exceptional circumstances, provided they in turn take certain steps to ensure that their R&D is compatible with the operation of the NHS.
18. Please note that the arrangements set out in this document do not apply to charitable funds which are wholly or mainly associated with a single or a group of NHS hospitals.

19. The arrangements apply to Universities only in so far as the latter take direct responsibility for their staff. In other words, they do not automatically apply to University employed academics pursuing work on their own initiative and without the backing of their Universities. Support for such work needs to be discussed and agreed locally. Likewise they do not apply to work undertaken by Universities or their staff for commercial gain.

Expectations on NHS Commissioners and NHS Providers

20. The NHS Executive requires NHS Commissioners and NHS Providers\(^4\) to play their part in honouring these arrangements, by making available appropriate funding and assistance in respect of externally funded R&D due to start on or after 1 April 1998. In particular that

**NHS Providers will:**

- provide support in the development of R&D proposals for external funding;
- confirm their ability to host proposed R&D before researchers apply for external funding;
- meet Service Support Costs from their R&D Support Funding; or (where permissible) obtain ad hoc funding from the NHS Executive; and
- obtain funding for Treatment Costs through normal commissioning arrangements - as set out above.

**NHS Commissioners will:**

- provide support in the development of R&D proposals as appropriate;
- ensure that Treatment Costs are met through normal commissioning arrangements (as set out in Part I); and

\(^4\) For these purposes NHS Providers includes all those who provide patient care services funded by the NHS, including GPs and other Family Health Services practitioners. Because GPs and similar practitioners are independent contractors, the NHS Executive cannot oblige them to follow these procedures in all cases. It will however, encourage them to do so, and will make Service Support and Treatment Costs funding available as appropriate.
• make it a condition of their arrangements with Providers that those Providers meet expectations under the Statement of Partnership in respect of the NHS services for which they are being funded.

Costs excluded from these Arrangements

21. The guarantee of NHS support extends only to Service Support and Treatment Costs incurred directly as a result of individual pieces of R&D. It does not extend to the provision of Infrastructure, which for these purposes means those costs which cannot reasonably be attributed to single R&D projects, groups of closely related projects or other specific activities. Thus infrastructure covers, for example:

• R&D offices, peer review, professional panels;

• general allocation of clinicians’ time to R&D (eg consultant sessions) or “established” academic posts;

• any share of the purchase or hire of equipment of any value which
  • was not acquired for a specific R&D activity; or
  • was acquired for a specific R&D activity, but if fully utilised, could over the course of its lifetime reasonably be employed to a significant extent for activities other than the specific piece of R&D activity for which it was bought;

• the provision, construction or alteration of accommodation;

• the employment of additional staff who
  • will be occupied on a range of different R&D activities; or
  • who would not otherwise have been employed but for a specific piece of R&D, but whose activities would not be wholly or mainly related directly to the R&D in question.

22. The costs of paying for locum cover for staff (or other compensation for lost productivity), and the limited employment of additional staff on a sessional basis, should not be regarded as Infrastructure, provided they are associated with a discrete piece of R&D.

23. The NHS expects that researchers will only pursue R&D in NHS Providers where the necessary infrastructure exists; or where it is planned by the providers concerned (eg as part of general service developments or consequent upon a successful bid for NHS R&D Levy funding); or where it is to be funded by another source (eg Charity, University, Trustee fund).
24. These arrangements do not alter existing understandings about "knock-for-knock" arrangements between NHS Trusts and partner Universities. It is inherent in the principle of "knock-for-knock" that for convenience the NHS meets specific “University costs” and vice versa without cross charging. This is mutually beneficial in keeping transaction costs low. No new detailed itemisation of costs and cross-charging should be introduced as a result of this guidance, or the Statement of Partnership.

Notification Arrangements

25. Under the Statement of Partnership, NHS support is conditional on appropriate notification. Detailed operational guidance, including information requirements for researchers, research funders and NHS Providers, will be issued by Autumn 1997. However the key stages are:

- If their planned research is going to involve the patients in one or more NHS Providers (or otherwise incur costs for the NHS), the researchers must obtain confirmation from the Provider(s) in question that they are able to host the research;

- to do this, researchers will need to provide specified information on the nature of the research together with an estimate of likely use of resources or costs and other implications for the NHS Provider(s) concerned;

- Once they have received this information, NHS Providers will need to check that:
  - the work falls within the Statement of Partnership and/or other agreements, and that the NHS is not being asked to meet costs which more properly fall to the funder of the R&D;
  - the relevant infrastructure and capacity exists or is already being developed within the Provider for the work to be carried out, and that the resource implications of the work have been adequately estimated; and
  - (where relevant) the researcher has taken appropriate steps to secure contributions from commercial companies in respect of pharmaceuticals and other products (see below);

- If these conditions are met, Providers should confirm that they are able to host the work. They should not withhold confirmation solely on the grounds of concerns about the funding of Service Support and/or Treatment Costs, since it is their responsibility to ensure these are met. Non-response within a standard time period will normally be taken to
signal the Provider’s agreement.

- once funding and ethics approval has been secured for the research, the researchers will notify all relevant NHS Providers accordingly that the work is now ready to proceed, and of any changes that have arisen since the original request;

- researchers will simultaneously notify the NHS Executive if the planned work;

  (a) is a major multi-centre trial; or

  (b) is taking place in primary care, and likely to involve several practices; or

  (b) is University or Charity funded work which may fall within the Exceptional Circumstances arrangements set out later in this document (paragraph 29-31) and in the Statement of Partnership;

- unless the NHS Executive notifies otherwise (see Exceptional Circumstances, below) the work may then commence.

26. Researchers will not be required to notify NHS Commissioners direct of their proposals. NHS Providers should inform their Commissioners of any relevant implications for them as and when necessary. Commissioners will expect Providers to keep, and to share with them from time to time (eg during annual discussions), records of the R&D with which they are involved and which incurs NHS costs.

27. Normal patient flow should usually be sufficient to support the R&D in question. If this is in doubt, Providers are encouraged to negotiate longer term arrangements to underpin the patient flow needed for the R&D, in advance of the start of the work, wherever possible.

Non-Commercial R&D Involving Commercial Products

28. At present, industry frequently contributes to the costs of pharmaceuticals (and other products) which are the subject of non-commercial R&D in the NHS. Although, by definition, such items constitute Treatment Costs, the NHS will continue, under the Partnership Arrangements, to look to researchers and non-commercial research funders to secure such contributions before approaching the NHS for support.

Exceptional Circumstances

29. Under the Statement of Partnership the NHS Executive reserves the right after discussion to decline to fund Research Charity or University R&D which otherwise meets these criteria if it believes that there is a significant risk that
the value of the R&D to the NHS will not be sufficient to justify the NHS costs of supporting it. The NHS has decided that Government Departments', European Union and Statutory Research Councils' (eg MRC) research will automatically be supported.

30. To this end, once they have obtained funding for their R&D, researchers will be required to notify the NHS Executive of work funded by Universities and Research Charities which

- while in progress is likely to cost the NHS, or an individual NHS body, more than double what would otherwise be spent on the service or patients in question, where that sum would be significant; or
- whilst in progress involves a significant modification to existing or planned patterns of service; or
- once completed, and if successfully introduced into practice, would result in a new intervention significantly more expensive than any standard alternative.

31. This will allow the NHS Executive to consider whether the research presents an exceptional case in which NHS support cannot reasonably be provided. Where the NHS Executive thinks this may be the case, it will first discuss the issue with the University and/or Research Charity involved. To avoid delays, the NHS Executive will be happy to engage in informal discussion with Universities and/or Research Charities about possible exceptional cases earlier in the funding process, provided that the research in question stands a reasonable chance of being funded (eg it has passed any short-listing stage for R&D costs).

Central Subventions

32. In strictly limited cases, where the volume or concentration of Excess Treatment Costs associated with particular pieces of externally funded R&D would risk serious disruption to NHS services locally, NHS Executive may make available subventions to cover part of the Excess Treatment Costs.

33. These subventions will be made available direct to the NHS Providers concerned.

34. The amount of the subvention in each case will be determined by the NHS Executive, after discussion with the researchers, research funders, NHS Commissioners and Providers concerned. These subventions will not cover the full Excess Treatment Costs, part of which will be expected to be borne through normal commissioning arrangements (see Part I).

35. Researchers and external funders will be encouraged to refer potential
cases to the NHS Executive well before the R&D is due to start. The NHS Executive will give NHS Providers as much notice as possible of any subventions that will be available.

36. NHS Providers may themselves wish to draw potential candidates for subvention to the attention of the NHS Executive when they confirm the availability of NHS support in advance of the R&D commencing. However, the NHS Executive will not entertain “bids” for subventions from NHS Commissioners or Providers once the work in question has started. Nor may Providers’ agreement to host R&D be made conditional on the receipt of a central subvention.

37. Where the NHS Executive is, at 1 April 1998, already partly meeting Excess Treatment Costs associated with an individual piece of externally funded R&D, it will continue to do so.

Monitoring and Review

38. The Partnership Arrangements are intended to formalise and strengthen existing informal understandings and practice. They are not intended to alter the respective overall contribution of either the NHS or external funders to health and health services R&D.

39. The NHS Executive will monitor the working of these arrangements jointly with the NHS and the external funders to ensure they work effectively. The Executive does not, however, intend to require evidence from external funders in each case that the partnership arrangements have been followed to the letter, nor does it expect Commissioners or Providers to do so. That would create an excessive bureaucratic burden.

40. If NHS Commissioners or Providers have concerns about the working of the arrangements, or believe that they are being contravened in either letter or spirit, they should first discuss them with the researchers, Universities and research funders concerned.

41. If problems cannot be resolved locally, they should bring them to the attention of their NHS Executive Regional Office. They should not, however, delay or obstruct the progress of particular pieces of R&D whilst any problems are considered and resolved.
Annex A

Distinction between R&D, Service Support and Treatment Costs applied to a particular service provided to a patient

In the case of a new or modified service under evaluation, the Treatment Costs are those costs which the NHS would expect to continue to bear after the research had finished and, assuming the trial or evaluation was successful, the service had been put in place.
STATEMENT OF PARTNERSHIP ON NON-COMMERCIAL R&D IN THE NHS IN ENGLAND

Introduction

i. The NHS Executive recognises and values the considerable contribution which Universities and Research Charities make to the NHS, not least in funding R&D. The NHS wishes to work in partnership with them to promote high quality health and health services R&D. For these purposes R&D means work which is intended to produce new knowledge which is generalisable and which is planned to be widely disseminated.

Mutual Obligations of the NHS and its Partners

ii. When funding R&D in the NHS, charities often look to the NHS to provide assistance by meeting the costs of the patient care associated with and required for the R&D. Likewise Universities look to the NHS to meet patient care costs associated with the R&D they carry out, either on their own or with funding from another source.

III. The NHS will as a general rule provide such assistance when requested, provided:

- the R&D is not primarily for commercial gain; and the body funding the R&D in question is a charity which funds work of scientific value relevant to health and health care and, if required to be, is registered with the Charity Commission or it is carried out on behalf of a University in the UK;

- the aims of the R&D are not incompatible with the objectives of the NHS;

- the Charity and/or University has taken steps to ensure that the work is necessary (e.g. does not inappropriately duplicate work already completed or in progress elsewhere);

- the Charity and/or University takes appropriate account of the priorities, needs and realities of the NHS, and encourages its researchers to do likewise;

- in particular:

  - where the R&D may involve significant costs to the NHS either in the short-term or on its completion, advice is sought from appropriate sources on the implications for the
NHS and NHS perspectives on the proposed R&D;

- before submitting proposals, researchers have considered and, where appropriate, discussed with the NHS locally, plans for the continuation or termination of any new or modified service (as appropriate) after the R&D project ends;

- where R&D directly involves patient care services, appropriate consideration has been given to how the work could be made most valuable to those in the NHS and elsewhere who may subsequently wish to use its findings (for example, the need for economic and quality of life components in the R&D);

- the Charity and/or University has taken into account the need to ensure that wherever sensible and practical R&D involving patients should be carried out in the context of actual patterns of patient care services, and has encouraged potential researchers to do the same;

- the Charity and/or University has taken into account the need to ensure the involvement of patients or their representatives in the design and implementation of research and dissemination of the results;

- for research into commercial products (eg pharmaceuticals) the Charity and/or University has encouraged the researcher to seek and obtain appropriate funding or other support from the commercial organisation(s) concerned;

- the Charity and/or University makes sure that the NHS receives appropriate notification of the likely support it will need to provide, according to arrangements published from time to time by the NHS Executive after discussion with the NHS and other funders;

- in particular, the Charity and/or University has made sure that the researcher has obtained any necessary agreement from the NHS Trust(s) or other NHS Provider organisation where the R&D is to take place;

- the Charity and/or University has encouraged the researcher to meet the highest possible professional scientific standards, and that as a minimum the research meets minimum standards published by the NHS Executive for example in its Strategic Framework, issued in January 1997, which is reviewed from time to time;

- the research has gained any necessary Research Ethics Committee
approval;

- the Charity and/or University intends to disseminate information about the work it is funding and requires its researchers to share information with other researchers in the same field of study and widely disseminate the findings of the R&D; and

- in particular the Charity and/or University has ensured that the researcher makes available information to the NHS and other researchers according to reasonable standards published from time to time by the NHS Executive after consultation with the NHS and other funders.

iv. By deciding to fund or support R&D which has or will incur NHS costs, Charities and Universities are deemed to be agreeing to abide by this Statement of Partnership.

Extent of the NHS Support

v. Where a University or Charity funds R&D in accordance with the above, the NHS will support it by meeting associated patient care costs. This includes meeting the costs of experimental services, and of arranging referrals where necessary (and where patients consent) to centres where the research is being carried out.

vi. The NHS is unable, however, to guarantee that it will meet costs of R&D (or patient care) infrastructure on demand. Infrastructure means those costs which cannot reasonably be attributed to single R&D projects, groups of closely related projects or other specific activities. Thus infrastructure covers, for example:

- R&D offices, peer review, professional panels;

- general allocation of clinicians’ time to R&D (eg consultant sessions) or “established” academic posts;

- any share of the purchase or hire of equipment of any value which
  - was not acquired for a specific R&D activity; or
  - was acquired for a specific R&D activity, but if fully utilised, could over the course of its lifetime reasonably be employed to a significant extent for activities other than the specific piece of R&D activity for which it was bought;

- the provision, construction or alteration of accommodation;

- the employment of additional staff who
  - will be occupied on a range of different R&D activities; or
  - who would not otherwise have been employed but for a
specific piece of R&D, but whose activities would not be wholly or mainly related directly to the R&D in question.

vii. The costs of paying for locum cover for staff (or other compensation for lost productivity), and the limited employment of additional staff on a sessional basis, should not be regarded as Infrastructure, provided they are associated with a discrete piece of R&D.

viii. Charities and Universities should expect their researchers to plan R&D only where the necessary NHS infrastructure already exists, or funding for it has been identified in advance.

ix. Exceptionally, the NHS reserves the right after discussion to decline to fund R&D which otherwise meets these criteria if it believes that there is a significant risk that the value of the R&D will not be sufficient to justify the costs to the NHS of supporting it. The NHS will not attempt routinely to assess R&D on this basis, but must reserve the right to do so, especially where clinical research involving very expensive experimental treatments is proposed. The NHS Executive will act on behalf of the NHS as a whole making decisions about whether to provide support to R&D.

x. This Statement does not apply to charities or other charitable funds which are wholly or mainly associated with a single or a group of NHS hospitals or other bodies.

Monitoring and Reviewing the Statement

xi. Beyond agreed notification arrangements, the NHS Executive will not seek to scrutinise individual pieces of R&D. It will, however, seek discussions with the Charities and/or Universities concerned about particular R&D activity which it feels may not be in line with partnership arrangements. In return the NHS Executive expects charities and Universities to cooperate in jointly monitoring the operation of these arrangements.

xii. This Statement will be subject to periodic review.

Corresponding Arrangements

xiii. Corresponding arrangements exist for R&D in the NHS which is funded by Statutory Research Councils and Government Departments and the European Union.