



*The NHS as an
Innovative Organisation*

*A Framework and Guidance on
the Management of Intellectual
Property in the NHS*

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Executive Summary

- 1 This Framework and Guidance is principally for Chief Executives and for Directors of R&D, Finance, Clinical Operations and Human Resources of NHS trusts and Primary Care Trusts. It is also important for Independent Providers of NHS Services.
- 2 NHS trusts and Primary Care Trusts will need to ensure that Intellectual Property (IP) arising in their organisation is managed within the given Framework and according to Directions which relate to additional powers under Section 5 of the Health and Social Care Act 2001. The Guidance contains model management arrangements and employment conditions which, if adopted, will establish for their organisation a structure to manage innovation for the benefit of NHS patients and employees. This Framework and Guidance takes effect on 9 September 2002, the date that Section 5 of the Act comes into force.
- 3 The Health and Social Care Act is intended to support the delivery of the NHS Plan. Section 5, as commenced, will allow the Secretary of State and NHS trusts and Primary Care Trusts to form or invest in companies in order to facilitate income generation. The NHS Plan commits the NHS to ensuring that new technologies are identified and developed in the interests of NHS patients and society as a whole, and that innovation leads to new products, improved interventions and services for health and social care. The NHS needs to develop as an organisation which has innovation at the heart of its business, generating wealth for better health.
- 4 In the NHS, innovation occurs in the delivery of patient care, in the education and training of employees and in R & D programmes. Innovation occurs naturally in the normal course of employment. The innovation may be a novel treatment, a device, a new drug, data, software, training material or a new management system. Most innovations are best implemented by making them freely available through normal knowledge management processes when they have demonstrated a quantifiable health gain. However, some innovations are inventions which can be realised only through commercial development, and for these the professional management of associated intellectual property (IP) is crucial. There must be wider recognition across the NHS that protection of IP facilitates, rather than impedes, uptake of inventions.
- 5 This Framework and Guidance sets out how NHS trusts, Primary Care Trusts and Independent Providers of NHS Services can contribute to the development of the NHS as an innovative organisation by capturing those new technologies and ensure that those inventions which can make more income available for improving the health service are appropriately developed and exploited.
- 6 This document has four parts. Part 1 sets out the context for managing inventions within a national framework for supporting innovation. It introduces the Department of Health Management Framework for IP which:
 - sits within the Department of Health Research Governance Framework and the Science and Innovation Strategy;
 - recognises that bringing inventions into practice requires some cost and some risk;
 - explains the need for NHS employment contracts to address IP issues;
 - sets out the legal framework for exploitation of NHS IP.

7 Part 2 is the Management Framework within which NHS trusts, Primary Care Trusts and Independent Providers of NHS Services can operate. The Management Framework builds on the Policy Framework for the Management of IP set out in HSC 1998/106, extending it:

- to include IP generated by NHS employees in the delivery of patient care;
- to enable NHS trusts and Primary Care Trusts to use companies for the exploitation of IP when authorised under Section 5 of the Health and Social Care Act 2001;
- to include management of IP through Primary Care Trusts.

Part 2 also sets out:

- how identified IP can best be managed;
- how NHS funds may be used in this management process;
- how income may be dealt with and losses written off within a developing system of expert risk management.

8 Part 3 is an Employment Guidance which describes the steps that a NHS trust and Primary Care Trust can take to become an innovative organisation managing its inventions with the encouragement and support of its employees. The Employment Guidance:

- provides good practice guidance on employment conditions and arrangements for their employees who may generate IP;
- sets out model employment conditions and a model Staff Handbook entry.

9 Part 4 is a Statement of Partnership setting out the principles under which NHS Trusts, Primary Care Trusts and Independent Providers of NHS Services, their funding partners and universities should treat IP that is generated by joint work.

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Part 1

Part 1: Introduction and Context

The NHS and the Cross-Government Strategy on Innovation

1.1 This Framework and Guidance is to inform Chief Executives and their senior managers in the NHS and in particular Directors of R&D, Finance, Clinical Operations and Human Resources how Intellectual Property (IP) generated by NHS employees should be managed for the purposes of income generation. This Framework and Guidance applies to

- NHS trusts some or all of whose hospitals, establishment or other facilities are situated in England
- Primary Care Trusts
- Independent Providers of NHS Services (e.g. general practitioners, dentists) who are to provide services in England under arrangements with Primary Care Trusts.

In this Framework and Guidance, the term NHS bodies means NHS trusts, Primary Care Trusts and Independent Providers of NHS Services and the term Trusts means NHS trusts and Primary Care Trusts.

1.2 This Framework and Guidance takes effect for NHS bodies on 9 September 2002, the date that Section 5 of the Health and Social Care Act 2001 comes into force in relation to Trusts.

1.3 The NHS Plan¹ recognises the need for the NHS to develop as an organisation which has innovation as the heart of its business. It commits the NHS to ensuring that innovations are identified and developed in the interests of patients and society as a whole. New technologies should lead to new products, improved interventions and services for health and social care.

1.4 The Health and Social Care Act 2001² is intended to support the delivery of the NHS Plan. Section 5 empowers the Secretary of State and Trusts and other bodies to which Section 5 applies to participate in spin-out companies established for income generation, including share ownership. If a Trust holds shares in a spin-out company then an employee, subject to the terms of the employment contract, may also hold shares in that company.

1.5 Section 5 of the Act is to be commenced for Trusts. Certain other bodies including Special Health Authorities also have powers to exploit IP for the purposes of income generation. Section 5 of the Health and Social Care Act will come into force for these bodies at a later date. Separate Directions will be issued to these bodies. These other bodies may wish to use this document as a general reference on IP.

1 *'The NHS Plan 2000' A Plan for Investment A Plan for reform*; <http://www.nhs.uk/nationalplan/nhsplan.pdf>.

2 *'Health and Social Care Act 2001' 2001 Chapter 15*; <http://www.legislation.hmsso.gov.uk/acts/acts2001/20010015.htm>

- 1.6 Innovation occurs naturally in the NHS through the work of its employees. Innovation could be through the delivery or the management of patient care, in the education or training of employees or through an R&D programme. The innovation may for example be a novel treatment, a new diagnostic, a device, a new drug or its new use, use of data, software, training material, a treatment protocol, or a new management system.
- 1.7 Most innovations when they have demonstrated a quantifiable health gain are best brought into use by using normal knowledge management processes and making them freely available to practitioners and managers for the benefit of patients. There are some innovations which can only be brought into use through commercial development of new products. There is always IP associated with an innovation, but for an innovation best developed commercially the IP and its professional management is crucial in its realisation. In this document, innovations which need to be developed commercially are called inventions and the employee responsible for the innovation is called the inventor.
- 1.8 There needs to be wider recognition across the NHS that understanding and protection of IP facilitates rather than impedes uptake of innovations. This Framework and Guidance is intended to provide NHS bodies with the advice they will need to manage the IP generated by their employees.
- 1.9 IP has an owner and can be bought, sold or licensed and should be adequately protected. The owner of the IP may or may not be the inventor. The owner of IP can control and be rewarded for its use and by so doing can encourage further innovation bringing benefit to all. The owner of IP has legal rights when IP is protected, and the principal form of these rights are patents, copyright, design rights, trade marks and know-how.
- 1.10 In July 1998 the NHS Executive published a Policy Framework for the management of IP arising from Research & Development funded in whole or in part from the NHS R&D budget³. It also published a Researchers Guide '*Handling Inventions and other Intellectual Property: a Guide for NHS Researchers*'⁴ and a Handbook '*The Management of Intellectual Property and Related Matters: an Introductory Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services*'⁵. The Researchers Guide or the Handbook provides the background that NHS employees will require to understand IP and its management.
- 1.11 The 1998 Policy Framework applies to the management of IP arising in NHS bodies from NHS funded R&D. However IP is often generated by employees of NHS bodies during the normal course of their duties outside R&D. IP generated from any source is now recognised by the NHS as an asset of value which should be used in the best interests of the NHS and the country as a whole by those best able to do so. This Framework and Guidance sets out how this can be achieved for IP which can only be used by exploiting it through commercial channels.
- 1.12 In the Science and Innovation White Paper⁶ the Government has set out a national framework for supporting innovation and the inventions that arise from the innovation. Guidance documents have been published including the Government Response to the Baker Report⁷. An essential aim of wider-

3 HSC 1998/106 'Policy Framework for the management of Intellectual Property within the NHS arising from research and Development'; <http://tap.ukwebhost.eds.com/doh/coin4.nsf/Circulars?ReadForm>

4 '*Handling Innovation and other Intellectual Property*': A Guide for NHS Researchers; <http://www.doh.gov.uk/pub/docs/doh/integuid.pdf>

5 '*The Management of Intellectual Property and Related Matters: An Introduction Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services*'; <http://www.doh.gov.uk/pub/docs/doh/intehand.pdf>

6 '*Excellence and Opportunity*' A science and innovation policy for the 21st century; <http://www.dti.gov.uk/ost/aboutost/dtiwhite/pdf/whole.pdf>

7 '*The Government's response to the Baker Report: "Creating Knowledge, Creating Wealth" Realising the economic potential of Public Sector Research Establishments*'; <http://www.hm-treasury.gov.uk/mediastore/otherfiles/government%20response%20to%20the%20baker%20report.pdf>

Government strategy, captured in the Baker Report⁸, is to capture and exploit innovations for the benefit of the UK economy. A central element of the national framework is that when an invention generates income this income may be shared with inventors. The 1998 NHS Policy Framework is fully consistent with this national framework for supporting NHS inventions and inventors.

- 1.13 The Science and Innovation White Paper encourages Government bodies to use a spin-out or joint venture company as a vehicle for exploiting IP when it is most appropriate to do so. A Guidance Note has been published⁹.
- 1.14 The Patent Office has published Guidelines¹⁰ for public sector purchasers of research and research providers dealing with IP in Government research contracts. These Guidelines apply to Trusts undertaking R&D and the content of this document is consistent with these Guidelines.
- 1.15 The commercial exploitation of IP incurs some cost and some risk. The National Audit Office has announced¹¹ that it will adopt an open-minded and supportive approach to innovation and will support well thought through risk taking in the exploitation of valuable IP. In terms of public sector research, when examining these activities the National Audit Office will address
- whether organisations have adequate procedures in place for identifying and developing outputs with commercial potential
 - the extent to which opportunities are identified and explored
 - the quality of risk management which adequately assesses risks against potential benefits.

The Audit Commission, which has responsibility for appointing auditors for Trusts, has agreed to adopt the National Audit Office approach with respect to NHS IP activity.

- 1.16 The Department of Health has responded to the Science and Innovation White Paper by publishing its own Science and Innovation Strategy¹². Publication and implementation of this Framework and Guidance is part of the Department of Health strategy.
- 1.17 The Department of Health has also published a Research Governance Framework for Health and Social Care¹³ which sets standards for research and defines mechanisms to deliver them. Protection and exploitation of intellectual property is one of the responsibilities of a high quality organisation undertaking R&D.

8 *'Creating Knowledge Creating Wealth: Realising the Economic Potential of Public Sector Research Establishments'*; Baker Report (Treasury); [http://www.hm-treasury.gov.uk/Documents/Enterprise Enterprise_and_Productivity/Research_and_Enterprise/ent_sme_baker.cfm](http://www.hm-treasury.gov.uk/Documents/Enterprise_Enterprise_and_Productivity/Research_and_Enterprise/ent_sme_baker.cfm)

9 *'A Guidance Note for Public Sector Bodies Forming Joint Venture Companies with the Private Sector'* 2001; <http://www.partnershipsuk.org.uk/news/jointventureguidance.pdf>

10 *'Intellectual Property in Government Research Contracts. Guidelines for Public Sector Purchasers of Research and Research Providers'*; <http://www.patent.gov.uk/about/notices/ipresearch.pdf>

11 *'Commercialisation Activities by Public Sector Research Establishments'*; National Audit Office Press Notice; <http://www.nao.gov.uk/pn/9899psre.htm>

12 Science and Innovation Strategy 2001, Department of Health; <http://www.doh.gov.uk/research/documents/s&i.pdf>

13 Research Governance Framework for Health and Social Care, Department of Health; <http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance/govhome.htm>

Management Framework

1.18 The Framework for managing IP is developed here in three main directions

- IP generated by all NHS bodies through all their activities, not only from R&D, is now to be managed as an asset
- Primary Care Trusts will have broader powers to commission NHS services from October 2002 and therefore they are brought in to the Framework
- Section 5 of the Health and Social Care Act 2001² allows Trusts subject to the Secretary of State's approval, amongst other things, to form or participate or invest in the formation of a company as a vehicle to exploit IP with commercial potential.

1.19 Part 2 is the Management Framework which describes how a NHS body owning IP should manage it, and gives guidance on the use of NHS funds for this purpose. It builds on the Introductory Handbook⁵. In particular it sets out a framework for the use of companies to manage IP.

Employment Guidance

1.20 IP can be generated where R&D, delivery or management of care or other creative work is being undertaken. Generally speaking, UK law provides that (unless otherwise agreed) IP produced by employees in the course of their employment or normal duties belongs to the employer.

1.21 It has been rare for employment contracts of NHS employees to include provisions for IP and as a result confusion has existed and conflicts have arisen. The complexity of this area means that there are many benefits to be obtained by confirming the position in a contract of employment. Without clarity on ownership and management arrangements adopted by an NHS body valuable IP will almost certainly be lost. A detailed Employment Guidance is given as Part 3 and sets out employment and management issues to assist NHS bodies in their application of the Management Framework. It includes general principles of

- employment conditions for NHS employees
- management arrangements under which employees will be expected to operate.

It also includes, as an aid, a model insertion into an employment contract and a model entry for a Staff Handbook which can be used by NHS bodies. For some NHS employees changes to employment contracts will need to be agreed with their professional bodies.

1.22 The Department for Education and Skills and the Department of Health have jointly adopted a review¹⁴ which includes recommendations on substantive and honorary contracts for senior NHS and university staff posts with academic and clinical duties. The Employment Guidance given here is intended to contribute to the detail of IP arrangements within these contracts.

2 'Health and Social Care Act 2001' 2001 Chapter 15; <http://www.legislation.hms.gov.uk/acts/acts2001/20010015.htm>

5 'The Management of Intellectual Property and Related Matters: An Introduction Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services'; <http://www.doh.gov.uk/pub/docs/doh/intehand.pdf>

14 'A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior NHS and University Staff with Academic and Clinical Duties': a report to the Secretary of State for Education and Skills by Professor Sir Brian Follett and Michael Paulson-Ellis; <http://www.dfes.gov.uk/follettreview>

Statement of Partnership in Intellectual Property

- 1.23 IP will sometimes be generated by research undertaken jointly by the NHS and a partner such as a charity or a university. A Statement of Partnership is given as Part 4 which sets out the principles under which the NHS and its funding partners may treat this IP. This has been agreed with Universities UK on behalf of UK universities.

Legal Framework

- 1.24 The exploitation of Intellectual Property by NHS bodies falls within the scope of their Income Generation powers. In other words it is subsidiary to, and must not significantly interfere with, their core health service duties.
- 1.25 The Secretary of State has the power under Section 7(2) of the Health and Medicines Act 1988 to develop and exploit ideas and exploit intellectual property in order to make more income available for improving the health service. NHS trusts have the power by virtue of paragraph 15 of Schedule 2 to the NHS and Community Care Act 1990. Primary Care Trusts have the power by virtue of Section 18A(5) of the NHS Act 1977.
- 1.26 The 1988 Act specifically states that the Secretary of State will exercise this power ‘only after consulting (to the extent that appears to him to be practical) any person who appears to him to have an interest through his own previous research in the ideas or intellectual property in question as to whether he should exercise them and, if so, as to any financial arrangements.’ This duty applies to NHS trusts and Primary Care Trusts.
- 1.27 Section 5 of the Health and Social Care Act 2001 amends Section 7(2) of the Health and Medicine Act 1988 so as to enable the Secretary of State and certain bodies (including Trusts) to form, or participate in the formation of or invest in, companies for income generation purposes. Where these Trusts form companies to exploit IP, they will be exercising income generation powers and will be subject to statutory and other limitations. In particular Trusts may only exercise the power to the extent that its exercise does not to a significant extent interfere with the performance by the Trust of its functions or of its obligations under NHS contracts (Section 18A (6) of the 1977 Act for Primary Care Trusts and Section 5 (9) of the 1990 National Health Service and Community Care Act for NHS trusts).
- 1.28 The Directions at Part 2 Appendix 5 relate to use by Trusts of the powers in Section 7(2) of the Health and Medicines Act 1988 and require that in the exercise of those powers by means of forming or participating in companies they must comply with the conditions set out in the Directions.
- 1.29 Independent Providers of NHS services operate under statutory arrangements, the terms and conditions of which are set out in regulations. They are persons providing primary care services under Part 2 of the National Health Service Act 1977 or performing personal medical or dental services under the National Health Service (Primary Care) Act 1997.
- 1.30 If an executive director of a NHS trust or an officer member of a Primary Care Trust owns shares in a company set up to exploit IP, then the director or member and the Trust must ensure that they comply with requirements of the NHS Trusts (Membership and Procedure) Regulations 1990 (S.I. 1990/2024) or the Primary Care Trusts (Membership, Procedure and Administration Arrangements) Regulations 2000 (S.I. 2000/89).

- 1.31 In making financial provision in respect of companies, NHS bodies should take care to ensure that this provision does not amount to State Aid. In broad terms, State Aid is any assistance from the State which distorts or threatens to distort competition and which could affect trade between Member States. In awarding contracts to companies outside the NHS for the provision of IP services, Trusts should operate within procurement legislation including the Public Services Contracts Regulations 1993. Part 2 of this document provides advice on these two issues. Trusts should take specific legal advice in respect of their particular circumstances at the time on these issues.

Sharing Best Practice

- 1.32 A web site is being constructed to inform and to develop and share best practice in the management of NHS IP. It can be found at **www.innovations.nhs.uk**. The web site will also provide access to this document and to other background documents.
- 1.33 The NHS is putting in place an IP management system across the country and contact details for access to this system can also be found at **www.innovations.nhs.uk**
- 1.34 Further advice on this document is available from:

Dr Tony Bates, NHS Intellectual Property Adviser, United Bristol Healthcare NHS Trust,
Trust Headquarters, Marlborough Street, Bristol, BS1 3NU.

e-mail **Tony.Bates@ubht.swest.nhs.uk**

or **Tony.Bates@doh.gsi.gov.uk**

- 1.35 Specific details on the accounting treatment of IP can be obtained from:
Anne.Rylatt@doh.gsi.gov.uk or
Steve.Warren@doh.gsi.gov.uk
Business case advice can be obtained from **www.doh.gov.uk/pfi.htm**

Part 2

Part 2: Management Framework

Extension to Existing Policy Framework

- 2.1 The Policy Framework for the Management of Intellectual Property (IP) under HSC 1998/106³ remains operational, but in addition:
- IP generated by a NHS body from activity outside R&D is now included within the management structure set up under HSC 1998/106.
 - From October 2002, subject to legislation, Primary Care Trusts will commission services from Independent Providers of NHS services, in place of Health Authorities. This has implications for the way Independent Providers will need to treat IP arising from their work.
 - Trusts and certain other bodies constituted under the 1977 NHS Act may use companies to exploit IP subject to authorisation by the Secretary of State.
- 2.2 Under HSC 1998/106 there is a responsibility on NHS bodies in receipt of NHS R&D funding to identify and exploit the IP generated by this R&D. The Research Governance Framework for Health and Social Care¹³ states that employers of researchers should ensure that agreements are in place between them and their staff and between them and research funders and care organisations about ownership, exploitation, and income from any IP that may arise from research conducted by their employees; they have a responsibility for ensuring that employees identify and protect IP. The delivery or support of patient care may also generate IP with significant potential to improve the health service if this is captured, evaluated and then disseminated or exploited. This Management Framework covers this IP.
- 2.3 There is no formal responsibility on NHS bodies to capture IP associated with patient care e.g. through audit, but NHS bodies and the employees who generate the innovation will wish to bring it into the same management framework as for R&D.
- 2.4 An innovation can be used to improve the health service in one of two ways. First, after suitable evaluation, it could be freely disseminated across the NHS by knowledge management processes. Second, the evaluation may show that it is best treated as an invention and the method of doing this is the subject of this document. It may not be clear until after evaluation which path an innovation should follow. NHS bodies will need to have in place a management process to comply with Research Governance responsibilities, with an identified lead person able to respond professionally to employees.
- 2.5 The formal audit process carried out by NHS bodies to review their R&D outputs, commonly called 'technology audit', may also identify IP that is a 'good practice' innovation which needs to be evaluated and disseminated freely when appropriate. Plans are being put in place to capture these innovations which have no commercial value but the potential to improve health and to save expenditure by the NHS.

3 HSC 1998/106 'Policy Framework for the management of Intellectual Property within the NHS arising from research and Development'; <http://tap.ukwebhost.eds.com/doh/coin4.nsf/Circulars?ReadForm>

13 Research Governance Framework for Health and Social Care, Department of Health; <http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance/govhome.htm>

- 2.6 Since 1998 NHS bodies have had the power to exploit IP in order to make more income available for improving the health service. The 1998 Policy Framework for IP generated from R&D allowed this income to be retained by the NHS body which created the IP. NHS bodies are also able to share this income with those responsible, the inventors. These conditions are now extended to IP generated outside R&D, with the IP managed as if it had originated from R&D.
- 2.7 Cross-Government policy is for an organisation exploiting IP to retain income from it, and so provide an incentive for the organisation and inventor employees. For Trusts, these incentives come at the expense of commissioners' discretion to use all revenue resources for health priorities. Income arising from IP can be one-off payments, licence fees, flows of royalties, dividends or sales of shares, and such income flows are generally small in relation to NHS bodies' budgets. One-off sales, such as of shares when IP marketing is realised, or international licence agreements, can yield significant income. However, the flow of these funds, their amount and timing are very difficult to predict.
- 2.8 Where a Trust has achieved a surplus in its income and expenditure account for the year, all or part of the element of surplus arising from IP activities (as evidenced by a memorandum trading account) may be retained in the Trust for future developments which it determines. It is intended that such sums may be spent in the following year, where necessary, at its discretion. It has been agreed that:
- a Trust is able to retain and use for its own purposes in improving health care any surplus on its revenue account arising from IP activity. The limit for such retentions for any one year is the larger of £100k or 0.2% of turnover. This surplus is after deduction of costs and distribution to inventors;
 - where this surplus is earned and spent by the Trust within any given financial year, there is no need for commissioners to take any special action and planned funding may be left in place unchanged. All other things being equal, a breakeven position will be achieved;
 - the IP surplus (below the limits noted above) that is earned and applied in year should be reported to the relevant commissioners. Where a higher surplus is achieved, or monitoring in-year indicates that it may be achieved, its utilisation must be discussed with the Strategic Health Authority and main commissioners at the earliest opportunity;
 - in the event that a Trust does not spend an IP-generated surplus in a financial year, commissioners and the body will need to agree how the body can benefit from the surplus in the following period. Unplanned surpluses are undesirable, as they deny the health community the opportunity to utilise them to best effect. It remains policy that Trusts should break even (neither generating surplus or deficit in the final accounts) each year. Commissioners will wish to utilise a budgeted surplus elsewhere in the community, according to local priorities, and will achieve this by redirecting funding from the Trust in surplus to others where income and expenditure pressures exist. To meet the policy objectives of IP exploitation, it is clearly necessary to make that funding available to the IP-generating body in the next period, to fund projects it wishes to take forward.
- 2.9 The statutory purpose of exploiting IP is to make more income available for the health service, and this must be the case when an invention is exploited successfully. It is not always the case that actually maximising income is best for the health service. There will always be other strategic priorities to consider such as improving health for the maximum number of patients and providing savings to the NHS. It would be inappropriate to discard an invention because it generated a small income if it is capable of providing health improvement to patients across the NHS and further afield or if it could result in delivering a service more cheaply. Those charged with exploiting NHS IP will need to take these considerations into account.

- 2.10 An essential aim of cross-Government strategy is to capture and exploit innovations⁷ for the benefit of the UK economy. Government funding, through for example DTI funding schemes and Regional Development Agencies, is available to NHS bodies in support of this work. Now that Trusts may use a spin-out company to exploit their IP, the NHS can play its full part in generating wealth for health.
- 2.11 HSC 1998/106 applies to NHS trusts and Independent Providers of NHS Services. Independent Providers of NHS Services are persons providing care Services under Part 2 of the National Health Service Act 1977 or performing personal medical or dental Services under the NHS (PC) Act 1997. Under HSC 1998/106 they share under a contractual arrangement with the NHS Executive (now the Department of Health) any benefit derived from exploitation of IP arising from their R&D.
- 2.12 HSC 1998/106 states that IP should be owned by those best able to exploit it. Generally an Independent Provider of NHS Services does not have the resources to support the development of IP, or have access to the expertise to exploit it. Now that Independent Providers will provide NHS Services under arrangements with a Primary Care Trust, it is the Primary Care Trust which normally will be best placed to arrange access to the means of exploiting IP. It should then be the Primary Care Trust which takes ownership of the IP and assumes responsibility for its exploitation. If the Independent Provider agrees to this transfer of ownership then the requirement to share any benefit with the Department of Health will be waived. The transfer of ownership and responsibility for exploitation does not prevent the inventors sharing in the rewards of its exploitation.
- 2.13 If IP is exploited successfully by a Primary Care Trust then benefit derived by the Trust will be passed to the Independent Provider of NHS Services for distribution according to that Provider's agreed policy. Primary Care Trusts are advised to adopt a sharing formula common to all of their Providers.
- 2.14 The powers in Section 5 of the Health and Social Care Act 2001² allow Trusts to exercise the powers in Section 7 (2) of the Health and Medicines Act 1988 to use a company as a vehicle to exploit IP they own. This brings these bodies in line with Independent Providers of NHS Services and with other Public Sector Research Establishments.
- 2.15 These extensions to the Management Framework have particular consequences for the exploitation of NHS IP with the potential to generate income. The remainder of this part of the Framework and Guidance describes these consequences and expands on issues introduced in the 1998 Policy Framework. In particular it describes the management procedures that NHS bodies are advised to adopt, including the use of companies, to exploit their IP.

Management Arrangements for Commercial Exploitation: the Appointment and Role of the Adviser Organisation

- 2.16 NHS bodies generally do not have the in-house skills to identify and manage IP with the potential to generate income. Development of those complex skills within individual NHS bodies is not cost-effective in the vast majority of cases because the opportunities identified from the work of one NHS body would be insufficient. Such activity could also contribute to mission drift. A NHS body is advised to contract with an organisation to provide high quality advice on its behalf and to act as Adviser

⁷ *'The Government's response to the Baker Report: "Creating Knowledge, Creating Wealth" Realising the economic potential of Public Sector Research Establishments';*

<http://www.hm-treasury.gov.uk/mediastore/otherfiles/Government%20response%20the%20Baker%Report.pdf>

² *'Health and Social Care Act 2001' 2001 Chapter 15; <http://www.legislation.hms.gov.uk/acts/acts2001/20010015.htm>*

Organisation to the NHS body. The Adviser Organisation was given the name Adviser in the Introductory Handbook⁵ and Researchers Guide⁴ published in 1998 alongside HSC 1998/106. Access to high quality advice is a requirement of good research governance.

- 2.17 Specialist commercial organisations exist which could carry out the work of an Adviser Organisation and most universities have expertise in this area. In commissioning IP services from an outside body, any NHS body will need to take account of procurement legislation and value for money policy. It will need to conduct a competitive tender if the contract value is above any relevant threshold. Procurement should be in line with the Public Services Contracts Regulations 1993.
- 2.18 The tendering requirement could cover contracting with an external body (such as a university or specialist commercial organisation) to provide specialist IP management services.
- 2.19 A NHS body will need to implement management systems to facilitate the work of its appointed Adviser Organisation. This includes identification of a lead person to act as a bridge between employees and the Adviser Organisation. It also includes making its employees aware of their responsibilities under the policy, through their employment contract, their Staff Handbook and an appropriate training programme. Training should ensure that employees, particularly researchers, have the level of understanding of IP described in the Researchers Guide⁴, and that the lead person has the understanding laid out in the Introductory Handbook⁵. Training costs would normally be met by the NHS body. The Adviser Organisation is likely to play a part in the delivery of this training.
- 2.20 The NHS body would normally be expected to meet costs of identification of IP, initial patent protection and training. The NHS body can make funds available to its Adviser Organisation, perhaps as an annual fee, to carry out those functions. It could also make a loan to a Hub repayable when the Hub has excess funds attributable to the body that makes the loan. The remaining costs of exploitation, including continuing patent costs, will come where possible from external sources of finance through the Adviser Organisation. NHS bodies are encouraged to participate in the range of Government schemes which are available for this purpose, often engaging with both universities and industry. Where valuable IP is identified and these external funds are not available the NHS body may meet costs of exploitation, e.g. professional and legal costs, within the context of the National Audit Office statement on risk.
- 2.21 Identified IP, however it arises, would be evaluated by the Adviser Organisation to determine whether exploitation, commercial or otherwise, is appropriate. If the IP has commercial potential, part of this evaluation is to resolve the question of ownership (see Part 3). In evaluating whether to follow a commercial route the Adviser Organisation will carry out a risk appraisal including the costs of exploiting the IP, the expected value to the NHS and the financial return.
- 2.22 When income is generated by commercial exploitation of IP there will be costs incurred by the Adviser Organisation in obtaining this income. NHS bodies should have a contractual agreement with their Adviser Organisation which defines the proportion of this income which the Adviser Organisation will receive as its commission and the balance (the residual income) which will be due to the NHS body. Treatment of residual income by a NHS body is discussed in more detail in paragraphs 2.73 to 2.80. This agreement should also cover responsibilities for meeting future patent and legal costs. The role of the Adviser Organisation is crucial to the exploitation process. The contract with the Adviser Organisation should deal with issues such as the responsibility and the liability of the Adviser Organisation and of the NHS body.

⁴ 'Handling Innovation and other Intellectual Property': A Guide for NHS Researchers;
<http://www.doh.gov.uk/pub/docs/doh/integuid.pdf>

⁵ 'The Management of Intellectual Property and Related Matters: An Introduction Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services'; <http://www.doh.gov.uk/pub/docs/doh/intehand.pdf>

A NHS Hub as the Adviser Organisation

2.23 Plans are in hand to create a network of Adviser Organisations, Hubs, serving the needs of NHS bodies on a regional basis. A Hub would normally be an unincorporated association of NHS bodies with agreed arrangements for risk-sharing and for assuming liabilities and responsibilities. Such a Hub could employ staff as NHS employees located in one or more places. Each Hub organisation, essentially a technology transfer office acting for several NHS bodies, is intended to provide a cost effective and expert resource for management of NHS IP. The IP services that a Hub might provide could include:

- identification of IP through technology audit;
- training for NHS employees in the importance and understanding of IP;
- evaluating the IP and initiating additional R&D to produce evidence of clinical application;
- registering the IP;
- commissioning the production of prototypes;
- advising on and exploiting the IP through licensing or through the setting up of companies;
- collaborating with universities and other third parties in the exploitation of IP generated jointly with Trusts.

2.24 Each NHS body would enter into an arrangement with other NHS bodies which wish to be a member of the unincorporated association. The arrangement would in most circumstances be an NHS contract as defined by Section 4 of the Health Service and Community Care Act 1990. Such an arrangement would establish the obligations of the Hub (including confidentiality) and funding arrangements. A Hub and its collaborating NHS bodies will need confidentiality agreements to allow information about exploitable IP to pass between them. A Hub can in most circumstances provide IP services for other NHS bodies without a competitive tender.

2.25 Hubs are part-funded by the Secretary of State and by Government. NHS funding for this network of Hubs will be to lead Trusts through the NHS Priorities and Needs R&D funding stream. NHS bodies are strongly encouraged to join Hubs as they develop.

Commercial Exploitation Agreements

2.26 There are three main ways of obtaining income from IP:

- outright sale of the IP to an existing company;
- licensing or assigning the IP to an existing company in return for fees and royalties;
- licensing or assigning the IP to a spin-out company set up specifically to exploit the IP in return for fees, royalties and shares.

Whatever route is chosen a NHS body through its Adviser Organisation needs to ensure that the chosen method and the subsequent agreement is in the best interest of NHS patients and that the decision-making process, which will include the management of risk, is transparent and defensible.

- 2.27 A NHS body through its Adviser Organisation will further need to ensure that its future research and training activities in the subject area of the IP are not unnecessarily or unduly restricted by any agreement. For example an agreement needs to allow the NHS body to retain the right to use the IP for NHS internal research and training purposes. Agreements where the other party is given an option or a right of first refusal to acquire or licence other developments made by the NHS body in the same area are to be avoided. In addition ongoing financial obligations (such as ongoing costs for patents) will normally be the responsibility of the commercial partner. Warranty on the validity of the IP should be avoided and no liabilities should be accepted for the quality of the invention etc which is the subject matter of the IP. There may be some scope for a limited warranty that the NHS body had not previously licensed or assigned the IP in question, but this would need to be rigorously checked through due diligence procedures to ensure that the warranty could be given. Costs which could arise, for example due to patent infringement and product liability, would normally fall only on the commercial partner even when the agreement is with a spin-out company in which the NHS body has a shareholding. Costs of a future research programme and for support of the licence by employees of the NHS body would need to be included in the licence.
- 2.28 Financial return will be to the NHS body as the source of the IP. The Adviser Organisation through the exploitation agreement should consider whether other NHS bodies could benefit through, for example, preferential terms of sale.
- 2.29 It is likely that most exploitable items of NHS IP will have an international market and that a licence will cover manufacture and sale in more than one country. Adviser Organisations setting up licence agreements should seek to include terms that are likely to give patients in developing countries access to products at reasonable cost.
- 2.30 A commercial exploitation agreement will often involve other organisations (e.g. universities) with an interest in the IP. Ownership and management issues for the IP should be clearly defined in a contract with the other organisation agreed well before the commercial exploitation agreement is completed. Guidance on employment and management issues is set out in the Employment Guidance in Part 3 and in the Statement of Partnership in Part 4.
- 2.31 A checklist of the terms which would be considered for a licence agreement is given as guidance at Part 2 Appendix 1. Examples of possible terms which could provide safeguards for patients in developing countries are given at Part 2 Appendix 2. Further advice on the exploitation process for NHS bodies is provided by the Introductory Handbook⁵.
- 2.32 Patient biological samples may also be obtained by NHS employees of NHS bodies during the course of their duties in delivering patient care or in carrying out R&D. Fully informed consent for all intended or any purpose should be obtained if it is anticipated that such biological samples might be used in research, whether immediately or in the future. If subject to such consent a NHS body transfers these samples for further research, e.g. to a university, then it may be appropriate to seek a share in any benefit obtained by subsequent exploitation on previously agreed terms.
- 2.33 Transfer of biological samples may be to a third party, allowing the third party to carry out research (in its own right or on behalf of a NHS body) or to enable the third party to evaluate the materials for possible licensing arrangements. The third party could be a university, a public sector research establishment or a commercial organisation. Transfer of materials, which would be dependent on appropriate written consents being obtained, should be according to terms of a Materials Transfer Agreement between the NHS body and the third party and which should be entered into before the

⁵ *The Management of Intellectual Property and Related Matters: An Introduction Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services*; <http://www.doh.gov.uk/pub/docs/doh/intehand.pdf>

material is transferred. The NHS body may have rights in the material which need to be protected and these rights might be lost or compromised by the transfer unless an agreement is made which makes appropriate provision. An explanation of a Materials Transfer Agreement has been produced by the BioIndustry Association¹⁵. The Adviser Organisation will be able to advise on the IP aspects of a Materials Transfer Agreement.

Companies as Vehicles for Exploiting NHS IP

- 2.34 Section 5 of the Health and Social Care Act enables the Secretary of State to authorise Trusts to form or participate in the formation of companies and to invest in companies for income generation purposes. In particular this enables them to participate fully in companies established to exploit Trust IP, including acquiring shares. Unless otherwise Directed, a Trust will be able to exercise this power only when the Secretary of State has authorised the scheme in question. Authorisation will normally depend on a business case approved by the PFI Unit of the Department of Health
- 2.35 There are two distinct circumstances in which it may be appropriate to establish companies for the exploitation of NHS IP for income generating purposes. The first is where the company is intended to grow in value or act as a route to market (commonly called a spin-out company and limited by shares); the second is where the company is not intended to make a profit and uses its available income and property only for its objects (normally a company limited by guarantee).
- 2.36 A Trust through its Adviser Organisation should take professional and legal advice before proposing a structure for a company set up to commercialise Trust IP.

Spin-out Companies set up as Companies Limited by Shares

- 2.37 Where a product with the potential to deliver better health has been progressed along a commercial route so that it is ready to be developed further or taken to market, the Trust will have invested human and other resources (e.g. patent costs) in achieving this position. A spin-out company enables additional external resources to be attracted (e.g. from business angels or venture capital companies) to complete the development. The Trust would own a percentage of the shares in recognition of the value of its past work, as normally would the inventors. For a Trust its shareholding will normally be obtained without further investment, since any further public investment might constitute State Aid. The Trust would license or assign ownership of the IP to the company. The company would be limited by shares. Shares would be issued for a small sum, say £1 each, or perhaps less, which limits the liability of shareholders and contributes to the share capital of the company. Shares may be issued to the Trust in return for its IP, but tax advice would need to be sought as to the most appropriate way of licensing or assigning the IP to the company. As the company becomes profitable so the market value of its shares would increase and other parties would be able to purchase shares in the company to raise more capital for any expansion plans that the company may have. The market value of a share (the price for which it might be sold) is a reflection of its potential as an investment. The Trust's investment yield may be capital growth (increased value on sale of shares) or revenue e.g. dividends paid.
- 2.38 A spin-out company is appropriate when it represents the best option for exploiting the IP for the benefit of the health service. Sometimes there may be no other option because there may be no company operating in the area, or those that could take a licence choose not to do so.

15 Contact details for the BioIndustry Association; Admin@bioindustry.org

2.39 A spin-out company may be a convenient route to market for IP which needs developing to the stage where it can be licensed or where it can attract external funding. The shares have little value until external funding is introduced but they can be held by interested parties in numbers which reflect their contribution to development of the IP. Establishing such an entity gives freedom to operate in a commercial framework and provides access to public and private development funding available to small businesses.

Managing Risk in Spin-out Companies

2.40 Formation of such a spin-out company is regarded as a higher risk method of IP exploitation but with a greater potential for significant reward. Not all spin-out companies succeed. Hence, those companies in which the public sector has a shareholding must be established through a Shareholders Agreement and Memorandum and Articles of Association which pass as much of the risk as possible to the external investors and restrict consequential liability for the public sector.

2.41 Whilst the format of such documents will vary there are certain issues which will in most circumstances need to be addressed. These are set out in the Questionnaire as Part 2, Appendix 3. The documents as a whole should in most cases provide that the Trust has, subject to compliance with domestic, European and other relevant legislation, a veto over:

- any reorganisation of the company's share capital;
- creation of share options;
- issuing of more shares;
- changing the objectives of the company;
- changing the Articles of Association of the company.

2.42 These provisions are to protect the Trust's position as shareholder. Care must always be taken to avoid the Trust becoming a shadow director of the Company. A shadow director is a person in accordance with whose directions or instructions the directors of the company are accustomed to act and who may, as a result, incur similar liabilities to those of an appointed director.

2.43 There are various effects of different levels of shareholding in a company and Trusts through their Adviser Organisation need to be aware of these considerations. They are set out at Part 2 Appendix 4.

2.44 A Trust taking a shareholding will normally have a Trust employee, nominated by the Trust Chief Executive, on its Board or as an observer to the Board, with a residual right to appoint a director if it desires. If an employee of the Trust is a director the legal duties of good faith owed to the company by a director would be paramount to any duty owed to the Trust. This employee will have a sole duty to support the development of the company, providing this does not give rise to a conflict of interest, but can help to ensure that risk to the Trust continues to be minimised and benefits to the NHS are maximised. The director would have no personal financial interest in the company, but may receive material benefit from the relationship with the company if agreed by the Trust Chief Executive. Indemnity cover for the directors should be provided by the company. Even as a director the Trust nominee may be outvoted on certain issues, except to the extent that protections are built into the Shareholders Agreement or the Articles of Association. The employee's duty would only be to the Trust if he or she were simply an observer. An observer would not have right to vote at a Board meeting but

should be given rights to receive information and speak at Board meetings in the governing Shareholders Agreement or the Articles of Association of the company. The Trust itself and any individual acting as an observer will need to be careful not to become a shadow director.

- 2.45 Shareholder duties are limited by a Shareholders Agreement which sets out the relative shareholding, the rights of the shareholders, voting rights and Board membership. The Shareholders Agreement and Articles should deal with future allocation and transfer of shares as new external investment is introduced and should protect the future rights of NHS shareholders as new shares are issued through:
- rights of pro-rata allotment in the Articles;
 - a right to veto the issue of new shares in the Shareholders Agreement;
 - rights of pre-emption (right of first refusal for the other shareholders) in the Articles.
- 2.46 The Trust needs to understand however that as new investment comes into the company there will be a need to issue new shares. It should take this into account when coming to agreement on the percentage of shares it is initially allotted in the company. A balance has to be drawn between taking a larger number of shares initially in the knowledge that as new shareholders come in there will be dilution or taking a smaller number of shares initially and building anti-dilution provisions into the Shareholders Agreement.
- 2.47 Ownership of IP would in most cases be retained by the Trust until external funding is brought into the company. An exception would be where it is believed there may be greater benefit in assigning the IP early before it has any substantial value. When external funding is introduced, the Trust can either license or assign the IP to the company in return for shares and/or other benefits e.g. royalties. The exploitation agreement will reflect the state of development of the IP. If the IP is assigned, either initially or later, the agreement should always provide the Trust with right of first refusal or an option to buy back the IP in the event that the company ceases to trade or the Trust reasonably believes the company has not exploited the IP for a specified period e.g. 2 years, or has stopped exploiting the IP.
- 2.48 A Trust will need to be careful if it allows its physical assets (such as laboratory space and equipment) to be used by the company. In the early stages of establishing the company this may be necessary to help get the company started, but if they are used it should be only when they are not required for direct patient care-related activities. When used by the company the cost and conditions should be part of a formal agreement approved by the Trust Board and which should also address issues of confidentiality. Cost recovery should be based on Costing for Contracting. Where the Trust does not actually own the physical assets e.g. where they are provided by the private sector under PFI, the Trust will need to check its rights to allow the company to use them.

Participation of NHS Employees in Spin-Out Companies

- 2.49 NHS employees responsible for generating Trust IP should be able, if they wish, to participate fully in the commercialisation of the IP provided that:
- they have created or contributed to knowledge which has commercial value;
 - they have a potentially important role in the successful commercialisation of that knowledge;
 - conditions ensuring probity are met;
 - no conflict of interest arises.

Care should be taken in allotting shares to NHS employees, otherwise the NHS employee may be liable for income tax if the shares are deemed to be a benefit of their employment. Both the Trust and the employees will need to take appropriate tax advice. It may be more appropriate for the spin-out company to be a company in which the NHS employees already have a shareholding before the Trust takes its shares.

- 2.50 Participation includes having a position on the Board (perhaps as Technical Director), holding a consultancy and holding shares. Shares can be held whether or not the person remains an employee, is seconded or moves into the spin-out company. Allocation of shares if the employee remains a Trust employee would be based on the agreed Trust reward structure. Trusts should ensure that employees seeking to hold shares are fully aware of the risks as well as the potential benefits arising from their shareholding. Becoming a company employee may entitle the employee to participate in share option schemes established by the company.
- 2.51 Trust employees may have direct participation in a spin-out company if:
- the Trust has agreed the probity of the arrangements including consideration of possible conflicts of interests;
 - the Trust has a recognised process for managing the commercial exploitation of its IP with access to high quality expertise through an Adviser Organisation;
 - success of the activity will bring value to the NHS and contribute to promoting economic prosperity;
 - the Trust owns shares in the company reflecting its investment in the intellectual assets;
 - the capacity of the Trust to pursue its key objectives is not compromised.
- 2.52 If the employee responsible for generating the IP is to continue to be an employee of the Trust, explicit permission for the inventor to participate in the work of the company needs to be given, with a new contract of employment if the work conflicts with normal working hours. The advantages of allowing continuity of scientific or other specialist input should be balanced against any possible detriment to the working of the Trust. In such situations an agreement should be drawn up setting out roles, responsibilities, payments, the amount of time to be spent on company as opposed to Trust business, and ownership of IP generated whilst working for the company.
- 2.53 Trust Standing Financial Instructions should be applied, amended as necessary, to ensure probity and avoid conflict of interest. Trusts should ensure that an employee with direct participation in a spin-out company does not normally act as Trust contact with the company on day to day matters and is not involved in negotiating any form of contract with the company. In particular the employee should never be permitted to conduct, or take part in, a Trust clinical trial where one of that company's products is being examined. Other codes of practice on commercial sponsorship may also be relevant in such situations.
- 2.54 If the employee in question is an executive director of the Trust then the director and the Trust must ensure that they comply with the appropriate Membership, Procedure and Administration regulations. They may impose restrictions on involvement at Trust Board meetings on account of individual pecuniary interests, and other provisions of the standing orders relating to conflicts of interest. In particular, where a matter relating to the company is being discussed at the meeting, the director would be required to declare an interest and withdraw from any discussion or vote on that matter.

Hubs set up as Companies Limited by Guarantee

- 2.55 A company limited by guarantee is a not-for-profit company with members rather than shareholders. Shares are not issued and there is no share capital; it is not intended to grow in value. Members instead have a guarantee agreement to provide a nominal amount, e.g. £1, in the event that the company is liquidated. The company is run as a business with the rights to employ staff. Directors are appointed by the members, and are subject to a similar duty of care as a director of a company limited by shares.
- 2.56 A company limited by guarantee is an appropriate vehicle for a Hub Organisation should it be established as a company. All Trusts who wished to join would be members. In a Hub company employees from a few member Trusts (normally chosen to provide best advice) could be nominated as some members of the Board.
- 2.57 In order to assist initial operation of the Hub, lead NHS trusts (who receive Secretary of State and Government funding for the purpose of IP exploitation) and other NHS bodies in the unincorporated association are advised to establish a Hub as a company limited by guarantee only after having joined the unincorporated association as set out in paragraph 2.23 and entered into a NHS contract as set out in paragraph 2.24. The NHS contract, which should be limited in time to no more than five years, would be expected to carry over into the company. When the NHS contract expires, Trusts will need to procure services under a new contract. This new contract may be subject to the application of the Public Services Contracts Regulations 1993. According to the services to be procured a competitive tender may need to be carried out.
- 2.58 Subject to achieving the purposes given in paragraph 2.9, establishing the Hub external to any host should ensure that all partners can have equal access and that transparency is maintained in its activity and in its accounts (the accounts must be published). The exposure of any one member will be limited to a nominal sum (e.g. £1).
- 2.59 A Hub operating as an unincorporated association or as a company limited by guarantee can offer its services to Trusts which are not members subject to compliance with legal and any other obligations relating to procurement. It can also offer its services to other bodies (e.g. the Public Health Laboratory Service) which have the powers in Section 5 of the Health and Social Care Act.
- 2.60 The Hub, as a company limited by guarantee, should operate as an extension to the health service, providing the same services as if it was part of the health service. It would be a company purely for operational reasons, and it would be providing a service of general public interest. Unlike similar organisations its sole purpose would be to exploit IP in such a way as to improve the health service.
- 2.61 Benefits to members in a company limited by guarantee would be according to the Memorandum and Articles of Association. If such a company was the vehicle for a Hub organisation, a percentage of the income derived from an IP exploitation agreement would be due to the company to offset expenses as agreed and the remainder would be due to the member owning the IP. The agreement between the Hub and the NHS body would define this percentage and also set out details of the financial arrangements. If the Hub is particularly successful and it had more funds than it could use to carry out its business it could seek to gift the surplus under Gift Aid to a charitable institution subject to specialist advice on tax and other matters.

Approval Process for setting up a Hub or Spin-out Company to Exploit IP

- 2.62 Under Directions, Trusts are for the time being required to submit a business case to the Department of Health for all companies they wish to establish including those which are not for profit. The business cases will be considered and approved by the Private Finance Unit on behalf of the Secretary of State. The purpose of the approval process is to develop best practice in establishing companies in which the NHS has an interest and to ensure best value for the public.
- 2.63 The risk to a Trust taking a shareholding in a spin-out company to exploit IP is small if the procedures outlined in this Management Framework are closely followed, but it is important that a robust business case is produced to demonstrate this. A Trust Chief Executive is accountable for minimising the potential for liabilities and maximising benefit to the NHS from the exploitation of its IP. The Trust will need to show in the business case that it has satisfied the requirements.
- 2.64 The business case for a spin-out company will set out:
- why a spin-out company represents the best option for exploiting the IP for the benefit of the health service;
 - the different options considered before arriving at this conclusion;
 - the funding and management structures, the costs, benefits and the risks, and in particular how the risks are to be managed.
- 2.65 More detail on the content of the business case is set out in the Directions at Part 2 Appendix 5. The Questionnaire at Part 2 Appendix 3 provides background for an Adviser Organisation preparing the business case. The shareholding and royalty structure should be explained, together with any marketing arrangements which will benefit the NHS as a whole. Where it is intended that an employee will hold shares the arrangements will be reviewed to ensure probity.
- 2.66 It is expected in time that as experience and good practice develops Trusts will be allowed to set up a company to exploit IP without reference to the Private Finance Unit. It has already been agreed that a Trust designated as a 3-star Trust which has had one business case for such a company approved by the Private Finance Unit may participate in further spin-out activity without express approval by the Unit whilst it retains 3-star status.
- 2.67 Trusts should channel business cases through Hub organisations which in turn will transmit them to the Private Finance Unit and Hubs will provide advice as necessary on the business case. 3-star Trusts which no longer need approval by the Private Finance Unit should still transmit their business case to an appropriate Hub organisation which will make the Private Finance Unit aware of the proposed new activity. Under paragraph 5 of the Directions at Part 2 Appendix 5, Trusts are directed to submit to the Secretary of State published accounts and reports including changes to the Memorandum or Articles of Association on all companies in which they have exercised the powers under Section 5 of the Health and Social Care Act. Trusts must make arrangements, through the Hub organisation, for this information to be sent to the Private Finance Unit so that a consolidated annual report can be submitted to Parliament.
- 2.68 When external finance has been raised to establish a spin-out company it is likely that there will already be a business plan in existence. It is expected that this business plan will form the main substance of the business case needed to satisfy the requirements of the Department of Health. Detailed help with writing

good cases can be found in the Capital Investment Manual¹⁶. NHS bodies may also make local contact at www.doh.gov.uk/pfi. It is intended that business case approval will be an efficient and facilitative process, with Adviser Organisations having an important role. Advice may also be obtained from the NHS Intellectual Property Adviser¹⁷ and Partnerships UK¹⁸.

Independent Providers of NHS Services and their use of Companies

- 2.69 An Independent Provider of NHS Services which generates IP from NHS-funded R&D is required under the terms of HSC 1998/106 to share any benefit with NHS Executive (now the Department of Health). If this IP is exploited through a spin-out company it wishes to set up independently from its Primary Care Trust, agreement with the Private Finance Unit will be required in particular on the ownership of shares.
- 2.70 An Independent Provider can also generate IP with commercial potential through its delivery of patient care, and provided no further NHS resources are utilised to develop this IP, it can establish a spin-out company outside its Primary Care Trust and without reference to the Private Finance Unit.
- 2.71 For IP generated through NHS-funded R&D or where additional NHS resources are needed to develop the IP derived from the delivery of patient care so that it is ready for commercial exploitation, the Independent Provider will need to agree with the Private Finance Unit the shareholding and benefits due to the Department of Health on the basis of a business case prepared as previously described. The business case will also need to deal with matters of probity.
- 2.72 Where the Independent Provider decides to assign the IP to the Primary Care Trust and the Adviser Organisation for the Primary Care Trust recommends management through a spin-out company, the Independent Provider will normally receive all the benefits due under the Trust sharing scheme without sharing with the Department of Health.

Income from Commercial Exploitation

- 2.73 Income from successful commercial exploitation of IP, through sale or licensing of IP, through dividends or sale of shares, will normally be received by a NHS body. In achieving this income, the NHS body and the Adviser Organisation may have incurred expenditure for patent or legal work and it is normal to recover this expenditure as a first charge on the income. The net income, after deduction of these costs, would then be shared between the Adviser Organisation and the NHS body responsible for generating the IP. Normally the Adviser Organisation will receive between one quarter and one third of the net income, but this could be larger if the Adviser Organisation is a source of funding to further develop the IP.
- 2.74 The residual income (the net income less the proportion received by the Adviser Organisation) will go to the NHS body which is the owner of the IP. Apart from the statutory exception noted below, there is generally no legal requirement for a NHS body to share the income with an employee (the inventor) who created the IP in the course of employment or normal duties. However, to give an incentive to the inventor to support the exploitation process a reasonable share of the income should be offered. Each

16 *Capital Investment Manual*: Business Case Guide, 1994 London: HM Stationery Office

17 Tony.Bates@ubht.swest.nhs.uk

18 <http://www.partnershipsuk.org.uk>

NHS body should agree its policy on income sharing and make it known as discussed fully in Part 3. The inventor can decide whether to take the income as a personal benefit. The Introductory Handbook⁵ sets out suggested sharing arrangements with an inventor. It is common practice to give the inventor a share of about one third of the residual income. Where the inventor is a shareholder in the relevant spin-out company this share should be agreed individually when the company is established.

- 2.75 When the Adviser Organisation is a regional Hub, the residual income will be remitted only to the NHS body which is the source of the IP. It is good practice that no individual employed by a Hub acting as Adviser Organisation is rewarded personally from income received from a successful negotiation on behalf of the NHS body. Performance targets could however be part of an employment contract.
- 2.76 The statutory exception referred to above relates to the provisions of the Patents Act 1977. An employee whose invention belongs to the employer and in respect of which a patent has been granted may apply to the Court of the Controller for compensation if the patent proves to be of 'outstanding benefit' to the employer. It is unusual for any patent (rather than invention) to be of such outstanding benefit as to trigger this right to financial reward but consistent with national policy, a reward is given by the NHS whenever benefit is received.
- 2.77 Income from the successful exploitation of IP is often derived from R&D undertaken collaboratively with universities. NHS bodies for whom this is likely to arise should take care in setting their reward structures to ensure, as far as possible, that their employees have sharing arrangements similar to those of employees in their collaborating university.
- 2.78 When IP arises from collaborative work with universities it is normal for employees of both organisations to have contributed to the generation of the IP. This is discussed more fully in Part 3 and 4 of this document, but it could be decided that the university rather than the NHS Adviser Organisation is best placed to handle the IP. If so the university would be entitled to recover a proportion of the net income and the residual income would be shared between the university and the NHS body as previously agreed. If the Adviser Organisation handles the IP then the residual income would be shared with the university, again as previously agreed.
- 2.79 Royalty rates and the proportion of shares held in any spin-out company will vary from case to case, negotiated between the Adviser Organisation representing the NHS body and the outside organisations responsible for exploiting the IP. Some illustrative examples of the elements of such agreements, through license of an existing company or through spin-out activity, are given at Part 2 Appendix 6.
- 2.80 An especially successful exploitation may result in a Trust receiving considerable residual income (revenue or capital). The Secretary of State has powers to take excessive balances for use elsewhere in the NHS.

Accounting for Income, Expenditure and Losses

- 2.81 Subject to the provisions of paragraph 2.8, Trusts are able to retain the residual income less the amount distributed to their employees. It is normal practice to reward in some way the unit that generated the IP, with the remaining surplus used generally to improve the health service. This can include further investment in IP. IP-related income, expenditure and surplus or deficit should be disclosed separately in annual accounts if they are material. Memorandum trading accounts for IP activity should be maintained, as these will be required to support the retention of surplus funds.

⁵ *The Management of Intellectual Property and Related Matters: An Introduction Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services*; <http://www.doh.gov.uk/pub/docs/doh/intehand.pdf>

- 2.82 The NHS Manual for Accounts is being redrafted to include guidance on accounting treatment of IP. It is expected that investments in spin-out companies will be accounted for as fixed asset investments, subject to Treasury approval.
- 2.83 In the event that an item of IP (e.g. a patent or a shareholding) turns out to be worthless, or have a value lower than the balance sheet carrying value, then the asset and the costs of its management will be deemed to be 'impaired' and the fall in value should be taken to the income and expenditure account of the NHS body for that year.
- 2.84 It is by no means certain that every filed patent will bring a return to the NHS and impaired value in the majority of cases should be expected. The main concern will be the failure of a NHS body to identify opportunities which could bring benefit to the NHS, or to manage these opportunities appropriately and to learn from them.

Audit of Companies

- 2.85 It will be a requirement for any company set up to exploit NHS IP to make available its annual audited accounts to the NHS body. Auditors of NHS bodies, the National Audit Office and Audit Commission, will have right of access to the accounts and records of these companies for the purpose of their audits.

Part 2: Appendix 1

Check List of Contents for a Licence Agreement

Set out below in brief form are the types of issues and options that need to be considered when negotiating a licence agreement between a NHS body and a commercial organisation. It is not an exhaustive list.

Issue	Option
Parties	Specify parties involved.
Subject matter of licence	Accurate definition of technology to be licensed, may refer to a Schedule. Include all registered numbers. For unregistered IP refer to specific documents identifying the IP (e.g. laboratory notebooks).
Field of use	Definition of technical application, technical aspects, product markets etc. giving use of the technology to be permitted under the licence. Note that defining by customer types needs careful review.
Geographical scope	Territory to be covered by the licence: territory needs to be considered in relation to each type of right. Territory can be a country, several countries or part of a country
Type of licence	Exclusive, non-exclusive or exclusive in relation to some areas, fields or applications.
Qualifications to type/exploitation of licence	Performance requirements: consider annual minimum royalty payments on sales, especially if any form of exclusivity is given. Consequence of failure to meet targets e.g. loss of exclusivity, termination
Term	Period of licence, break periods, renewal provisions, conditions which could lead to termination. Maximum length should not usually be beyond term for which IP remains valid (but see Royalty Rate).
Rights granted under licence	Specify how the licensee is allowed to use the IP. Could include, for example, R&D on prototypes and products based on the technology, manufacture, use and sale. Subcontracting conditions, if allowable.
Sub-licence rights	Sublicensing conditions including safeguards (e.g. prior approval requirement). Safeguards would usually repeat limitations on licence e.g. manufacture outside territory.
Assignment and change of control	Circumstances in which either party will have the right to assign the licence. Effect of change of control or ownership of the licensee.
Research and development responsibilities	Continuing R&D responsibilities of the licensee, including the cost and conditions.
Research rights	Licence to ensure that NHS body retains right to use IP for internal research and training purposes.
Exploitation responsibilities	Best efforts or reasonable efforts, specific targets, minimum royalties. Promotional efforts and expenditure, checking and reviewing exploitation performance, effect of substandard performance.
Transfer of technology	Means by which the licensee receives the technology, disclosure, samples, technical assistance, training.

Issue	Option
Technical assistance	Specification of assistance, limitations on assistance, type of assistance, period of assistance, payment for assistance.
Mutual assistance	Responsibilities of both parties stated.
Training	By whom, to whom, qualifications, language, skills, where will it be provided, how long for, responsibility for arrangements, responsibility for payment of delegates, insurance for trainers.
Benefits to NHS patients	Licence to include, where possible, preferential terms of sale for NHS bodies not associated with the IP.
Patients in developing countries	Licence terms to take account where possible of needs of patients in developing countries by including terms which are likely to give access to products at reasonable rates.
Partner organisations with an interest in the technology	Ownership and management issues (e.g. with universities) in a contract between the partner organisations to form part of the licence agreement.
Costs for IPR protection	Continuing patent costs (normally fall on licensee). Impact on licence if not maintained. Responsibility for registering licence, where applicable.
Patent infringement	Licensee responsible for any costs. Specify who may take/defend any such action. If IP is licensed to more than one licensee, licensor may need to retain control to ensure consistency of approach across portfolio.
Warranties	The licensor could warrant that it had not previously licensed or assigned the IP in question. No warranty by the licensor on the validity of the IP or the quality of the invention.
Liability	Costs for product or trademark liability to lie with the licensee. Licensor to be indemnified.
Payments	Lump sum fees, repayment of patent costs, royalties on sales. Schedule of payments. Payments to a VAT registered licensor are subject to VAT. There may be withholding taxes especially on royalties received from overseas. The licensee to assist in any recovery.
Royalty rate	Royalty rate on sales, not on profits. Frequency of calculation or payment e.g. quarterly. Anti-avoidance provisions to stop supplies at less than market value. Royalty rates can vary for different levels of aggregate sales. Royalty provision beyond life of some or all licensed IP.
Records and record keeping	Reporting requirements and auditing. Interest on late payments.
Currency treatment	Usually payment in sterling. Provisions for currency conversion if sales on which royalties are based are in a different currency.
Improvements	Improvements by licensor made available to licensee on same terms agreed for licensed IP in licence. Licensee to grant licensor a royalty-free, irrevocable, world-wide licence of its improvements (with a right to sub-license). Responsibilities of both parties should be stated.
Confidentiality	Responsibility of both parties. Confidentiality of transferred information, materials and samples. Return of information and samples.
Publication	Responsibility of both parties on publication of information relating to the technology. Clearance to publish.
Marking	Requirement to state that product is patented e.g. 'manufactured under patent licence from'.
Specification	Any specification which products must meet.
Trademarks/Licensor's name	Application of licensor's trademark or name, requirements. Approval, quality control.

Issue	Option
Publicity	Specific obligations and/or requirements; provisions for joint publicity or sharing in publicity; approval of public relations content.
Termination	When and in relation to what events would this occur e.g. breach, insolvency, change of control, challenging validity of licensor's IP.
Effect of termination	Effects such as royalty accounting, disposing of stock etc.
Law/Jurisdiction clause	English law to apply to the contract. The contract should be subject to either (i) non-exclusive of English courts or (ii) exclusive jurisdiction of English courts, except where injunctive relief is needed elsewhere. Where validity of registerable IP is at issue, the contract should be subject to the jurisdiction under which that IP is registered.

Part 2: Appendix 2

Possible Licence Terms to Protect Patients in Developing Countries.

These terms are taken, with permission, from documentation produced on Management of IP for Health R&D by the Rockefeller Foundation, November 2001.

Topic	Basic concept	Public sector consideration
Areas of use	Provision is usually made in a licence to specify the limitations on the application of the patent in developing products. The simplest approach is to grant the licensee an exclusive right to all possible applications of the patent including not only those specified in the patent but others that may emerge as further R&D proceeds.	The licence could grant an exclusive licence only for those products that the licensee actually wishes to pursue. Also, it could grant exclusive rights only for those products that were unlikely to have a significant market among the poor in developing countries.
Territory	A licence would specify the geographic areas in which the licensee has the right to exercise the patent. The simplest approach is to grant the licensee an exclusive right to all possible territories. Usually a licence is valid only in the countries where a patent has been filed, but the licence can give the licensee the right, at the licensee's expense, to file for patent protection in additional countries.	The licence could grant an exclusive right to a major portion of developed countries, e.g., North America. The licensor could grant another exclusive limited licence to Europe. Finally, the licensor could grant non-exclusive licences to both licensees for an agreed list of developing countries. Then the two primary licensees would have to compete for sales to developing countries.
Price	In most licensing agreements, there will be no conditions with respect to price. The licensor assumes the licensee will determine the best price to ensure the greatest return on investment.	<p>The licensor can consider several options for setting a condition on the price to the public sector in developing countries.</p> <ul style="list-style-type: none"> • The price could be specified, e.g., \$0.30 per tablet. This is feasible only when the licensor has detailed technical knowledge of the production, marketing and distribution costs. • The price could be set at cost of production plus a reasonable mark-up, e.g., 15 percent of cost of production. This is feasible when the licensor has a reasonable expectation of being able to monitor the cost of production. • The price could be set at 'no higher than the lowest price offered to any buyer.' This may be preferred in cases where it is expected there will be large bulk purchases by private sector buyers who are good at negotiating the very best price. <p>Price is probably the most difficult area for a licensor to get involved in. Some believe that licensors should stay away from this issue because of its complexity.</p>

Topic	Basic concept	Public sector consideration
Labelling	In most licensing agreements, there will be no conditions about labelling. The licensor assumes the licensee will prepare labelling in conformity with national drug regulatory agency requirements.	The licensor can help ensure that the product is licensed properly especially in developing countries where national regulatory agency requirements for labelling may not be rigorous or enforced. For example, if some of the research that led to the patent was supported by WHO, the licence can specify that the name of WHO cannot be used without prior written approval of WHO. Additionally, the licence could state that any claims for the use, safety and effectiveness of the product should receive prior written approval.
White Knight condition	This concept has been developed by the U.S. National Institute of Health. It calls for the licensee to undertake some specific actions that will benefit the public sector.	The licensor can ask for a number of actions including donation of product for clinical evaluation in public sector research programs, joint efforts to develop markets in developing countries, free supply under specified conditions to developing countries, etc.
Royalties	Usually a licensee will negotiate the largest royalty in order to maximise revenue from the licence.	The licensor can specify that royalties apply to sales only in developed countries. Sales to the public sector in developing countries would be free of royalties. The impact for the licensor would normally be minimal. For example, 5 percent of a sale in a developed country of a million doses of vaccine at \$10 per dose would be \$500,000. Five percent of the same quantity at \$0.10 per dose for a developing country sale would be \$5000.

Part 2: Appendix 3

Spin-out Company Questionnaire

This questionnaire can be used and discussed with legal advisers by those intending to set up a spin-out company in which a NHS body has a shareholding

Which Company

1. Is an existing company to be used for the spin-out? If so, what are its name, company registration number, registered office, names of directors and secretary and its Memorandum and Articles of Association?
2. If there is no existing company is it intended to create or acquire one off the shelf? If yes, the following will be needed
 - desired company Name (if not covered above)
 - directors' full names, residential addresses, dates of birth, occupations and details of any current directorships or directorships held by them during the last 5 years
 - Secretary's full name and residential address.
 - proposed objects of company
 - required number of shares available for allotment (it is common to start with 1000 shares of £1 each).
3. From which premises will the Company carry out its business?

Company Name Consideration

1. What are the possible names for the company?
2. Have searches been carried out at Companies Registry to check the availability of the names? If not, who will do these searches?
3. Have Trade Mark Registry searches been undertaken to check the registerability of the names as trade marks? If so, which country's registries have been checked? If not, who will do them?
4. In which countries is the company expected to trade? Have trade mark registerability searches been carried out in each of these countries?
5. Have searches been made to check the availability of the proposed company names as domain names, such as, '.co.uk' or '.com' If not, who will do them?

Funding and Shareholding

1. What are the full names and addresses of the proposed subscribers to Memorandum and Articles of Association and of the proposed shareholders?
2. What will be the proposed split of shares between the shareholders?
3. Will all the shares be issued at once or in instalments and, if in instalments, what will trigger the further allotments?
4. Will the shares be subscribed for in cash or in kind (e.g. for IP)?
5. If in cash will it be for their par value (e.g. £1 for £1 shares) or at a premium (e.g. £1.50 for £1 share)? If a premium, how much will the premium be?
6. If in kind for IP, what will the IP be and how will the non-cash contribution be valued?
7. Will there be different classes of shares e.g. ordinary or preference, and, if so, what will their preferred dividend be?
8. Will any shares be redeemable, and if so when will they be redeemed and what rights will they have?
9. Will new shares be offered in proportion to existing shares?
10. Will any funding be by way of loan? If so, who is to be the lender? How is the loan to be secured? Is the loan to be subordinated to other creditors?
11. Will the loans carry interest?
12. When are they to be repaid?
13. What is the intention about further funding of the company (e.g. venture capital) and on what basis?
14. If further funding is required will there be any obligations on shareholders to provide it? Will this be tied to any target achievements?
15. Will anyone be supplying guarantees to support bank borrowings?
16. What costs have already been incurred by the NHS body or the Adviser Organisation and what further costs will be incurred on behalf of the spin-out company? Will these costs be paid by the company in due course. e.g. market research fees, Chairman's fees? Have these been approved by the other shareholders/participants?
17. Who will bear the cost of preparing the Shareholders Agreement and other documentation and undertaking searches and other due diligence work? Is there any supporting documentation?
18. Is there any particular tax relief from which shareholders may wish to benefit and which would affect the structure of the transaction?
19. Are the rights and obligations granted under the Shareholders Agreement to be assignable?

Transfer of Shares

1. Will shareholders have to offer shares to other existing shareholders before they can be offered to third parties?
2. Will there be 'tag along' rights (a transfer of shares requires that the proposed purchaser offers to buy other shareholders' interests for the same price per share)? 'Tag along' rights protect minority shareholders from the majority selling out the bulk of the shares without the minority having an equivalent benefit.
3. Will there be 'drag along' rights (if a certain percentage of the shareholders want to sell then the others must also sell at the same price)? If so, what is the correct percentage, will any 'drag along' rights only apply to a particular shareholder? ('Drag along' rights conversely prevent a minority shareholder from stopping a sale of the company by holding out with its small shareholding.
4. Can a shareholder transfer to a family member or family trust or associate e.g. partner?
5. If employee or director shareholders cease to be employees or directors will they have to sell their shares? Will the price vary depending on why the person leaves e.g. sacking, resignation? Will the same apply to researchers working under consultancy contracts with the company?
6. Will there be a minimum period after formation of the company or entering into the Shareholders Agreement before shares can be offered to third parties?
7. How will shares be valued for the purpose of any pre-emption rights e.g. by a formula, referral to an accountant, or discount for minority interest?
8. What rights will shareholders have to information from the company? (Note that audited accounts must be made available to a NHS body and the Department of Health and accounts and records must be made available on request to auditors of the NHS body.)

Directors

1. Will certain shareholders have the right to appoint or remove directors. Will the chairman have the casting vote?
2. What, if any, will be the maximum or minimum number of directors?
3. How much notice must be given for a board meeting? How frequently will they be held? What will be the quorum? Will directors appointed by certain shareholders have to be present to form a quorum or vote in favour of a resolution for it to be passed?
4. Will a Trust have a right to appoint an Observer and if so, will the Observer have rights to attend every board meeting?

Management

1. Will any senior management be given service contracts with the company? If so, what are their proposed salary, holiday entitlement, pension entitlement, sick leave arrangements, job description, place of work, hours of work?

2. Will there be other employees for whom basic conditions of employment will be required?
3. Will anyone be given a consultancy contract? If so what are the proposed fee, hours of work, services to be supplied, termination provisions?
4. How do any NHS employees intend to split their time between the NHS and the company? Is this compatible with their terms of employment and has it been discussed with their Chief Executive?
5. Will there be any share option schemes?
6. How will annual budgets/forecasts be prepared?
7. Who is advising the various parties to the arrangements, including the company?
8. Will the company be entering into any contracts with third parties to carry out research? If so, what are the terms, including ownership of IP, rights to use background IP?
9. Will anyone be contracted to supply management services to the company e.g. company secretarial services, accounting services?
10. Is any key man insurance required? If so, who are the individuals, their dates of birth and are they smokers or non-smokers?
11. Will any of the following require the unanimous consent or the consent of the majority of shareholders or any one person holding more than 50% of the shares in the company? If so, tick the item and if a greater majority is needed specify the percentage. (Those already ticked require the Trust's consent.)
 - reorganising the company's share capital ✓
 - creating share options ✓
 - issuing more shares ✓
 - changing the company's name –
 - creating subsidiaries –
 - incurring expenditure or liabilities outside the ordinary course of business ✓
 - borrowing money in excess of £ [] (specify limit) –
 - giving a guarantee, indemnity or other security –
 - charging or encumbering any assets of the company –
 - declaring dividends –
 - changing the objects of the company ✓
 - changing the Articles of Association of the company ✓
 - entering into contracts or arrangements for amounts exceeding £[] (specify limit) –

- acquiring or disposing of IP (including licensing) ✓
- acquiring or disposing of freehold or leasehold property –
- disposing of the whole or a substantial part of the business of the company ✓
- employing or dismissing any employee or consultant with remuneration of more than £[] per annum (specify limit) –
- changing the terms of employment or engagement of any employees or consultants ✓
- appointing or removing auditors ✓
- winding up the company –
- dealings with shareholders except on an arm's length basis in the ordinary course of the company's business ✓
- others (specify) –

Shareholder Restrictions

1. Will shareholders be restricted from competing with the company?
2. Will shareholders be restricted from soliciting the company's employees?
3. Will there be confidentiality obligations?

Intellectual Property

1. What patents or patent applications are to be assigned or licensed to the company? You should have a list and copies available including the country of registration, number, date of registration, inventors, owners and brief description of invention. If the owner is not the inventor, how has the invention/patent/ patent application become vested in the owner?
2. What know-how is to be assigned or licensed to the company including how it is identifiable and recorded e.g. reduced to writing? How will it be delivered to the company, and where is it located? Has any third party had access to any of the know-how and if so on what basis? Are there any relevant confidentiality agreements? If so they should be available.
3. What unregistered design right or copyright material is to be assigned or licensed to the company including drawing numbers where relevant? Are original drafts available and who is the owner? If the owner is not the original creator how have the rights become vested in the owner?
4. What registered designs are to be assigned or licensed to the company including country of registration, number, details of owner and description of design? Are copies available? If the owner is not the creator, how has the registered design become vested in the owner?
5. What trade marks are to be assigned or licensed to the company including country of registration, number, class, mark registered, date of registration and next renewal date?

6. What grant or third party funding have been used to fund the R&D out of which any IP has arisen? Are copies available of any terms and conditions of the grants or funding?
7. Are copies available of collaboration agreements relating to any R&D out of which the IP has arisen and confidentiality agreements covering any of the know-how?
8. What papers have been published relating to any of the R&D which gave rise to the IP in question?
9. What searches have been undertaken to see what other R&D has been carried out or IP registered in relation to the same type of technology and what were the results?
10. What agreements have been entered into assigning, licensing, charging or granting any other rights in respect of any IP referred to at points 1–5 above?
11. Is the IP to be assigned or licensed to the company? If it is to be assigned rather than licensed, why is this?
12. If registered or registerable rights are to be licensed who is to be responsible for dealing with registrations, paying renewal fees etc? If it is not the licensee, why is this?
13. What are the arrangements for ongoing royalty payments to the NHS body as the current or previous owner of the IP?
14. Are there any circumstances in which the IP is to be returned to the NHS body? In such circumstances how will IP which has been created subsequently by or for the company be dealt with?
15. Apart from any parties named previously as inventors or creators of the IP, who else has been involved with the work which gave rise to the IP? What was their status? Is it clear that they have not created any IP?
16. Does the NHS body or any other current owners require licences back of rights to enable them to carry out other projects? Will there be any restrictions on the nature of those projects?

Termination/Deadlock

1. What provisions should there be to terminate the arrangements under the Shareholders Agreement e.g. insolvency of a shareholder or the company, breach of the Shareholders Agreement?
2. What would happen in the event of a voting deadlock between the shareholders? If there is deadlock is it to be referred to an independent third party, casting vote, arbitration, buy/sell option, sealed bids for shares from the company by the shareholders highest wins?
3. Under what circumstances might the Company be liquidated? If this happens, how should the assets be distributed and how will any IP be dealt with and how will employees be dealt with? (Note that a Trust should have a right of first refusal or option to acquire IP which it assigned to the Company.)

Part 2: Appendix 4

Effect of Different Levels of Shareholding in a Company

Voting Power for the purposes of English company law

For the purposes of English company law, the two significant percentages in terms of shareholding in a company are 50% and 75%.

The holder of greater than 50% of the voting share capital of the company has effective control of that company. It may pass ordinary resolutions at shareholders' meetings which will enable it, for example, to increase the authorised share capital of the company and to remove and appoint directors of the company (i.e. the holder controls the board of directors). Most decisions of shareholders can be decided by ordinary resolution.

The holder of 75% or more of the voting shares of the company has even greater control over it, being able to pass special resolutions. A special resolution can only be passed if 75% or more of the votes at a general meeting are cast in favour of it, and it is needed, amongst other things, to change the Articles of the company. Conversely, a shareholder who holds greater than 25% of the voting shares of the Company can block the passing of a special resolution.

Other Significant Shareholding Percentages under Company Law

Short Notice Consent The holder of 95% or more of the voting shares is entitled to agree shorter periods of notice for general meetings. As there are statutory notice periods of 14 days for ordinary resolutions and 21 days for special resolutions, this power could be used to significantly speed up the decision making processes of the Company.

Call EGM The holder of 10% or more of the voting shares of the Company may oblige the Board of Directors to call an extraordinary general meeting.

Requisition Members' Resolution The holder of more than 5% of the total voting shares of the Company may requisition the Company to circulate a members resolution to be considered at a shareholders meeting.

Forced Sale/Purchase If an offer has been made to purchase the entire issued shares of a company and the purchaser acquires 90% or more of the shares which are the subject of such offer, the purchaser may give notice to those shareholders who have not yet accepted the offer that they are required to sell their shares pursuant to such offer. In such circumstances, therefore, a shareholder who holds 10% or less of the shares may be forced to sell his shares. Similarly, where a purchaser has acquired 90% or more of the shares in a company, the remaining minority shareholders are entitled to request that the purchaser acquire his minority shareholding.

Shareholder Protections

It is possible to include provisions in a Shareholders Agreement and the Articles of the company which protect the position of a minority shareholder and enable it to exercise a greater degree of control over the management of the company than its proportion of the voting shares would otherwise allow under English company law. Such protections may provide, for example, that the consent of all the shareholders is needed before the constitution of the company is changed. There are many other provisions which may also be considered as appropriate in the circumstances although a balance needs to be reached between protection of the minority shareholder and extensive protection which would restrict the company in the conduct of its business.

State Aid

Some government grants and soft loans e.g. SMART Awards, are not available to companies where 25% or more of their shareholding is owned by public bodies such as the NHS. This relates to the current EC definition of a Small and Medium Enterprise (SME) and the State Aid rules under which the programmes operate. Awards not complying with these requirements will need to be reviewed in the light of State Aid rules.

Part 2: Appendix 5

DIRECTIONS RELATING TO THE EXERCISE OF POWERS UNDER SECTION 7(2) AND (7A) OF THE HEALTH AND MEDICINES ACT 1988

In exercise of the powers conferred on the Secretary of State ^(a) by sections 17 and 18A(6) of the National Health Service Act 1977 ^(b) and section 5(9) of the National Health Service and Community Care Act 1990 ^(c), and of all other powers enabling him in that behalf, the Secretary of State makes the following Directions:-

Commencement, Application and Interpretation

1. – (1) These Directions shall come into force on 9th September 2002.

(2) These Directions apply to the exercise of the powers in section 7(2) and (7A) of the 1988 Act ^(d) by –

(a) a National Health Service trust all or most of whose hospitals, establishments and facilities are situated in England; or

(b) a Primary Care Trust established for an area of England.

(3) In these Directions –

“the 1977 Act” means the National Health Service Act 1977;

“the 1988 Act” means the Health and Medicines Act 1988;

“the 1990 Act” means the National Health Service and Community Care Act 1990;

“business case” means a document which relates to a proposal by a relevant body for the exercise by it of any of the powers in subsection (7A) of section 7 of the 1988 Act in relation to the company, in connection with the exercise by it of any of the powers in subsection (2) of that section, and which sets out –

^a Concerning NHS trusts, functions that are exercisable in relation to a cross-border body which by their nature cannot specifically be exercised in relation to Wales are exercisable concurrently by the Secretary of State – see article 2(c) of the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672. Concerning Primary Care Trusts, the function of establishing such Trusts is conferred on the Secretary of State by section 16A of the 1977 Act. By virtue of article 2(a) of that Order, that function, so far as it is exercisable in relation to Wales, is transferred to the National Assembly for Wales.

^b 1977 c.49. Section 17 was substituted by section 12(1) of the Health Act 1999 (c.8); section 17 was amended by Schedule 5, Part 1, paragraphs 5(1) and (3), to the Health and Social Care Act 2001 (c.15); section 18A was inserted by section 5 of the Health Act 1999.

^c 1990 c. 19; section 5(9) was substituted by section 14 of the Health Act 1999 (c. 8).

^d Subsections (7A) and (7B) were inserted by section 5 of the Health and Social Care Act 2001 (c. 15); the powers referred to in subsection (7A) are expressed by that subsection to be powers included within the power in section 7(2)(g) of the 1988 Act.

- (a) how, in the view of the relevant body, the exercise of the powers in subsection (7A) will facilitate or be conducive or incidental to the exercise of the powers conferred by subsection (2), and the rationale for exercising the powers in subsection (7A), as opposed to taking other measures, in connection with the exercise of the powers conferred by subsection (2);
- (b) the projected income and expenditure for the company, in so far as is practicable and appropriate in the form described in sections 226 to 232 of the Companies Act 1985 ^(a) and any statutory modification or re-enactment thereof for the time being in force, over a period of at least 3 years, or the period during which the body proposes exercising the powers in subsection (7A), if less;
- (c) the projected income which it is anticipated will be made available for the improvement of the health service, through the activities of the company connected with the exercise of those subsection (7A) powers, over the period referred to in paragraph (b) above;
- (d) the commercial assumptions and operational plans in relation to the company's business which form the basis for the projections referred to in paragraphs (b) and (c) above; and
- (e) how the body proposes to manage any financial risks to it or to any other health service body which may arise from its exercise of the powers in subsection (7A) or from the activities of the company connected with the exercise of those subsection (7A) powers;

“the company” means the company in relation to which a relevant body proposes to exercise any of the powers in section 7(7A) of the 1988 Act;

“document” includes information transmitted using electronic communications;

“dormant company” means a company which has never traded;

“electronic communications” has the same meaning as in section 15 of the Electronic Communications Act 2000 ^(b);

“the proposal” means the document referred to in paragraph (a) of the Schedule to these Directions;

“relevant body” means a body specified in sub-paragraph 1(2).

- (4) In these Directions, save where the contrary intention appears, any reference to a numbered paragraph is a reference to the paragraph which forms part of these Directions and which bears that number, and any reference, in a paragraph which forms part of these Directions, to a numbered sub-paragraph is a reference to the sub-paragraph of that paragraph which bears that number.

Proposal for the exercise of the powers in section 7(2) and (7A)

- 2.** – (1) The Secretary of State directs that, save as otherwise allowed by him, a relevant body shall not exercise any of the powers in subsection (7A) of section 7 of the 1988 Act in connection with the exercise of any of the powers in subsection (2) of that section, unless it has submitted to the Secretary of State a proposal, and the other information and documents specified in the Schedule to these Directions and the Secretary of State has notified the body that he considers that the proposal–

^a 1985 c.6. These sections were inserted by sections 4 to 6 of the Companies Act 1989 (c.40). Section 228 was amended by S.I. 1992/3178, 1993/3246 and 1996/189 and by the Welsh Language Act 1993, section 30.

^b 2000 c. 15.

- (a) satisfies the tests specified in section 7(8) of the 1988 Act;
 - (b) where the body is a Primary Care Trust, satisfies the criteria specified in section 18A(6)(a) of the 1977 Act;
 - (c) where the body is a National Health Service trust, satisfies the criteria specified in section 5(9) of the 1990 Act; and
 - (d) represents an appropriate exercise of the powers in subsection (7A) by the body, having regard in particular to the matters specified in sub-paragraph (2) below.
- (2) The matters referred to are –
- (a) the financial risks for the health service and the financial benefits for the health service (in terms of greater income for improving the health service) which appear to him to be associated with the proposal;
 - (b) where the proposal concerns the exercise of the powers in subsection (7A) in connection with the powers in subsection (2)(f) (ideas and intellectual property), the conditions on which the ideas or intellectual property may be made available to bodies established in countries outside England and Wales being bodies that are concerned with the delivery of health care in those countries, following the exercise of the powers in subsection (7A); and
 - (c) where the proposal concerns the exercise of the powers in subsection (7A) in connection with the powers in subsection (2)(f) (ideas and intellectual property), the conditions on which the ideas or intellectual property may be made available for the purposes of the health service, following the exercise of the powers in subsection (7A).

Conditions applying to the exercise of the powers in section 7(2) and (7A)

3. The Secretary of State directs that a relevant body which exercises any of the powers in subsection (7A) of section 7 shall, subject to any enactment, rule of law or any person's contractual or proprietary rights–
- (a) save where otherwise allowed by the Secretary of State, and subject to sub-paragraph (b), exercise the powers in subsection (7A), and any powers in subsection (2) in connection with which the powers in subsection (7A) are exercised, in accordance with the proposal which has been the subject of a notification by the Secretary of State as referred to in paragraph 2(1) including the documents referred to in paragraph (a)(vii) and (viii) of the Schedule to this Order, but otherwise excluding any documents attached to the proposal;
 - (b) exercise the powers in subsection (7A) in accordance with any restrictions laid down by the Secretary of State at any time (being restrictions which do not have retrospective effect) relating to –
 - (i) the amount of money or other property which the body may provide in connection with investment in the company, including any restrictions as to the amount which may be provided within a particular period or periods of time; and
 - (ii) the amount which may be provided to or in respect of the company by way of loans, guarantees or other financial provision, including any restrictions as to the amount which may be provided within a particular period or periods of time; and

- (c) in exercising the powers in subsection (7A), and any powers in subsection (2) in connection with which the powers in subsection (7A) are exercised, have regard to any relevant guidance issued by the Secretary of State.

Information concerning the exercise of the powers in section 7(2) and (7A)

- 4. The Secretary of State directs that, where the Secretary of State has notified a relevant body as referred to in paragraph 2(1), the relevant body shall supply the Secretary of State with such information in its possession, or to which it is entitled, concerning –
 - (a) the exercise by it of any of the powers in section 7(7A) of the 1988 Act, and of any of the powers in section 7(2) of the 1988 Act in connection with which the powers in section 7(7A) are exercised; and
 - (b) the activities of the company connected with the exercise of those powers,as the Secretary of State may request at any time.

Annual report

- 5. The Secretary of State directs that, where the Secretary of State has notified a relevant body as referred to in paragraph 2(1), the relevant body shall, no later than 30th September in each year, serve on the Secretary of State a report giving –
 - (a) a summary by reference to the financial year ending on the preceding 31st March of how it has exercised the powers in section 7(7A) of the 1988 Act in relation to the company, and of how it has exercised any of the powers in section 7(2) of the 1988 Act in connection with which the powers in section 7(7A) were exercised;
 - (b) on the basis of the information in its possession, or to which it is entitled, a summary of the activities of the company connected with the exercise of those powers; and
 - (c) particulars of any changes to the Memorandum or Articles of Association of the company, and of any statutory returns made to the Registrar of Companies, during that year.

On behalf of the Secretary of State for Health



C Marc Taylor
Head of NHS R&D Policy
Department of Health
Quarry House
Quarry Hill
Leeds LS2 7UE

5th September 2002.

SCHEDULE

Paragraph 2

Information and documents to be submitted

The information and documents referred to are –

- (a) a document (“the proposal”) setting out which of the powers in subsection (2) of section 7 of the 1988 Act the relevant body proposes to exercise, describing the subject matter of that proposed exercise of powers, and –
 - (i) setting out the power or powers in subsection (7A) of that section 7 which it proposes to exercise in connection with the exercise of the power or powers in subsection (2);
 - (ii) where it proposes to exercise the powers in subsection (7A) by forming or participating in the formation of a company, setting out the type of company in question and its proposed name, and attaching a draft of the documents to be submitted for registration of the company including a draft of the Memorandum and Articles of Association;
 - (iii) where it proposes to exercise the powers in subsection (7A) in respect of a dormant company, and where the exercise of the powers involves the transfer or allotment of the shares in the company–
 - (a) setting out the type of company in question, its name and, where applicable, its proposed new name;
 - (b) setting out the names of the shareholders in the company before and after the proposed transfer of or allotment of shares in the company; and
 - (c) attaching a copy of its Memorandum and Articles of Association and of any document required to be submitted under the Companies Act 1985, including sets of its annual accounts, for the three financial years preceding the submission (or, if less, for the financial years since the creation of the company);
 - (iv) where it proposes to exercise the powers in subsection (7A) in respect of a dormant company, and where the exercise of the powers involves a change in the membership of the company –
 - (a) setting out the type of company in question, its name and, where applicable, its proposed new name;
 - (b) setting out the names of the members of the company before and after the proposed change in the membership of the company; and
 - (c) attaching a copy of its Memorandum and Articles of Association and of any document required to be submitted under the Companies Act 1985, including sets of its annual accounts, for the three financial years preceding the submission (or, if less, for the financial years since the creation of the company);

- (v) where it proposes to exercise the powers in subsection (7A) in respect of an existing company (otherwise than in the circumstances referred to in paragraph (iii) or (iv) above), setting out the identity of the company and attaching a copy of its Memorandum and Articles of Association and of any document required to be submitted under the Companies Act 1985, including sets of its annual accounts, for the three financial years preceding the submission (or, if less, for the financial years since the creation of the company);
 - (vi) setting out any proposed arrangements for the appointment of officers or members of the body as directors of the company and with respect to any other form of involvement of the body in the management of the company;
 - (vii) attaching a copy of any actual or proposed agreement between the shareholders or members in the company (including any proposed shareholders or members) or between the shareholders or members and any other person or persons, in connection with the proposed exercise of the powers in subsection (7A), the management of the company or the activities of the company connected with the exercise of the powers in subsection (7A);
 - (viii) attaching a copy of any actual or proposed agreement between the body and the company (whether or not together with any other person or persons) in connection with the proposed exercise of the powers in subsection (7A), the management of the company or the activities of the company connected with the exercise of the powers in subsection (7A), including any agreement with respect to the fees or other benefits to which the body is to be entitled, or which it may potentially receive, in that connection;
 - (ix) setting out details of the type (and, where appropriate, the amount) of any investment or of any loan, guarantee or other financial provision which the body proposes that it will make to or in respect of the company, including the number of shares in the company which it is proposed will be acquired by the body;
 - (x) setting out how the relevant body proposes to reward individuals it employs, or contracts with, in connection with any fees or other benefits accruing to it from the exercise of those powers;
 - (xi) setting out the grounds on which the body considers that the criteria referred to in paragraph 2(1)(a) to (c) will be satisfied; and
 - (xii) setting out the conditions that will apply as referred to in paragraph 2(2)(b) and (c);
- (b) a business case in respect of the proposal; and
 - (c) any other information or documents the Secretary of State may require concerning the proposal.

Part 2: Appendix 6

Examples of the Exploitation of Intellectual Property

Exploitation agreements are not simple to summarise, and the examples given are illustrative and only loosely connected to real cases. In the interest of brevity, not all terms of the agreement are included. For example, each NHS body will have an agreement with its Adviser Organisation on how the Adviser Organisation is to be rewarded and will establish its own procedures on how its residual income is to be distributed. Details of agreements are not always given below.

1. A clinical need was identified to determine whether capillary blood flow was still present in skin which had been damaged by a severe burn. In addition to potential benefit to patients there was a possibility that the NHS could save the cost of unnecessary skin graft operations. The medical physics department in a NHS Trust came up with an answer and built a prototype piece of equipment. A patent application was filed by the Adviser Organisation on behalf of the Trust. The Adviser was a large UK technology transfer organisation which was acting under contract for several neighbouring Trusts and universities. The Adviser Organisation filed European and US patent applications and located a company with the necessary background and market penetration. The company brokered a patent licence agreement for the manufacture and sale of the equipment within Europe. An option agreement was also signed for US exploitation rights with the licensee's US partner. The option would be exercised when the licensee met development and sales milestones. The licensee agreed to meet all patent costs for European and US patents and agreed an up-front fee of £30,000 to cover the Trust's initial patent and development costs and to secure their exclusive position. A 5% royalty on sales was agreed, minimum royalty provisions were included in the licence agreement. The up-front fee and royalties were to be shared between the Trust and the Adviser Organisation in a 2:1 ratio according to the terms of their contract.
2. A physiotherapist saw a need for an improved method for moving patients whilst they were in hospital. She used her research and ergonomic skills to design a new kind of blanket for this purpose. The R&D Department of the NHS trust designed a trial to test the effectiveness of the new design compared with existing methods. The Trust through its Adviser Organisation filed a European patent application. The results of the trial were successful and a licence agreement was entered into with a UK company with strong European market penetration in the healthcare field. The licence agreement was exclusive to the company but there was a non-exclusive option should contractual minimum royalty requirements not be met. The licensee agreed to meet continuing patent costs and on signing reimbursed the patent expenditure already incurred. A 5% royalty on sales was agreed. The physiotherapist received one third of residual income received by the Trust in line with her employment conditions.
3. A researcher in a primary care practice which received NHS R&D Support Funding developed a software programme for managing its community care support programme. On evaluation, the procedure was shown to be more efficient on practice time and delivered a more effective care for patients. The Adviser Organisation to the practice established that it had generalisable value and identified a software company already selling to the NHS and keen to develop the software as a commercial product. The practice recognised there was development work still to be done and there would be need to support a developed product. The practice concluded it had to be a commercial product. The researcher helped the company generalise the software, the practice retained the copyright. The Adviser Organisation achieved a royalty return of 25% of the selling price for each package sold.

The primary care practice had independent status, and under the contractual terms of R&D Support Funding the terms of the exploitation agreement needed to be agreed and the benefit shared with the Department of Health. The then Regional Office negotiated to receive 20% of the royalty income received by the practice. The researcher and the practice agreed to share equally the income retained by the practice, having previously adopted this at a practice meeting. The researcher shared her portion with her GP supervisor who brought his medical knowledge (and a great deal of his own time) to the project.

4. Joint research between a NHS trust and a university had led to the potential for a series of new products to treat dental caries. Initial patents had been filed which were held by the university but with an agreement to share benefit equally with the Trust. The Adviser Organisation for the Trust, in collaboration with the university, agreed that more research was necessary before the patents could be translated into products. The technology was new and there was no obvious route to market by licensing it to an existing company, so a spin-out company was considered to be the best option. Together they attracted a group of private investors who were prepared to fund the research and the development of a new business. A business plan was approved by the Private Finance Unit and the spin-out company established. The investors put in £600,000. £500,000 was to support research over the next three years and £100,000 was reserved to cover patent and administrative costs. The value of the previous investment in research was agreed to be £300,000 and the Trust university and inventors shared a 33% shareholding in the company. A Trust employee and the lead university researcher were on the Board. One of the investors acted as both Managing Director and Finance Director of the company. The university signed a patent licence agreement with the company giving it exclusive rights to exploit the existing and any new patents extending the technology. The licence agreement included provision to review the exclusive rights provision in three years time and for the Trust and the university to receive royalties on sales, the royalty levels to be set once the products to be sold had been identified.
5. A community mental health researcher, holding a joint appointment with a university, developed a questionnaire to measure clinical outcomes from psychological therapies. The motivation for this was that the currently available measures were under copyright elsewhere and were costing the NHS about £20,000 per annum. He showed through research that his questionnaire was robust and superior, and together the university and Trust agreed to make this new questionnaire available free of charge on the internet. The copyright was retained by the Trust, a condition for use was that the users downloaded data from its use on to the Trust web site maintained for this purpose. In this way the Trust was able to continue with its research using the largest available database. The Trust Adviser Organisation was able to put the researchers in touch with a source of free advice to allow them to design the web site. They obtained external funding to allow them to establish, publicise and support the site.

Part 3

Part 3: Employment Guidance

Introduction

- 3.1 The Policy Framework for the Management of Intellectual Property (IP) in HSC 1998/106³:
- informed Trusts that ownership of Intellectual Property (IP) may require explicit recognition in contracts of employment of their employees;
 - drew attention of NHS bodies to the need to agree a policy on ownership of IP for employees holding joint appointments with universities or for employees engaged in R&D away from their place of employment;
 - recognised the need to provide an incentive to NHS bodies for the appropriate and cost-effective exploitation of IP by allowing them to retain income generated and to establish schemes to share this income with their employees.
- 3.2 The Research Governance Framework¹³ requires NHS bodies employing researchers to ensure that agreements are in place between them and their employees and between them and research funders and care organisations about ownership, exploitation and income from any IP that may arise from research conducted by their employees. They have a responsibility for ensuring that employees identify and protect IP.
- 3.3 The Policy Framework for IP under HSC 1998/106 is now extended to cover IP derived from the management or delivery of patient care and, as for IP arising from R&D, this calls for agreements with employees.
- 3.4 Dealing with IP in contracts of employment can be complex, but without such provision there will be uncertainty, when IP does arise, over its legal ownership. The employee will also need to know how the NHS body intends to manage the IP and what personal reward will be available if the IP is exploited successfully to produce income.
- 3.5 This Employment Guidance is to help Trusts act correctly in conforming with research governance requirements and with the Management Framework at Part 2 and making these issues known to employees. It also provides advice on related contractual arrangements entered into by those working in some way for the NHS.
- 3.6 It is recognised that many NHS employees have employment contracts negotiated through their professional organisation, and that amendment of these contracts will need to be agreed with them. Local arrangements may be possible in the interim.

3 *HSC 1998/106 'Policy Framework for the management of Intellectual Property within the NHS arising from research and Development'*; <http://tap.ukwebhost.eds.com/doh/coin4.nsf/Circulars?ReadForm>

13 Research Governance Framework for Health and Social Care, Department of Health; <http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance/govhome.htm>

- 3.7 This Employment Guidance is for NHS employees. Independent Providers of NHS Services may find the content useful in agreeing how to deal with IP in their organisation.
- 3.8 IP generated by NHS employees, often employed under complex arrangements, has potential commercial value. The advice in this Employment Guidance is NOT a substitute for appropriate legal advice.

Employment Conditions: General Principles

- 3.9 IP is the generic term for a diverse range of rights including patents, copyright, trade marks, design rights, and know how. The owner of IP has exclusive rights to license others to carry out certain agreed activities or to exploit an invention commercially. As a result IP is of commercial value to its owner and so it is important that IP-generating organisations such as Trusts properly provide for its regulation and protection.
- 3.10 It has been rare for the employment contracts of NHS employees to include provisions for IP. Without clarity on ownership and other issues, confusion and conflict often arise. There is a risk that inconsistent and inappropriate employment conditions may be introduced. Employees sometimes believe they have rights in IP which they do not. The complexity of this area means that there are many benefits to be gained by confirming the statutory position in writing between employer and employee to avoid future disappointment. It is one purpose of this document to provide model employment conditions to which Trusts can refer.
- 3.11 In the absence of express contractual provision, ownership of IP is determined by statute. Generally speaking, under statute an employer will be the owner of IP generated by an employee in the course of employment or normal duties unless the employer and employee have agreed otherwise. Such an agreement does not have to be in writing and can have arisen through custom and practice. Any agreed custom and practice should ideally be reflected in writing in the contract of employment. Where there are no contrary agreements then this should be stated expressly in the contract. However for patentable inventions there are additional conditions which must be met in order for the employer to own the rights to the invention. Not only must the invention be made in the course of normal duties, or in the course of duties falling outside the normal duties but specifically assigned to the employee, but it must also have been reasonably expected that an invention may result from such duties. In addition, when looking at patentable inventions, the employer not the employee will be the owner where the invention is made by the employee in the course of duties which, because of their nature and particular responsibilities, imposed on the employee a special obligation to further the interests of the employer NHS body.
- 3.12 Deciding legally whether an invention might reasonably be expected to be made in the course of normal employee's duties has proved difficult in the past. For NHS employees engaged in R&D, patentable inventions made in the normal course of duties might reasonably be expected to arise from these duties and ownership would be with the Trust. For NHS employees delivering patient care, or indeed employed in some other capacity, it will be a question of fact as to whether inventions might also be reasonably expected from these duties. New terms of contract would make it clear that making and reporting innovations and inventions is part of every employee's duties.
- 3.13 If an invention does arise, for example through the work of a nurse or a hospital doctor, the inventive steps would need to be defined precisely in a patent application and shown to have industrial application. If the process used NHS resources as would be normal then the Trust might have a stronger claim to ownership of the IP.

- 3.14 In order to bring all NHS employees into the IP Framework and Guidance and to avoid detailed discussion on ownership, the Secretary of State's present position is that the NHS will offer reward on the same basis to all NHS employee inventors, in return for assignment of IP to the Trust when that is necessary. In this way inventions of value can have the best chance of being exploited, through the Trust Adviser Organisation, and deliver an improved health service. Bringing an invention into practice is a complex task which is best carried out by those able to do so.
- 3.15 Under certain circumstances there is a statutory procedure whereby the Court or Comptroller may order an employer to reward an employee inventor. NHS policy is for a Trust to share with its employees the benefit derived from any successful exploitation of IP generated by those employees where it is owned by the Trust. Employees who are prepared to sign, or have already signed, amended employment contracts containing revenue sharing arrangements may already be in a position to benefit. Each Trust needs to agree a sharing scheme and to inform its staff.

Model Employment Conditions

- 3.16 The model employment conditions given here as Part 3 Appendix 1 are intended to be suitable for all existing and new NHS employees. They include recognition that the NHS is a research-based organisation, committed to the application of best practice and providing a creative environment in which employees can work. Advice on amending existing local employment contracts is given below. Trusts may wish to use their own form of words within the context of their own employee contracts. The commitment to revenue sharing (see above) is within the model employment conditions.
- 3.17 HSC 1998/106³ includes copyright as one of the categories of IP owned by the Trust when arising in the course of an employee's employment. In order to encourage employees to publish freely in academic or professional journals or through an electronic medium, Trusts will normally assign to the author the ownership of copyright in any work to be published and will waive any claim to financial benefits arising from the publication. However the Trust will need to secure within the employment contract a world-wide, irrevocable, royalty-free licence to use such a work for its own non-commercial purposes (e.g. training, further research) as a condition of the assignment. Otherwise, once assigned, the Trust will have no further rights in relation to that work. It will have transferred ownership to the author.
- 3.18 There are some items of copyright (e.g. training material, patient information leaflets, software, design drawings) which the Trust will wish to retain and not to assign. The issue of copyright is addressed specifically in the model employment conditions and further in the model management arrangements.

Jointly Appointed or Managed Staff

- 3.19 In addition to employees whose payroll costs are met entirely by the NHS, there are many who hold joint appointments where part of their payroll costs are partially or totally funded by another party (e.g. a university, a medical charity, a commercial sponsor). Sometimes a Trust uses its own funds to support an employee in a university (e.g. through distinction awards) with the employee holding a university contract. Normally the employer holding the employment contract would own the IP with a commitment to share the benefit e.g. royalties with the other party. This is only a starting point, is insufficient by itself to decide ownership and individual consideration will often be necessary. Factors which affect a decision include consideration of the source of funding for the post and the resources

3 *HSC 1998/106 'Policy Framework for the management of Intellectual Property within the NHS arising from research and Development'; <http://tap.ukwebhost.eds.com/doh/coin4.nsf/Circulars?ReadForm>*

used to support the post including the use of NHS patients. For such employees holding a NHS contract, the model employment conditions for dealing with IP owned by the NHS would be appropriate if agreed with the other party.

3.20 It is appropriate that revenue sharing and income streams in relation to work resulting from joint appointees be agreed by the joint employers. Factors to be taken into consideration in agreeing these include:

- proportion of funding and other resources from each party, including access to NHS facilities and equipment and involvement of patients;
- IP management resources provided by each party;
- ownership of background IP.

3.21 If it is concluded that ownership of IP generated by an employee with a joint appointment will not lie with the NHS then the contractual conditions between the parties would normally include:

- a commitment to use best endeavours to exploit this IP;
- a commitment to share benefit with the Trust;
- return of the IP to the Trust by means of an assignment if the other party fails to exploit and the Trust so wishes;
- a commitment to acknowledge the contribution of the NHS in any publication.

3.22 IP of potential commercial value arising at the NHS/University interface can be generated by an employee holding joint appointments or by employees holding individual appointments with the two bodies. This IP can be generated through R&D or by the delivery of patient care. Discussion on ownership, management and benefits can be complex and a simple starting point can be to agree joint ownership of the IP with one party having exploitation rights, and to share equally the cost and the benefit. Equal shares, for example, might typically be the starting point for IP arising from R&D within a NHS/university collaborative programme under the NHS Priorities and Needs R&D system, but subject to variation where the parties agree that equal shares are inappropriate.

3.23 When an honorary contract purely recognises the research status of a NHS employee or the NHS service status of a university employee, such a contract would not be expected to affect the ownership of IP; it should continue to belong to the organisation holding the substantive employment contract. Where the NHS funds a university appointment which includes specific NHS service provision the provisions of paragraph 3.20 would be expected to apply.

Other Circumstances

- 3.24 The NHS carries out R&D in which costs are often jointly met by charities, universities and the NHS. The Guide to collaboration in R&D between the NHS and other research funders¹⁹ summarises the ways in which the NHS may collaborate with non-NHS bodies on R&D, and a Concordat formalises the arrangements with the Medical Research Council²⁰. A Statement of Partnership on IP which sets out the principles under which the NHS and its funding partners can treat IP arising from R&D they jointly fund is given at Part 4 of this document.
- 3.25 A Trust sometimes acts under contract as host to employees from another organisation or the Trust seconds its own employees to another organisation. Any IP arising from those employees will vest in the employer organisation unless otherwise agreed between the parties. In all such cases, the Trust would need to agree in a contract with this organisation how IP is to be managed and who will own it. It is normal for the Trust to seek ownership of the IP where appropriate (by means of an assignment from the other organisation if necessary) but whether or not it owns the IP it would always aim to share benefit from successful exploitation.
- 3.26 Agreement on the management of IP needs to be reached between parties, whatever the arrangement, before any employment begins and considered routinely in any joint-appointment, host or secondment agreements whether or not it is judged likely that IP will be generated during the course of that employment.
- 3.27 Senior academics in medical schools who hold honorary contracts with a recognised NHS employer sometimes receive an additional contribution to salary (a distinction award) in recognition of outstanding professional work of wider benefit to patient care in the NHS as a whole. This work can include R&D, or innovation and improvement in the service. Trusts will wish to agree formally with the university how any derived benefit should be shared when NHS resources are used to generate exploitable IP.
- 3.28 Employees may have a part-time NHS contract and be self-employed part-time (for example in private practice). IP arising through the NHS contract work will be owned by the NHS (generally speaking and subject to the patent proviso set out in paragraph 3.12 above), and IP arising from work undertaken by the employee which is unconnected with the normal course of NHS contract duties will be owned by the employee. However the situation is often less clear cut with the self-employed work undertaken overlapping the NHS contract work. In such circumstances any IP arising may be owned by the Trust if it is construed to relate to the duties under the NHS employment. If there are special circumstances which make it more likely for that IP to arise within the self employment, the Trust may agree with the employee revised terms for the sharing of benefit. To avoid such confusion it is advisable that any appointment under a part-time NHS contract includes clear provisions for what is expected of the specialist appointee and what exactly is expected to flow to the Trust from that appointment.
- 3.29 A Trust often acts as a host for training purposes during which IP might be generated. For the purposes of IP management it is advisable to treat the trainee within the training agreement as an employee of the Trust and subject to the management arrangements of the NHS body. A trainee may not be an 'employee' for the purposes of the statutory provisions regulating IP. It is therefore advisable that specific provision is made within the training contract for ownership of any IP rights generated to vest in the

19 'Collaboration in R&D between the NHS and other Research Funders'; <http://www.doh.gov.uk/research/rd3/sfsnextstep.htm>

20 'Concordat with Department of Health'; http://www.mrc.ac.uk/index/strategy/strategy-health-health_departments/strategy-concordat.htm

Trust. It is important that this issue is dealt with routinely before the trainee starts in a fair, reasonable and clear contract. If the trainee is employed by a third party then agreement with this employer will be necessary to ensure that IP created by the trainee can belong to the Trust.

- 3.30 For other third parties who are not employees of a Trust, but who generate IP on its behalf, the statutory provisions mean that the Trust will not automatically own such IP. Instead the author or inventor will own the IP rights in their work or invention or, if they are employed by another body or have otherwise agreed to it, then the IP will be owned by that body. This situation usually arises in relation to individuals who are employed as consultants and with whom there is therefore a consultancy contract rather than a contract of employment. It would be normal for the Trust to wish to retain the IP rights in the output of the work, and for this to be stated within the contract of engagement.
- 3.31 A Trust may contract with a third party such as a charitable or voluntary sector organisation or a private health care organisation to provide services to NHS patients. Also the Secretary of State may provide funds to charitable or voluntary sector organisations to support R&D. As mentioned in paragraph 3.11, any IP generated from this work would normally be owned by the organisation which employs the person who generates the IP unless there is an agreement to the contrary between the commissioning authority and the third party service provider.

Guidance for Contracts

- 3.32 The model employment conditions set out in Part 3 Appendix 1 provide a template for new contracts of employment.
- 3.33 The Research Governance Framework¹³ requires Trusts to have agreements in place with their employees on the management of IP. Where there are existing employees whose contracts do not deal with the ownership of IP, Trusts will wish to take appropriate steps to incorporate the relevant terms in their contracts of employment. A Trust cannot unilaterally change the terms of an employee's employment contract, i.e. without the individual's consent. Any such unilateral action which amounts to a fundamental variation of an employee's terms and conditions of employment may give rise to a claim by the employee for breach of contract and/or constructive dismissal. A Trust will wish to ensure that employees are fully aware of the potential benefits to them as a consequence of accepting the new contracts of employment.
- 3.34 The model conditions on the whole reflect the current legal position on IP and should not amount to a fundamental variation of contract for many employees. Where, however, employees have been entitled, as a contractual right, to exploit IP belonging to the Trust for their own gain, Trusts need first to consult and reach agreement with the individual before varying that employee's terms and conditions of employment by inserting the new employment conditions. It is recommended that the Trust takes professional advice.

13 Research Governance Framework for Health and Social Care, Department of Health;
<http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance/govhome.htm>

Management Arrangements: General Principles

3.35 A Trust will wish to inform its employees, or to have available on request, its arrangements for dealing with IP of value. These arrangements will include:

- general management arrangements in the organisation;
- particular arrangements for employees engaged in R&D;
- arrangements for sharing with employees the rewards from commercial exploitation;
- special conditions concerning copyright.

The Staff Handbook, or equivalent, is seen as the most appropriate vehicle for this information.

3.36 General management arrangements would set out who in the Trust has the responsibility for dealing with IP issues and the responsibilities of employees within these arrangements.

3.37 A Trust engaged in R&D has requirements within the Research Governance Framework¹³ to identify IP of value arising from this R&D and to exploit it. The responsibilities that this obligation implies for employees need to be set down. In addition, employees engaged in R&D sometimes undertake work under contract which is funded by an external sponsor. Trust procedures for dealing with IP within these contracts will need to be made known to employees.

3.38 Each Trust will need to decide formally how rewards derived from commercial exploitation of IP are to be shared between employees and the organisation. For a Trust with strong links to a university it will be usual for the Trust to adopt a sharing structure which matches that of the university to avoid employees in these organisations (particularly those with joint appointments) having conflicting reward structures. Background detail is given in the *Introductory Handbook*⁵.

3.39 Effective management of IP by a NHS body will usually include establishing agreements with partner universities on how IP generated through joint work, in particular R&D, is to be managed. These agreements will need to be negotiated using the content of this Employment Guidance as a basis.

3.40 The model management arrangements are given here at Part 3 Appendix 2 and intended as a model entry for a Staff Handbook. It is only guidance and may be modified as appropriate by a Trust, except to the extent that the Staff Handbook has contractual effect. It will need to include details of the specific revenue-sharing scheme agreed formally by the Trust.

3.41 Each Trust will wish to decide its strategy for informing employees of these new arrangements. All employees would need to receive a summary of the management arrangements and new employees would receive this information as part of their induction process.

⁵ *The Management of Intellectual Property and Related Matters: An Introduction Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services*; <http://www.doh.gov.uk/pub/docs/doh/intehand.pdf>

¹³ Research Governance Framework for Health and Social Care, Department of Health; <http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance/govhome.htm>

Part 3: Appendix 1

Model Employment Conditions

These model employment conditions are intended to be appropriate to employees of NHS trusts and Primary Care Trusts and to be of interest to Independent Providers of NHS Services. The employing body is referred to below as ‘the Trust’

1. Introduction

- 1.1. The Trust management procedures for intellectual property (IP) have been approved by the Trust Board and are available on request. Trust procedures are consistent with the Management Framework for IP of the Department of Health.
- 1.2. The Trust policy is to encourage and enable employees to participate in the generation and exploitation of IP as part of its commitment to delivering the best possible patient care. Sometimes an improvement to patient care can only come about by the protection of the IP and exploiting it commercially rather than by immediate widespread dissemination. The policy is to maintain a balance between the legitimate needs of the Trust to protect its interests, and the provision of a creative environment for employees to work where innovation and excellence are rewarded. The Trust has therefore agreed that
 - (i) income generated by successful exploitation of its IP and received by the Trust will be shared with the inventor(s) on an agreed sharing basis
 - (ii) the Trust will assign to its employee the copyright in any article produced by the employee intended for publication in an academic or professional journal and with no commercial value, in which event it will waive any claim to financial benefit arising from the publication unless specifically agreed otherwise. The Trust will however retain a world-wide, irrevocable, free licence to use the publication for its own non-commercial purposes, including research and training.

In this context, an inventor is defined as the person without whose intellectual contribution the development would not have taken place.

2. Ownership of Intellectual Property

- 2.1. From time to time during the normal course of employment you as an employee may generate IP which may have value in the delivery of better patient care. This IP can be in the form of inventions, discoveries, surgical techniques or methods, developments, processes, schemes, formulae, specifications, or any other improvements which may give rise to certain rights such as patents, trade marks, service marks, design rights, copyright, know-how, trade or business names and other similar rights (all of the foregoing rights being referred to as ‘Intellectual Property Rights’).

- 2.2 Where such IP is created in the course of your employment or normal duties then under UK law it will generally belong to the Trust, unless agreed otherwise in writing between you and the Trust. In relation to inventions potentially subject to patent protection this applies only if the duties of your employment would normally have been expected to give rise to inventions or if the nature of your responsibilities and duties are such that you are under a special responsibility to further the interests of the Trust. It is a condition of your employment not to exploit any IP Rights without the specific approval of [Trust should insert the job title of the relevant officer]. In addition you are also required to give the Trust all reasonable assistance required by the Trust in order to give full effect to this clause.

3. Confidentiality

- 3.1 Research outputs and resulting IP often represent a considerable investment by the Trust and are potentially of significant value to the Trust. You should treat as confidential and not disclose to any third party any research results or other information of a confidential nature without prior written approval of the Trust. For the avoidance of doubt the requirement to obtain this approval applies to submission of papers, abstracts or theses for publication and grant proposals.

Part 3: Appendix 2

Model Management Arrangements: Model Entry to a Staff Handbook

These management arrangements apply to NHS Trusts and Primary Care Trusts. They can also apply to employees of Independent Providers of NHS Services, except that if these Providers undertake to exploit their IP outside the Primary Care Trust they will be required to share benefit with the Department of Health on terms to be agreed. This applies when the IP arises from R&D funded by the NHS or if NHS resources are used to transfer into practice IP arising through the delivery of patient care. For convenience, the employing body is referred to below as 'The Trust'.

1. General Management Arrangements

- 1.1. These general management arrangements are within the current Department of Health Management Framework. The Department of Health has published a booklet '*Handling Inventions and other Intellectual Property: A Guide for NHS Researchers*⁴'. Although primarily for researchers, this Guide provides a general introduction to the subject. Details of this documentation are available from [the R & D Manager] or on www.innovations.nhs.uk.
- 1.2. The Trust recognises that from time to time, during the normal course of employment, an employee may generate IP which may have value in the delivery of better patient care. IP (patents, copyright, design rights, trademarks, know-how) which arises in, or could reasonably be expected to arise from, the course of the normal duties of an employee undertaking R & D normally belongs to the Trust, unless an existing contract with either the employee or with another party (such as an external sponsor) overrules.
- 1.3. For employees generating IP outside R&D, particularly patentable IP, it is not always clear where ownership lies. However, in return for assignment of the IP to the Trust, the Trust will offer employees the same potential benefit as to others where ownership by the Trust is more clearly defined. The Trust will then undertake to evaluate and exploit the IP when appropriate.
- 1.4. The Trust also recognises that some of its employees hold employment contracts funded jointly by the NHS and another party or funded entirely by another party (e.g. a university, a medical charity, a commercial sponsor). Others are fully employed by a university but receive a supplement to salary from the NHS. The Trust will agree and thereafter formalise with the other party how IP generated during the employment is to be managed to the maximum benefit of the Trust and the employee.
- 1.5. A Trust employee may have a part-time NHS contract and be employed part-time (for example in private practice). If IP arises during this period of NHS employment it will normally be owned by the Trust if it is construed to relate to that employment. If there are circumstances which make it more likely for the IP to arise within the self-employment, then the Trust may agree with the employee alternative terms for the sharing of benefit and will set these out in an agreement.

⁴ '*Handling Innovation and other Intellectual Property*' : A Guide for NHS Researchers;
<http://www.doh.gov.uk/pub/docs/doh/integuid.pdf>

- 1.6. A Trust employee may have an honorary contract with another organisation e.g. a university which recognises the research status of an employee. IP generated by such an employee will normally be owned by the Trust. Ownership of IP in other honorary contracts will need to be agreed as described in 1.4 above.
- 1.7. IP generated by an employee acting outside the normal course of their NHS duties will be owned by the employee subject to the terms of employment set out above.
- 1.8. Trust policy is to encourage and enable an employee to participate in the generation of IP as part of its commitment to encourage innovation and to deliver the best possible patient care. Sometimes an improvement to patient care can only come about by the protection of the IP rather than by immediate widespread dissemination. The policy is to maintain a balance between the legitimate needs of the Trust to protect its interests and the provision of a creative environment for employees in which to work. The Trust has agreed that income generated by successful exploitation of IP can be shared with the inventors, the employees responsible for the innovation.
- 1.9. Any employee wishing to discuss the protection of any idea or other form of IP should discuss the matter with the [R&D Manager] at the earliest opportunity and, in any event, before disclosure of the idea to any party outside the Trust either orally or in writing. Prior public disclosure (other than under explicit terms of confidentiality or to another employee of the Trust) may invalidate any subsequent patent application and diminish both potential commercial value and benefits accruing to the Trust and the inventor. It is essential therefore that ideas and inventions are not generally discussed and are reported instead through the correct channels. All employees should be aware of the importance of avoiding improper disclosure of their inventions.
- 1.10. A record will be kept of the date and time on which an employee reports to the [R&D Manager] that he or she is the inventor of a creative product. Employees are reminded of the importance of keeping accurate and dated laboratory notebooks so that, in the event of similar IP being generated elsewhere, the ownership of the invention can be legally attributed. Such notebooks can be important when applying for patents in the USA and also for identifying know-how.
- 1.11. The [R&D Manager] will be the initial contact point for advice, and can provide details of the support available for the management of IP
- 1.12. The Trust maintains a register of all IP rights owned by the Trust which have been licensed or assigned to a third party where an employee is a named inventor or originator. Details of these IP rights and the income they generate will be given to the Department of Health from time to time on request.
- 1.13. The Trust is the vehicle for holding patents and other IP, but is free at its absolute discretion to engage another party (e.g. an independent company) to exploit its IP on its behalf.
- 1.14. The Trust has arrangements in place for the exploitation of IP. Advice will be available to decide ownership and transfer of IP to the Trust when this is agreed to be necessary. Without transfer of the IP, NHS resources will not be available to the employee to exploit the IP. Employees should take no steps to exploit any Trust IP without the specific approval of the Trust Board. Employees are expected to co-operate with those charged by the Trust to execute its management responsibilities.
- 1.15. The Trust may at its absolute discretion decide that the IP is best exploited through a spin-out company. If the Trust owns a shareholding then the employee responsible for the IP may also own a shareholding. This is a complex procedure which will require the full co-operation of the employee with the Trust and with those responsible for setting up the company. Details of the procedures to be followed are set out in this Framework and Guidance document at **www.innovations.nhs.uk**.

- 1.16. Currently [a Trust should insert here its agreed percentage] of the income received from IP by the Trust is distributed to the employee who is the inventor of the IP. It is at the discretion of the inventor to agree to share this income with others if appropriate. Income is income received by the Trust after the deduction of any reasonable expenses incurred by the Trust in achieving the income (including patent and legal expenses).

2. Particular Arrangements for Employees Engaged in R&D

- 2.1. The [R&D Manager] will from time to time arrange for an audit of Trust R&D activity to satisfy Department of Health requirements for identifying potential IP of value. Employees are required to co-operate fully with this activity.
- 2.2. Employees will sometimes be engaged in contracts for R&D which are funded wholly or in part by external sponsors (e.g. universities, medical charities, industry). These contracts will ensure that adequate provision is made for the ownership and the exploitation of arising IP with the Trust retaining or obtaining ownership when appropriate. Employees should ensure that they understand their position and their obligations within these contracts, taking their own independent advice as necessary.
- 2.3. Employees engaged in R&D will sometimes engage in discussions with external sponsors on funding R&D. Employees are reminded that it is the Trust's responsibility to agree a price for carrying out this R&D, and in fixing this price the Trust will pay due regard to the IP which is likely to result from the contract.

3. Special Conditions Concerning Copyright

- 3.1. Statute provides that copyright in any work produced for the Trust by an employee in the normal course of employment belongs to the employer. The Trust will normally assign to the author copyright in a work intended for publication in a professional or academic journal or electronically, and waive any claim it may have to benefits arising from the publication. The Trust however reserves the right to itself at no cost to reproduce and use these publications for its own non-commercial purposes, including for research and training. The Trust does not assign any of its other copyright to the author including, without limit
- (i) course or training materials or patient information leaflets produced by an employee in the course of employment for the Trust and which are produced, used or disseminated within or outside the Trust
 - (ii) any software program generated by an employee in the normal course of their employment
 - (iii) any designs, specification or other works which may be necessary to protect rights in commercially exploitable IP.

Part 4

Part 4: Statement of Partnership on Intellectual Property

Introduction

- 4.1 NHS Executive introduced in July 1998 a new policy framework under HSC 1998/106 for the management of intellectual property (IP)³. It has also published a Guide to Collaboration in R&D between the NHS and other research funders which summarises the ways in which the NHS may collaborate with non-NHS bodies on R&D¹⁹. A Concordat formalises the arrangements with the Medical Research Council²⁰. This document is a Statement of Partnership on IP which sets out the principles under which the NHS and its funding partners should treat IP arising from R&D they jointly fund. 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.
- 4.2 The Department of Health recognises and values the fact that much of the R&D which it supports and from which IP is likely to arise is funded jointly by the Department and others including universities, statutory research councils, registered charities, government departments and the European Commission. It also recognises that many of those who carry out R&D under contract from the Department are employed by a university or jointly by a university and a NHS body.
- 4.3 Most universities already have in place their own arrangements for the management of IP they generate from their research, including the sharing of any resulting benefit which may arise with their employees. The NHS policy framework has many similarities to the practice adopted by universities including sharing of benefit with those carrying out the R&D for the NHS. A NHS IP Adviser¹⁷ has been appointed to support NHS organisations engaged in R&D.
- 4.4 NHS bodies meet the costs they incur by their involvement in R&D funded by their research partners. Where this R&D generates IP, ownership and the management of this IP should be addressed in the R&D contract. The research partner will recognise in the contract that the NHS body could be a contributor to the generation of this IP even if the contract for the R&D is placed with a partner university. The research contract should recognise the NHS body as a beneficiary in the event that the IP has commercial value.

3 *HSC 1998/106 Policy Framework for the management of Intellectual Property within the NHS arising from research and Development*; <http://tap.ukwebhost.eds.com/doh/coin4.nsf/Circulars?ReadForm>

17 Tony.Bates@ubht.swest.nhs.uk

19 Collaboration in R&D between the NHS and other Research Funders; <http://www.doh.gov.uk/research/rd3/sfsnextstep.htm>

20 *Concordat with Department of Health*; http://www.mrc.ac.uk/index/strategy/strategy-health-health_department_s/strategy-concordat.htm

Mutual Obligation of NHS Bodies and Universities

- 4.5 When IP is generated by joint R&D between NHS bodies and universities, for example by individuals holding joint appointments, then the organisations together should decide:
- who owns the IP;
 - who is to manage the IP and how costs are to be met;
 - how any derived benefit is to be shared.
- 4.6 The purpose is to ensure an outcome which will be fair for both organisations and their employees and lead to greatest return. Such arrangements should operate even if the originator of the IP (the inventor) is solely employed by one organisation. It is often the case that the other makes an indirect contribution to the employment costs as well as a direct contribution to the research costs and so contributes to the development of the IP.
- 4.7 Both parties should endeavour to agree ownership and details of revenue sharing well before any financial benefit is derived, preferably at the initial employment contract or research proposal stage.
- 4.8 Considerations of the organisations leading to a decision on ownership should include:
- employment status and sources of funding of the inventor;
 - contribution to funding of the R&D activity by each party;
 - contribution to and ownership of background and foreground IP.
- 4.9 In making the decision the organisations should recognise that if they agree joint ownership of IP with commercial value then one organisation should be given exclusive rights to exploit.
- 4.10 The party owning the IP should enter into an agreement with the other party which should include:
- a royalty-free licence to the other party allowing use of the IP for further research;
 - a commitment to use best endeavours to exploit this IP;
 - a commitment to share benefit on fair terms;
 - an agreement to offer assignment of the IP if the party owning the IP fails to exploit.
- 4.11 Management of IP, including the responsibilities for meeting the costs of exploiting the IP, should be agreed by both parties.
- 4.12 It is by no means certain that any IP will be successfully exploited, but when it is the parties should agree how the benefit, less the costs of exploitation, will be shared between them. Considerations should include the contribution of each party in its support of the research and the researchers.
- 4.13 It is expected that the parties will wish to adopt similar revenue-sharing agreements with their inventors so that there is no financial advantage or disadvantage resulting from employment status.

Benefits of the Partnership

- 4.14 It is in the mutual interest of the Department of Health and its funding partners for the IP arising from R&D they fund to be well managed. The funding partners collectively recognise it to be a valuable asset.
- 4.15 It is also in the mutual interest of NHS bodies and the universities that they establish a partnership in the identification and management of IP which values the contribution made by each party. The extent of the joint R&D activity requires each to be a responsible partner, maintaining confidentiality where necessary, so that maximum benefit is derived by both parties. The introduction of IP management by the NHS will contribute to a responsible partnership.
- 4.16 It is important to universities that the NHS is treating IP as a valuable asset. NHS organisations are required to set-up processes, as a condition for receipt of R&D funding, which continue to identify IP as it is generated. Because of the joint nature of much of the work this will lead to exploitation opportunities which will have benefits for both partners.

Supporting Documents and Addresses

1. *'The NHS Plan 2000' A Plan for Investment A Plan for reform;*
<http://www.nhs.uk/nationalplan/nhsplan.pdf>
2. *'Health and Social Care Act 2001' 2001 Chapter 15;*
<http://www.legislation.hmso.gov.uk/acts/acts2001/20010015.htm>
3. *HSC 1998/106 'Policy Framework for the Management of Intellectual Property within the NHS arising from Research and Development';*
<http://tap.ukwebhost.eds.com/doh/coin4.nsf/Circulars?ReadForm>
4. *'Handling Innovation and other Intellectual Property': A Guide for NHS Researchers;*
<http://www.doh.gov.uk/pub/docs/doh/integuid.pdf>
5. *'The Management of Intellectual Property and Related Matters: An Introductory Handbook for R&D Managers and Advisers in NHS Trusts and Independent Providers of NHS Services;*
<http://www.doh.gov.uk/pub/docs/doh/intehand.pdf>
6. *'Excellence and Opportunity' A science and innovation policy for the 21st century;*
<http://www.dti.gov.uk/ost/aboutost/dtiwhite/pdf/whole.pdf>
7. *'The Government's response to the Baker Report: "Creating Knowledge, Creating Wealth" Realising the economic potential of Public Sector research Establishments';*
<http://www.hm-treasury.gov.uk/mediastore/otherfiles/government%20response%20to%20the%20baker%20report.pdf>
8. *'Creating Knowledge Creating Wealth: Realising the Economic Potential of Public Sector Research Establishments'; Baker Report (Treasury);*
http://www.hm-treasury.gov.uk/Documents/Enterprise_and_Productivity/Research_and_Enterprise/ent_sme_baker.cfm?
9. *'A Guidance Note for Public Sector Bodies Forming Joint Venture Companies with the Private Sector' 2001;*
<http://www.partnershipsuk.org.uk/news/jointventureguidance.pdf>
10. *'Intellectual Property in Government Research Contracts. Guidelines for Public Sector Purchasers of Research and Research Providers';*
<http://www.patent.gov.uk/about/notices/ipresearch.pdf>
11. *'Commercialisation Activities by Public Sector Research Establishments'; National Audit Office Press Notice;*
<http://www.nao.gov.uk/pn/9899psre.htm>
12. *Science and Innovation Strategy 2001, Department of Health;*
<http://www.doh.gov.uk/research/documents/s&i.pdf>

13. Research Governance Framework for Health and Social Care, Department of Health;
<http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance/govhome.htm>
14. *A Review of Appraisal, Disciplinary and Reporting Arrangements for Senior NHS and University Staff with Academic and Clinical Duties*: a report to the Secretary of State for Education and Skills by Professor Sir Brian Follett and Michael Paulson-Ellis;
<http://www.dfes.gov.uk/follettreview>
15. Contact details for the BioIndustry Association;
Admin@bioindustry.org.uk
16. *Capital Investment Manual* Business Case Guide 1994 London: HM Stationery Office
17. Address for the NHS Intellectual Property Adviser;
Tony.Bates@ubht.swest.nhs.uk
18. Address for Partnerships UK web site;
<http://www.partnershipsuk.org.uk>
19. Collaboration in R&D between the NHS and other Research Funders;
<http://www.doh.gov.uk/research/rd3/sfsnextstep.htm>
20. *Concordat with Department of Health*;
http://www.mrc.ac.uk/index/strategy/strategy-partnership_strategy/strategy-health-health_departments/strategy-concordat.htm



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