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sets out a specific action on the part of the recipient with a deadline where appropriate

Policy Framework for the Management of Intellectual Property within the NHS arising from Research & Development

For action by: NHS Trusts - Chief Executives
Primary Care Independent Contractors engaged in NHS R&D

For information to: Health Authorities (England) - Chief Executives
Regional Directors
Regional Directors of Research & Development
Regional Managers of Research & Development
University Vice Chancellors
Deans of Medical and Dental Schools
Local Research Ethics Committee Chairs
Multicentre Research Ethics Committee Chairs
Community Health Councils - Chief Officers

Further details from: Dr Tony Bates
NHS Intellectual Property Adviser
United Bristol Healthcare NHS Trust
Trust Headquarters
Marlborough Street
Bristol BS1 3NU
Tel: 0117 928 3737 Fax: 0117 928 3724
email: Tony.Bates@ubht.swest.nhs.uk

Additional copies of this document can be obtained from:

Department of Health
PO Box 410
Wetherby LS23 7LN
Fax 01937 845 381

It is also available on the Department of Health website at
<http://www.open.gov.uk/doh/coinh.htm>

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Policy Framework for the management of intellectual property within the NHS arising from research & development

Summary

The NHS Executive has adopted a Policy Framework for the management of Intellectual Property within the NHS arising from Research & Development (R&D) funded from the R&D Levy. This Circular sets out this Framework which will help ensure that Intellectual Property derived from NHS R&D is owned and exploited in the best interests of the NHS and the country as a whole, by those best able to do so. It is intended to remove current uncertainties about roles and responsibilities.

Action

(i) NHS bodies engaged in R&D funded from the R&D Levy (particularly NHS Trusts and Primary Primary Care Independent Contractors) should review by October 1998 their arrangements for the management of Intellectual Property and ensure that satisfactory arrangements, in line with the attached Policy Framework, are in place as soon as possible thereafter. NHS bodies not currently receiving funding from the R&D Levy but who expect to apply for funding in the future should note the Policy Framework for information.

(ii) This will require these NHS bodies to

- * review their R&D management arrangements to ensure that they are in a position cost-effectively to identify and exploit any Intellectual Property that they themselves generate or own where that is appropriate
- * review their R&D funding arrangements to ensure that their contracts properly cover the ownership of and continued access to Intellectual Property and arrangements for sharing any profits generated by its exploitation
- * to respond to further advice on good practice for exploiting Intellectual Property when such reviews are complete.

Associated Documentation

1. The Management of Intellectual Property and Related Matters: - An Introductory Handbook for R&D Managers & Advisers in NHS Trusts and Independent Providers of NHS Services

2. Handling Inventions and Other Intellectual Property: - A Guide for NHS Researchers

This associated documentation is available on the Department of Health website at <http://www.open.gov.uk/doh/nhsexec/ipr.htm>

Background

1. At all levels, the NHS invests heavily in R&D. The primary purpose of this R&D is to provide evidence to improve the service which the NHS provides, by promoting evidence-based policy and practice in the NHS.
2. It is central to the NHS R&D Strategy that information on R&D which the NHS funds is widely and effectively disseminated, and that its findings influence policy and practice.
3. From time to time NHS funded R&D will produce results which are not only a valuable contribution to the evidence base, but which can be commercially exploited. This might say be in the field of new healthcare technology, IT software, or copyright on literature.
4. Such Intellectual Property represents a potentially valuable asset, which should not be disregarded. If properly protected and then exploited, Intellectual Property can be a source of income for the NHS and additional wealth for the country. It can be a springboard for further developments which will benefit the NHS and health in general.
5. Furthermore, and contrary to widespread belief, there is no conflict between the protection of Intellectual Property and proper dissemination of the findings of R&D. Indeed, the opposite is often true. The process of filing a patent application for a new product or process requires full details of it to be submitted which are then made public. Also, it is often the case that commercially published material achieves wider circulation than material published through non-commercial routes.
6. Because Intellectual Property is potentially such an important asset, it is important that it is well managed. A study for the NHS Executive suggested that there is little tradition of active management of Intellectual Property in the NHS, and that practice is diverse and probably less effective than it could be. This can probably be ascribed in great part to the lack of clarity throughout the NHS at all levels about roles, responsibilities and overall approach to Intellectual Property.
7. The NHS Executive has therefore developed this Policy Framework for the Management of Intellectual Property within the NHS arising from R&D funded from the R&D Levy. It is intended to provide a coherent framework which
 - * sets out roles and responsibilities
 - * ensures that the NHS benefits from the Intellectual Property it helps to create
 - * promotes the effective dissemination and uptake within the NHS of the results of R&D.

Management of Intellectual Property

8. It is intended to provide a high level framework only. The management of Intellectual Property is a highly specialised and complex field, and expertise in it is scarce. The NHS Executive is publishing alongside this Circular a Handbook for R&D Managers and Advisers and a Researchers Guide dealing with good practice and many technical and legal issues, and is appointing an NHS Intellectual Property Adviser. It will also be developing a programme of Intellectual Property training for NHS bodies to aid implementation of the Policy Framework.

Legal Framework

9. 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 services duties.
10. 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.

11. The 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 also to NHS Trusts who have the power by virtue of paragraph 15 of Schedule 2 to the NHS and Community Care Act 1990.

Enquiries

12 If you have queries on the content of this document please write to:

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

13. If you need advice on setting up arrangements for managing Intellectual Property you should contact your NHS Executive Regional Office R&D Directorate or the NHS Intellectual Property Adviser. They may be able to assist you in obtaining technical and legal advice when necessary and to suggest suitable partners for exploitation. Telephone numbers of NHS Executive Regional Office R&D Directorates are as follows:-

North Thames Regional Office	-	0171 725 5318
Anglia & Oxford Regional Office	-	01223 330 169
North West Regional Office	-	01925 704 234
Northern & Yorkshire Regional Office	-	0191 301 1451
South & West Regional Office	-	0117 928 7224
South Thames Regional Office -	0171 725 2515	
Trent Regional Office	-	0114 282 0332
West Midlands Regional Office	-	0121 224 4663

14. Limited copies of the associated documentation are available from Regional Office R&D Directorates.

This circular has been issued by:

Professor John Swales
Director of Research & Development

Policy Framework for Managing Intellectual Property in the NHS

1. The Intellectual Property which arises from Research and Development (R&D) funded by the NHS is a potentially valuable resource both for the NHS and for the country as a whole. The NHS has a responsibility to help ensure that this Intellectual Property can be appropriately exploited either within the NHS or by others, although this remains a subsidiary objective to securing the proper dissemination and take up of new knowledge.

1.1 Intellectual Property means products of creativity or innovation which can be given legal recognition of ownership as Intellectual Property Rights through for example patents, trademarks or copyright.

1.2 There will rarely be a conflict between the exploitation of Intellectual Property and the appropriate dissemination and take up of new knowledge to help improve the service which the NHS provides. However, should such a conflict arise, the best interests of the NHS and the country as a whole should prevail.

2. Intellectual Property arising from R&D funded by the NHS R&D Levy should normally be owned by those people best able to exploit it. This will generally be the organisation carrying out the R&D. It is the responsibility of NHS bodies to ensure that the question of ownership is properly dealt with in any contracts they issue for R&D.

2.1 When an NHS body (for these purposes an NHS Trust or a Primary Care Independent Contractor) commissions R&D it should make sure that the contract for the work contains, wherever appropriate, explicit agreement about the ownership of any resulting Intellectual Property.

2.2 Ownership of Intellectual Property should normally rest with those best able to exploit it. In general this will be the organisation contracted to carry out the R&D, whether that is a University, a commercial organisation or another NHS body. The contractor organisation is, almost certainly, most familiar with the work and best placed to assess and act on any opportunities for exploitation.

2.3 NHS bodies commissioning R&D should normally only seek to retain ownership of Intellectual Property where they believe that the contractor is not in a position adequately to manage the Intellectual Property, or where there are good grounds for thinking that the NHS body itself, or some other party, is better placed to exploit it.

2.4 Exceptionally, there may be other cases where NHS bodies should retain Intellectual Property, despite the potential that exists elsewhere for exploitation, if there is an overriding public interest.

3. The NHS should benefit from the profits of any commercial exploitation of Intellectual Property derived from R&D that it has funded or for which it has been funded, even where the Intellectual Property itself is to be owned by people or organisations outside the NHS.

3.1 NHS bodies should ensure, wherever appropriate, that an agreement to this effect is included in the contracts they issue for R&D or they enter into to undertake R&D funded by others.

3.2 This will generally be in the form of a requirement on the parties to take reasonable steps to ensure identification and exploitation of Intellectual Property, and an agreement that the NHS body concerned will be entitled to an appropriate share of any subsequent profits.

3.3 The size of such share will vary from case to case according to the relative contribution of the NHS body, the owner of the Intellectual Property and other interested parties.

4. NHS bodies are responsible for the cost effective exploitation of any Intellectual Property which they own. They should do this in a way which minimises speculative financial investment from public funds and which does not detract from their primary role in the NHS. In general, as much as possible of the financial risk of exploitation should be assumed by a partner outside the NHS.

4.1 NHS bodies will own intellectual property arising directly from their use of funds from the R&D Levy and they may also own Intellectual Property because they themselves have been contracted by another body to carry out R&D. They may occasionally retain Intellectual Property arising from R&D they commission from others.

4.2 Ownership of Intellectual Property may require explicit recognition in contracts of employment of their staff by NHS bodies. Where staff hold joint appointments with Universities, or where staff are engaged in R&D away from their place of employment, a policy on ownership of Intellectual Property arising from their work will need to be agreed locally between the parties.

4.3 Exploiting Intellectual Property involves both costs and risk, either directly or indirectly (for example through the identification of the Intellectual Property and the maintenance of patents). It will by no means always be appropriate or cost-effective to seek to protect and exploit potential Intellectual Property. The resources that NHS bodies devote should be commensurate with the likely benefits and with other calls on their funds. This can only be determined locally in the light of relevant circumstances.

4.4 Few NHS bodies have the expertise themselves actively to exploit Intellectual Property in a commercial way, and for the vast majority it will be inappropriate for them to develop such capacity. As a general rule, NHS bodies should seek to minimise the risk they take on, by assigning or licensing Intellectual Property to commercial or other organisations able and willing to meet all or most of the costs of exploitation in return for a greater share of any subsequent income.

4.5 Before using their powers to generate income by exploiting Intellectual Property NHS bodies will carry out any consultation with other interested parties required by statute.

5. To provide an incentive for the appropriate and cost-effective exploitation of Intellectual Property, NHS bodies will in general be able to retain any income they generate.

5.1 This general approach is subject to normal NHS financial disciplines, such as those relating to trading surpluses. It will also be subject, in exceptional cases, to the use by the Secretary of State of powers to expropriate excessive balances from NHS Trusts.

5.2 To provide a similar incentive within their own organisation, it is permissible for NHS bodies, in appropriate circumstances, to establish schemes for giving their employees reasonable financial rewards, linked to the commercial success of Intellectual Property.

6. The NHS Executive will be responsible for ensuring that Intellectual Property within the NHS is managed in accordance with this Policy Framework.

6.1 In line with this Policy Framework, when the NHS Executive commissions R&D from another NHS body under the NHS R&D Programme it will generally agree that any Intellectual Property is owned by that other body.

6.2 It will be a condition of R&D Support Funding for NHS Providers that they act in accordance with this Policy Framework when using that funding. The NHS Executive will not require a share of profits from Intellectual Property developed as a result of R&D funded by NHS Trusts using their NHS R&D Support Funding. Such revenue sharing will, however, be a condition of R&D Support Funding contracts with Primary Care Independent Contractors and voluntary or private sector healthcare providers.

6.3 The NHS Executive will monitor the implementation of this Policy Framework within the NHS.