Policy

Intellectual property (IP) management

Key messages
- To ensure that the Trust is in a position to identify, protect and disseminate any Intellectual Property that it generates and that
- All Intellectual Property is managed efficiently and effectively

Summary

‘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.’

The aim of the guidance is to establish within NHS Trusts, Primary Care Trusts and Independent Providers of NHS Services a structure for managing innovation to benefit NHS patients and employees. This forms part of the NHS Plan which commits the NHS to ensuring that new technologies are identified and developed in the interests of NHS patients and society; leading to new products, improved interventions and services.

The guidance recognises that most innovations are best implemented by making them widely disseminated, but some may only be realised through commercial development and for these, professional management of IP is crucial. Section 5 of the Act also allows the Secretary of State and NHS Trusts to form or invest in companies in order to facilitate income generation.

1 Scope
This document is for use Trust Wide.
2 Purpose

To ensure that the Trust is in a position to identify, protect, exploit and disseminate any IP that it generates and that all IP is managed efficiently and effectively.
To ensure that innovation and associated intellectual property (IP) arising in the Trust is managed and disseminated according to the Framework and Guidance on the Management of Intellectual Property in the NHS and Section 5 of the Health and Social Care Act 2001 and its amendments.

3 Definitions

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4 Responsibilities

4.1 All employees:

Are responsible for providing true and accurate information on the innovation being reported.

4.2 R&D manager:

Is responsible for holding regular meetings with the Adviser Organisations and reviewing progress made on the development and exploitation of IP innovation reported.

4.3 BRC Intellectual Property Manager:

Should be the first point of contact for information and advice regarding IP which is created using BRC funded staff or facilities. The BRC IP manager will identify, protect, manage and exploit intellectual property rights arising from research that is funded either wholly or in part by the BRC.

4.4 Cambridge Enterprise and Health Enterprise East:

Refer to 8.1

5 Innovation and intellectual property

There is always IP associated with innovation. Under the terms of the convention establishing the World Intellectual Property Organisation (WIPO), Stockholm 1967, IP was defined as:

- the rights relating to:
- literary, artistic and scientific works;
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- performances of performing artists, phonographs and broadcasts;
- inventions in all fields of human endeavour;
- scientific discoveries;
- industrial designs;
- trademarks;
- service marks and commercial names and designations;
- and all other rights resulting from intellectual activity in the industrial, scientific, literary and artistic fields.’

IP has an owner, it can be bought, sold or licensed and should be adequately protected. The owner of IP can control and be rewarded for its use. IP generated by all NHS bodies through all their activities is now recognised 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.

In this document, innovations which need to be developed commercially are called inventions and the employee responsible for the innovation is called inventor. The owner of the IP may or may not be the inventor.

The novel or previously undescribed tangible output of any intellectual activity can legitimately be described as innovation. It 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 or patient information leaflets
- treatment protocol
- a new management system.

6 Intellectual property rights

Intellectual property rights define the legally protected rights that enable owners of items of IP to exert monopoly control over the exploitation of these rights, usually with commercial gain in mind. They give the right to stop others exploiting this property, sometimes for a fixed period, sometimes indefinitely. The principal forms of these rights are:
- patents
- copyrights
- design rights
- trademarks
- know-how

7 Ownership and recognition of intellectual property

Although the Intellectual property rights created by its employees vests in the Trust, a confirmatory assignment of IP to the Trust is required as evidence to potential investors. The Trust will not proceed with the exploitation of the IP until such confirmatory assignment has been made.
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 (eg a university, a medical charity, a commercial sponsor). Sometimes the Trust uses its own funds to support an employee in a university (eg 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 (eg royalties) with the other party.

Where research is conducted by an employee in collaboration with other organisation(s), the project should not start until a written collaboration agreement defining ownership of any arising IP is in place.

Negotiation and conclusion of such agreement is the responsibility of the R&D legal team with advice from the project team and adviser organisations.

Factors which affect sharing of benefits, include consideration of the source of funding for the post and the resources 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. 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 and contribution to foreground IP
- the Department of Health’s attitude to access to essential medicines in the developing world

These considerations mean that although ownership of IP may reside with one party (University or Trust) the revenue derived from commercialising the IP may be split between the Trust, University and other funders depending on the exact circumstances.

8 Intellectual property management

8.1 Adviser organisations

The Framework and Guidance on the Management of Intellectual Property in the NHS advises NHS bodies to contract with an organisation to provide high quality advice on its behalf and to act as adviser. The adviser organisations for the Trust are:

- Cambridge Enterprise (CE)
- Health Enterprise East (HEE).
8.2 Cambridge Enterprise (CE)

Cambridge Enterprise is a wholly owned subsidiary of University of Cambridge responsible for commercialisation of intellectual property on behalf of the University.
CE provides a service for University of Cambridge staff working on the Cambridge Biomedical Campus (a list of University departments covered by the service is available in Appendix 2).

Cambridge Enterprise shall be lead project manager for any intellectual property, which has been created by University employees, whether or not Trust employees were also involved in their creation.

In order to facilitate the work of the adviser organisation, the Trust has employed a BRC IP Manager to act as a bridge between employees and the adviser organisation.

8.2.1 Health Enterprise East (HEE)

HEE is the NHS innovation hub for the East of England (Bedfordshire, Cambridgeshire, Essex, Hertfordshire, Norfolk and Suffolk).
HEE is a non-profit-making organisation set up to manage and exploit intellectual property generated by NHS staff for the benefit of patients and the wider health care community.
HEE shall be lead project manager for any intellectual property the creation of which did not involve a University employee.

8.2.2 Responsibilities of the adviser organisations

CE and HEE will assess all innovations generated by staff (NHS or University) on the Cambridge Biomedical Campus and will provide support in:
- identifying IP of potential value, through audit and other means
- assessing potential value of IP
- determining ownership of IP
- determining whether identified IP should be protected
- determining what type of protection is sought, if any
- arranging such protection
- determining the best route to market for any technology
- negotiating and concluding suitable agreements for commercialisation of technology
- using reasonable endeavours to successfully exploit technology via formation of a new company, licensing or other agreements

8.2.3 Commercial exploitation of intellectual property

Identified IP, however it arises, should 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. 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.
When income is generated by commercial exploitation of IP there will be costs incurred by the adviser organisation in obtaining this income. The Trust has a contractual agreement with CE and HEE 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 Trust. The Trust would normally meet costs of identification of IP, initial patent protection and training.

Section 5 of the *Health and Social Care Act 2001* authorises 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. In accordance with the regulation for three star Trusts, ‘business cases will still be required for such companies, although they will not be subject to approval by the Secretary of State.’

There are two circumstances in which it may be appropriate to establish companies for the exploitation of NHS IP.

1. 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).
2. 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).

Cambridge Enterprise will be the Trust adviser for formation of companies set up to commercialise Trust IP. The Trust and the employee inventor will be eligible to own an equity share in the company. The size of the shareholding will be decided on a case by case basis, taking into account the contributions of all the parties and other funders.

### 8.2.4 Revenue sharing

Income from successful commercial exploitation of IP, through sale or licensing of IP through dividends or sale of shares, will normally be received by the Trust. In achieving this income, the Trust and the adviser organisation may have incurred expenditure for patent or legal work. This expenditure will be recovered as a first charge on the income. The net income, after deduction of these costs, will then be shared between CE or HEE, as appropriate, and the Trust responsible for generating the IP. CE or HEE will receive 20% of the net income.

As an incentive to employees, the Trust will grant its employees and respective departments an interest in revenues arising from the successful exploitation of specific IP. The standard division of the revenues received by the Trust, after deduction of agreed costs and the share to CE or HEE, shall be:

- one third to the inventor(s)
- one third to his/her department
- one third to the Trust.
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Where third parties have funded work or provided resources, or where there are co-inventors from other institutions, there may be an obligation for the Trust to also share any revenue with those parties. In particular, the standard division of revenues received by the Trust, after deduction of agreed costs and the share to CE or HEE, from successful commercial exploitation of IP resulting from an invention coming from research or other work funded by Addenbrooke’s charities shall be:

- one third to the inventor(s)
- one third to his/her department
- one third to the charity.

These terms may be subject to review where there is deviation from normal practices. In particular, and in accordance with the provisions of the Framework and Guidance on the Management of Intellectual Property in the NHS which states that:

“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”, the R&D Manager will use discretion in such cases to agree an appropriate fee sharing structure with the inventors.

Revenues allocated to the Trust are to cover the cost of legal fees in relation to Addenbrooke’s IP development and for exploitation of new inventions. Where the exploitation of IP results in the formation of a company, the equity division will be decided on a case by case basis. Any revenue in this context will be distributed after the Trust has recovered all direct costs and/or support for patent and legal services to protect IP and negotiate commercial contracts.

In the event that the Trust and its employees cannot agree on issues of IP management (i.e. revenue share, ownership of intellectual property etc), a panel of experts will be set up to provide independent judgment.

8.2.5 Dissemination

IP that is a ‘good practice’ innovation, which has no commercial value but has the potential to improve health and to save expenditure by the NHS, should be evaluated locally and disseminated freely as appropriate.

9 Operational procedures

Two levels of advice and support are available to employees:

1. The BRC IP manager (see contacts section below) will provide a first level of advice and information on IP policy and procedure and will facilitate access to Cambridge Enterprise and Health Enterprise East.
2. CE and HEE will assess all innovations generated by staff (NHS or University) on the Cambridge Biomedical Campus and will provide support as identified in responsibilities of the adviser organisations.

9.1 Communicating ideas

9.1.1 University staff

University staff holding an NHS honorary contract or NHS Staff who have collaborated with University staff with an idea that may have commercial potential should initially fill in an invention disclosure form (Appendix 3). This form is the same for all inventions, regardless of their origin or funding. CE can give advice on matters relating to IP and how research can be applied to the commercial sector. The form provides a straightforward way of supplying the information needed by CE to start assessing the patentability and commercial opportunity of an invention.

**Note**: Non-confidential disclosure of inventions to other people or organisations can damage or destroy the possibility of obtaining patent rights. CE can advise on this. For this reason, CE recommends that the invention disclosure form is **not** transmitted by email.

Signed forms should be sent by **post** (only) to the address in the contacts section below.

CE will acknowledge receipt of the form within one working day, and a technology transfer professional will be allocated to the case in less than a week.

CE is also available for a confidential discussion of the commercial potential of an idea or invention.

9.1.2 Trust staff

Trust staff with an idea that may have commercial potential, and be of benefit to patients and the wider health care community should initially complete the HEE innovation disclosure form (Appendix 4).

Forms can be returned to Health Enterprise East using the postal or email addresses in the contacts section below.

Following receipt of the form, the case will be allocated to a project manager within one week. An alternative form for service delivery innovations can be obtained by contacting HEE.

HEE can assist Trust staff with enquiries relating to intellectual property and the commercialisation of ideas.

9.1.3 Continuing prosecution and maintenance

On further investigation of the commercial prospects of an invention, it may become apparent that the costs of commercialisation outweigh the benefits. The R&D Manager on advise from the appropriate Advisor Organisation will
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make the decision as to whether the Trust and the Advisor Organisation will continue to pay the costs of patent prosecution and maintenance. In specific instances the Trust may decide not to pursue its intellectual property rights (IPR) and may assign ownership of the intellectual property to the relevant inventors (assignees) with their agreement, the costs of such assignment to be borne by the assignee. In such cases, the assignees may pursue and exploit the relevant IP in their own time and without utilising Trust facilities and resources.

10 Contacts

10.1 R&D manager

Addenbrooke’s Hospital
Box 277
Hills Road
Cambridge
CB2 0QQ
Telephone: +44 (0)1223 217418
Fax: +44 (0)1223 348494
Email: stephen.kelleher@addenbrookes.nhs.uk

10.2 Cambridge Enterprise

Cambridge Enterprise Limited
University of Cambridge
Hauser Forum
3 Charles Babbage Road
Cambridge CB3 0GT

Phone: +44 (0)1223 760339
Fax: +44 (0)1223 763753
Email: enquiries@enterprise.cam.ac.uk

10.3 Health Enterprise East

Papworth Hospital Papworth Everard Cambridge CB23 3RE
Telephone: +44 (0)1480 364925
Fax: +44 (0)1480 364681
Email: hee@papworth.nhs.uk Web: www.hee.org.uk

11 Monitoring compliance with and the effectiveness of this document

a. Process for monitoring compliance and effectiveness
As part of routine monitoring visits, audit and inspection

b. Standards/Key performance indicators
This process forms part of a quality management system. Documents are reviewed every two years.

12 References

Department of Health. Health and Social Care Act 2001

List supporting documents to be read in conjunction with this document, eg:
- the Trust’s corporate style guidelines
- developing Trust documents policy

Equality and diversity statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

Disclaimer

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The table below will be completed by the Trust Documents Team:

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