

TRUST POLICY AND PROCEDURES FOR THE MANAGEMENT OF INTELLECTUAL PROPERTY

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	1	November 2014	Assistant Director R&D	New Policy
	2	December 2017	Assistant Director R&D	Review
Intended Recipients: All staff groups				
Training and Dissemination: How will you implement the policy, cascade the information and address training				
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Contact for Review	Assistant Director Research & Development
Executive Lead Signature	Medical Director
Approving Executive Signature	Medical Director

Trust Policy and Procedures for the Management of Intellectual Property

1. Introduction

All staff members are encouraged to innovate and develop new ways of working aimed at improving patient treatment and care. This will take place both within identified research studies and trials and the day to day delivery of service.

There will be occasions when the ideas and concepts developed have practical applications and commercial potential, for example, devices, software, training schemes, pharmaceutical products, new techniques. Such ideas and concepts are termed intellectual property (IP) and, like other kinds of property, can be owned, protected and sold. Sometimes, an improvement in patient care can only be secured by the protection of the IP rather than by immediate widespread dissemination.

NHS Policy and the framework and guidelines on the management of intellectual property place a duty on the Trust to audit, protect and exploit its intellectual property. This document outlines a policy for the effective management of IP and gives a brief definition of what intellectual property is, with information on who should be contacted if staff members have an invention / idea / innovation or for general advice on IP arising from work carried out in the Trust.

2. Purpose and Outcomes

NHS Policy and the framework and guidelines on the management of intellectual property place a duty on the Trust to audit, protect and exploit its intellectual property. This document outlines a policy for the effective management of IP and gives a brief definition of what intellectual property is, with information on who should be contacted if staff members have an invention / idea / innovation or for general advice on IP arising from work carried out in the Trust.

3. Definitions Used (bold, 12, underlined, small case)

Intellectual Property :	Intellectual property can be defined as products of intellectual or creative activity in the form of novel ideas, innovation or research and development (R&D) (e.g. inventions, discoveries, surgical techniques or methods, drug development, developments, processes, schemes, formulae, specifications, which can be given legal recognition of ownership through intellectual property rights such as patents, copyright, design rights, trademarks or know-how (see Appendix 1). An inventor is defined as the person without whose intellectual contribution the development would not have taken place
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4. Key Responsibilities/Duties

Trust Employees:	Where employees are contracted to undertake R&D, they have an obligation to inform the Trust (via the Assistant Director Research & Development) about identified or potential IP resulting from their activities and must not, under any circumstances, sell, assign, license, give or otherwise trade IP without the Trust's agreement (for more information see Appendix 2). Confidentiality Research outputs and resulting IP often represent a considerable investment by the Trust and are potentially of significant value to the Trust. Employees should keep as confidential and not disclose to any third party any research results or other information of a confidential nature without prior written approval by the Trust. For the avoidance of doubt, the requirement to obtain this approval applies to the submission of papers, abstracts or theses for publication and grant proposals.
Assistant Research Development: Director &	Is responsible for managing and protecting IP for the Trust using appropriate external, professional support. She is the initial contact point for advice and can provide details of the support available for the management of IP.

5. Implementation of the Intellectual property Policy

5.1 Justification of this Policy

People working in the NHS continuously generate IP. It arises from both service and research and development activities. The IP that Trust employees create may improve the health care services provided by the NHS.

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 therefore agrees 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 employees the copyright of 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, royalty-free licence to use the publication for its own non-commercial purposes, including research and training.

5.2 Persons Covered by this Policy

- a) All staff that are full or part time employees of the Trust
- b) Staff with Trust contracts of employment whose payroll costs are partially or wholly funded by another party (e.g. a university, medical charity, a government department, a commercial sponsor); and staff fully employed by a university but who 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.
- c) Staff who have a part-time Trust contract and who are self-employed or otherwise employed part-time.
- d) Trust employees 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 in (b) above.
- e) Trainee professionals hosted by the Trust who generate IP during the course of their training.
- f) Staff who generate IP outside normal working hours and / or away from the place of work, where the IP relates to their area of employment within the Trust.
- g) Trust staff seconded to another organisation or employees of another organisation hosted by the Trust under contract are subject to the arrangements for the ownership of IP agreed between the Trust and that organisation.

5.3 Ownership of Intellectual Property

Ownership of IP will often rest with the Trust employing the person(s) who generated it, unless otherwise agreed in writing. This applies to all intellectual property produced by Trust employees in the course of their normal duties. If IP is generated by activities outside the normal duties of the employee, then that IP will belong to the employee. This is in accordance with the Patents Act 1977 and the Copyright, Designs and Patents Act 1988.

If an employee's contract of employment requires him/her to undertake research and development or to invent, then there is an expectation that inventions may potentially arise. In this case, the IP belongs to the Trust and income generated by its successful commercialisation and received by the Trust will be shared with the inventors on an agreed sharing basis (see Section 4.4).

For employees who are not contracted to undertake research and development or to invent and who generate IP, 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, where appropriate, at no cost to the inventor and any income generated by its commercialisation and received by the Trust will be shared with the inventor(s) (see Section 4.4).

If an employee uses NHS resources (including premises, staff and facilities) to develop and exploit any IP, then that IP belongs to the Trust.

If an employee who is not contracted to undertake R&D or to invent wishes to claim ownership, then that person may try to protect and exploit the IP on their own and using their own resources. However, employees should be made aware that this is a complex and costly process and that, in these circumstances, NHS resources must not be used.

5.4 Disputes of Ownership

If the ownership of IP is disputed, dated written records relating to the IP in question will be assessed to establish the inventor(s) and their proportionate contribution. If such material is not available, the Comptroller General of the Intellectual Property Office will make a final decision.

5.5 Collaborative Projects

If work / research is conducted by the Trust or a Trust employee in partnership with, or at the request of, another organisation, then a formal agreement stating ownership of generated IP and the relevant revenue shares is required. It is the Trust's responsibility to agree a price for carrying out this work/research and development and, in fixing this price, the Trust will pay due regard to the IP which is likely to result from the contract. The Assistant Director of Research & Development will have primary responsibility for developing IP sharing agreements with collaborating institutions

5.6 IP Management Structure

Any employee wishing to discuss the protection of any idea or other form of IP should discuss the matter with the Assistant Director Research & Development 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 the explicit terms of confidentiality) may invalidate any subsequent patent application and diminish both potential commercial value and benefits accruing to the Trust and to the inventor. It is essential, therefore, that ideas and inventions are not generally discussed and are reported through the correct channels. All employees should be aware of the importance of avoiding improper disclosure of their invention.

A record will be kept of the date and time on which an employee reports to the Assistant Director Research & Development that he/she is the inventor of a creative product. Employees should keep accurate and dated laboratory notebooks/research files so that, in the events 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.

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 that they generate may be given to the Department of Health on request.

5.7 Particular Arrangements for Employees Engaged in Research & Development

5.7.1 Periodically, the Assistant Director Research & Development will arrange for an audit of Trust R&D activity to satisfy the Department of Health requirements for identifying potential IP of value. Employees are required to co-operate fully with this activity.

5.7.2 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, commercial sponsors etc). These contracts will ensure that adequate provision is made for the ownership and exploitation of arising IP with the Trust retaining or obtaining ownership when appropriate. Employees should ensure that they understand their position and obligations within these contracts, taking their own independent advice as necessary.

5.7.3 Employees engaged in R&D will sometimes enter into discussions with external sponsors on funding R&D. It is the Trust's responsibility to agree a price for carrying out this R&D and, in fixing this price, will pay due regard to the IP which is likely to result from the contract.

5.8 Exploitation of Intellectual Property

5.8.2 IP Audits

Periodically, audits may be carried out by external, professional organisations and/or professional staff employed by the Trust to manage IP on behalf of the Trust. This process is necessary to identify potential IP arising from R&D and other activities. Auditing is essential to ensure the correct action is taken to protect any IP that may later be exploited.

5.8.3 Decisions on Exploitation

It is the role of the Assistant Director Research & Development, in consultation with the inventor and other specialist staff, including employees and external, professional advisors, to decide on the potential for an idea / invention to be exploited. In strong cases, the information reported should effectively demonstrate the potential market and the likelihood of success of the venture.

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 appropriate. Without transfer of the IP (assignment), 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. Employees are expected to co-operate with those charged by the Trust to execute its management responsibilities.

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.

Where the Trust chooses not to exploit IP arising from the work of Trust employees, it will, in most cases, assign the IP back to the inventor, who may wish to pursue its further development.

5.9 Contract Negotiations

Any IP that is licensed, sold or otherwise transferred to another organisation will be negotiated in the best interests of the Trust by the Assistant Director of Research & Development supported where appropriate by professional, external advisors.

5.10 Revenue-Sharing with Inventors

The Trust wishes to encourage full participation of employees in the creation and commercial exploitation of IP. The policy will therefore be to reward employees who have contributed substantially to the generation of IP, which has subsequently provided revenue through exploitation. Such revenue will be shared between the Trust and the inventor according to the revenue sharing formula. In all cases the shared revenue will be the net of any protection and exploitation costs (e.g. patent costs).

In all cases, the gross revenue transferred to the Trust, following commercialization of any item of intellectual property, will be used to meet the cost of the activities of the external, professional advisors and/or professional staff employed by the Trust to manage IP.

Following this cost deduction, 30% of the remaining net income received by the Trust will be distributed to the employee who is the inventor of the IP. In cases where several employees have been involved in generating the IP, the proportion of income allocated to inventors will be divided between them on the basis of relative inventive contributions or intellectual effort. It is at the discretion of the inventor(s) to agree to share this income with others if appropriate. Income is defined as 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 and the cost of external professional advisors.

DESCRIPTION OF UNIT	REVENUE SHARING FROM IP EXPLOITATION
Inventor	30%
Trust (central corporate funds)	25%
R&D Office	30%
Inventor's Directorate / Department	15%

5.11 Special Conditions Concerning Copyright

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 or an academic textbook and will waive any claim it may have to benefits arising from the publication. However, the Trust reserves the right to itself at no cost to reproduce and use these publications for its own non-commercial purposes, including teaching and research. 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 and disseminated within or outside the Trust.
- (ii) Any software program generated by an employee in the normal course of their employment
- (iii) Any designs, specifications or other works which may be necessary to protect rights in commercially exploitable IP.

6. Monitoring Compliance and Effectiveness (bold, 12, underlined, small case)

You must include how you are going to identify deficiencies and that you will develop and produce action plans to implement changes accordingly.

Monitoring Requirement :	
Monitoring Method:	<p>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 that they generate may be given to the Department of Health on request.</p> <p>Periodically, audits may be carried out by external, professional organisations and/or professional staff employed by the Trust to manage IP on behalf of the Trust. This process is necessary to identify potential IP arising from R&D and other activities. Auditing is essential to ensure the correct action is taken to protect any IP that may later be exploited.</p>
Report Prepared by:	Assistant Director Research & Development
Monitoring Report presented to:	Clinical Audit & Effectiveness Committee
Frequency of Report	6 monthly

7. **References**

Relevant NHS Documents (published by NHS Executive):

“Policy Framework for the Management of Intellectual property within the NHS arising from R&D”

“The Management of Intellectual property and Related Matters”

“Handling Inventions and other Intellectual property – A Guide for NHS Researchers”

“The NHS as an Innovative Organisation. A Framework and Guidance on the Management of Intellectual property in the NHS”