

MANAGING INTELLECTUAL PROPERTY

Aspects of intellectual property management for the Trust, staff and organisations with which we collaborate.

Department / Service:	Chief Executive's Office
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Approved by:	Clinical Governance Group
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This is the most current document and should be used until a revised version is in place	
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	All departments
Target staff categories	All staff

Policy Overview:

This document outlines the Trust's approach to managing Intellectual Property to safeguard the Trust and the inventor.

Key amendments to this Document:

Date	Amendment	By:
September 2015	New Document	
September 2017	Document extended for 3 months as per TMC paper approved 22 nd July 2015	TMC
Nov 2017	Document extended whilst document under review	TLG
Jan 2018	Policy Reviewed. No changes recommended apart from approval through the CGG.	KS
Dec 2019	Policy reviewed. No changes recommended.	KS

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1. INTRODUCTION

All staff are encouraged to work innovatively and to develop new ways of working which benefit patients and their care. Many innovations will not be patentable or copyrightable but nevertheless have enormous potential benefits if successfully implemented. Staff should be given opportunities to pursue their ideas and the Trust has a responsibility to ensure that advancements in working practices are disseminated across the Trust and, if appropriate, nationally.

This policy sets out the rules of ownership of Intellectual Property arising from employees' work, and its protection and exploitation. It aims to maintain a balance between the legitimate needs of the Trust to protect its interests and the provision of a creative working environment for staff.

Trust employees have the potential to generate significant valuable Intellectual Property (IP) from both within and outside research and development activities. In some cases it will be necessary to protect this IP, to ensure that it benefits the health of patients, the interests of the innovator and the financial position of the Trust.

Intellectual property can be defined as the product of intellectual or creative activity in the form of novel ideas, innovation or research and development (R&D). Like most commodities, IP has the potential to be exploited through licensing or sale. Examples are the development of new techniques, devices, software, pharmaceutical products, formulae and writings. Such ideas and concepts are termed Intellectual Property and, like other kinds of property, can be owned and protected.

Acquiring legal recognition in the form of intellectual property rights (IPR) is an important part of protecting the exploitation process. IPR can be held as a patent, design, copyright, trade mark, database or as confidential "know-how". These are further defined in Appendix A.

Given the potential value of IP to the NHS, it is essential that the Trust instigate a policy to facilitate its protection. The Trust manages its Intellectual Property in accordance with Department of Health (DH) guidance "The NHS as an Innovative Organisation. A Framework and Guidance on the Management of Intellectual Property in the NHS" (DH, 2002). This, and other, guidance documents are available at the NHS National Innovations Centre website, <http://www.nic.nhs.uk/Pages/NHSIPGuidance.aspx>. Whilst this website has closed, there is a wealth of resources still available.

2 PERSONS COVERED BY THIS POLICY

- 2.1 All staff that are full or part time employees of the Trust.
- 2.2 Staff with Trust contracts of employment whose payroll costs are partially or wholly funded by another party (e.g. medical charity, a government department) unless the contract between the Trust and that party assigns ownership of any IP to that party.
- 2.3 Trainee professionals hosted by the Trust who generate IP during the course of their training.
- 2.4 Staff with Trust contracts of employment who are undergoing further education or are involved with joint academic research with another organisation or who have an honorary research appointment at an academic institution.

Where employees have joint contracts with other organisations, for example universities, a partnership agreement on intellectual property issues will need to be developed with each such organisation. Similarly these partnership agreements will need to cover situations in which the NHS would be considered a secondary employer, or where more than one member of staff is involved.

In general, the organisation which is the substantive employer of the principal inventor will be responsible for protecting the IPR and for any commercialisation. Agreement will need to be reached as to the way the costs and benefits will be apportioned between the two organisations. These working arrangements may differ with each particular organisation but the apportionment of benefits arising from jointly-held IP is likely to be based upon the number of inventors employed by each organisation and the level of other resources each organisation has contributed to the creation of the IP.

- 2.5 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.
- 2.6 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.

3 OWNERSHIP OF IP

As a general rule, Intellectual Property created by any person during the course of his/her employment, or training arising out of his/her employment, belongs to the employer. The Trust's conditions on the ownership, use and exploitation of IP are designed to reflect this position under the law: the Trust, on behalf of the NHS, asserts its right to ownership and use of all IP generated by staff during the course of their employment, and it likewise asserts its right to ownership and use of all IP generated by staff outside the course of their employment where substantial Trust resources have been used. The Trust is however committed to sharing with the staff concerned the rewards derived from successful commercial exploitation of IP which they have generated (see below).

There may be circumstances in which the Trust chooses not to take up its rights to the Intellectual Property, in which case the Intellectual Property rights of ownership (IPR) may be assigned to the employee.

Any intellectual property produced by Trust employees outside the scope of their normal duties will belong to the employee. This distinction is in legal accordance with the Patents Act 1977 and the Copyright, Designs and Patents Act 1988. While activities outside the normal duties of the employee that generate IP will normally belong to the employee, the Trust will assert and protect its interests in any IP developed using Trust resources or know-how.

The Trust will not make any claim over income earned by members of staff from academic publications unless an individual has been employed specifically for the purpose of producing a particular publication or where publication might result in the loss of opportunity for commercial exploitation by the Trust.

It is recognised that some IPR is generated on research or other third-party contracts the terms of which may give third parties (usually the funding body in question) rights over

some or all of the IP. Such rights are negotiated between the Trust and the funding body before the research contract in question is signed.

IP exploitation is often an expensive and time consuming process and requires specific expertise, presenting significant challenges for employees with their own IP. The Trust may, at its discretion, invite employees with their own IP to assign ownership to the Trust, in return for which the Trust will take responsibility for its further development and protection; employees will receive a negotiated share of any benefits from the IP, taking into account the costs already borne by the employee and future costs to the Trust. The originator is entitled to receive recompense in the form of a share of the derived net revenue similar to that detailed in section 7.

In many cases ownership of IP is often unclear and may be shared between several parties (it should also be noted that IP ownership can also be transferred between parties to expedite its commercialisation). Given the above, employees are advised to report IP to the Trust R&D Committee to determine ownership and interests. If work or research is conducted by an employee in partnership with another organisation then under UK law each organisation will normally own the intellectual property that its own employees generate. As this position can often result in uncertainty over intellectual property ownership, a formal agreement stating ownership (or sharing) of generated IP is required. The Company Secretary will have primary responsibility for developing IP sharing agreements with collaborating institutions.

If the relative 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 Chief Executive Officer of the Trust will make a final decision, taking professional advice as necessary.

Wherever possible, commercially funded research contracts should provide for the Trust to hold the resulting Intellectual Property to enable it to benefit from its exploitation.

In pricing commercially funded research contracts, regard must always be given to the value of the resulting Intellectual Property and the rights to the Intellectual Property which are granted to the sponsor, as well as the value of existing background Intellectual Property (especially software or patented inventions) which may be used in furtherance of the research project.

4 IP MANAGEMENT

Disclosure of an invention severely compromises opportunities for protection and exploitation. If an employee develops an idea or concept, which may have commercial potential, they must report this to their Director or Senior Manager, and ensure that the Trust's Company Secretary is informed about this at the earliest opportunity and, in any event, before disclosure of the idea to any party outside the Trust, either orally or in writing. Examples include the development of new techniques, devices, software, pharmaceutical products, formulae and writings.

It is often difficult to protect IPR and advice is needed at the earliest stages. If an employee thinks they have an item of Intellectual Property there are a few simple guidelines which will help maximise the chances of being able to protect it:-

- Keep it secret until expert advice has been obtained. Public disclosure (other than under explicit terms of confidentiality) will invalidate any subsequent patent

application and diminish both potential commercial value and benefits accruing to the Trust and the originator. Disclosure without entering into an undertaking of confidentiality may prejudice negotiations of commercial arrangements with a company.

- Resist pressure to announce or publish details until safe to do so (including presenting papers or posters at conferences, abstracts, chapters in books and any other verbal or written communication).
- Avoid giving away or selling samples.
- Don't involve external organisations or companies in testing or prototyping without a written agreement.
- Don't sign any contracts or agreements until they have been properly scrutinised.

It is the responsibility of the Chief Executive to manage and protect IP for the Trust. For information and advice on any matter regarding IP and its protection please speak to the IP Lead, the Company Secretary.

Employees should at the earliest opportunity, inform the Trust (via the R&D lead) about identified or potential IP arising from their activities. Any IP with the potential to be exploited must not be disclosed to anyone outside the Trust until IP advice has been sought from the Company Secretary. IP cannot normally be protected (especially in the case of filing patents) once prior informal disclosure has occurred.

It is Trust's policy to actively encourage employees to publish their work and the Trust will not normally object to an employees' right to be named as an author of copyright material. However, if intellectual property is to be exploited, all work needs to be kept confidential until it is correctly protected.

Despite the statutory provision whereby the copyright in any work produced by an employee in the course of employment belongs to the employer, the Trust normally grants the originator a free licence to the copyright in any work to be published in a recognised scientific, technical, professional, management journal, website or book.

In dealing with an external organisation, it is not always possible to ensure all contact is through the R&D Office. When staff are contacted directly by a third party company, it is important to keep full records, including copies of all correspondence and notes of telephone conversations and meetings, and to supply these to the R&D Office in order to provide detailed accounts of the progress of discussions relating to any Intellectual Property. All records and notes must show the relevant date(s) and action(s) agreed.

It is essential that staff working on projects which generate IP keep written, dated records of their activities and results. This is especially significant for subsequent patent applications in the US, since precedence is awarded to the first to invent, rather than the first to file the patent. It is imperative that all correspondence, including emails, telephone conversations and meetings are logged to provide a detailed account of any discussions relating to the IP. Besides maintaining optimum clinical practice, this diligence is in accordance with clinical and research governance guidelines.

The Company Secretary is responsible for maintaining a register of all the IP owned by the Trust, including the date and time it was reported to the R&D Office. Records will also be kept of arrangements entered into by the Trust for the protection and subsequent use of the Intellectual Property, including any disclosures made to a third party.

Audits will be periodically carried out by or on behalf of the Trust. This process is essential to identify potential IP arising from R&D and to ensure that the correct action is taken to protect any IP that may later be exploited.

5 DECISIONS ON EXPLOITATION

There are two main routes for commercialisation of the product, licensing and the creation of a spin out company.

5.1 Licensing

With licensing, the licensor normally secures a combination of a fixed “one off” licence fee and an agreed percentage royalty payment. With a company, the commercial value related to an equity stake in the new company (share ownership).

Any IP that is licensed, sold or otherwise transferred to another organisation will be negotiated in the best interests of the Trust by professional advisers. In the case of IP assigned to the Trust, it is the role of the R&D Office, in consultation with other specialists (e.g. the local IP Hub, patent agents, legal representatives), to decide on the potential for an idea/invention to be exploited.

Intellectual Property management decisions such as whether to patent or license reside with the Trust Board but may be delegated to the Company Secretary for UK patents and to the Chief Executive for all other patent applications. The Trust is the vehicle for holding patents and other Intellectual Property, but is empowered to engage another organisation to exploit its Intellectual Property on its behalf.

In cases where the Trust declines to proceed with the exploitation of an opportunity, ownership of the IP will normally be reassigned by the Trust back to the inventor.

All commercial exploitation activity is co-ordinated by the Company Secretary. Members of staff who are the originators of Intellectual Property are expected to co-operate with those responsible for its exploitation so that the maximum possible benefit is obtained.

Staff are reminded that no steps should be taken to exploit Intellectual Property that has been assigned to the Trust without the approval of the Trust Board. Staff are required to co-operate with the Company Secretary in the carrying out of its management responsibilities for Intellectual Property.

5.2 Creation of a spin out company

The formation of a company may be the most appropriate commercialisation route where an invention/technology needs to be developed to a point where it can attract external funding or be licensed. By creating a stand alone commercial entity it is possible to access public and private development funding intended for small business. A spin out company, rather than the normal route of licensing, is often appropriate where there are good long term prospects of a commercial return but the short term development costs and risks deter the private sector from getting involved at such an early stage. The IP is used as the asset to raise finance in return for an appropriate share of the equity.

In general terms licensing is the lower risk option, which also provides for an immediate return on investment. However, there are specific occasions, such as those described above when the creation of a new 'spin-out' company is more appropriate.

With a NHS Trust, the formation of a company is known as a 'spin-out' company. This essentially involves transferring the IPR to the new company and taking shares in the 'spin-out' (this could apply to an inventor who is an employee, as well as the institution depending on contractual arrangements).

Returns to the shareholders will be subject to the future success of the business. It should be noted that specialist skills are required to operate a business, particularly a high risk 'spin-out' business, and the future success and profitability of the company will depend on the quality of the Executive. Indeed, a decision by a Venture Capitalist to invest in a new company will often be based as much on the quality of the Executive as to the novelty and commercial potential of an invention/new technology.

If a spin out company is deemed to be the best for the inventor and Trust, further advice should be sought from the Company Secretary before proceeding any further. The possible process is shown in Appendix B.

6 TRAINING

IP issues will be included in general R&D training initiatives as and when these take place in the Trust. All new employees with an interest in R&D will have the intellectual property policy and procedures brought to their attention through the Division and the R&D function of the Trust. It will also be referred to in all new contracts of employment.

7 REVENUE-SHARING WITH INVENTORS

The Trust wishes to encourage full participation of employees in the creation and commercial exploitation of IP.

The policy will reward staff that have contributed substantially to the generation of IP which has subsequently provided exploitation revenue. Such revenue will be shared between the Trust and the inventor according to the revenue sharing formula.

In cases where several staff 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. In all cases the shared revenue will be the net of any protection and exploitation costs (e.g. patent costs).

The Cumulative Net Income received by the Trust will be shared as follows:

Cumulative Net Income	Inventor	Clinical Division	Trust
First £50,000	50%	25%	25%
Next £100,000	40%	30%	30%
Next £100,000	30%	35%	35%
Over £250,000	25%	35%	40%

Net income refers to the income remaining after recovery of patenting and other out of pocket costs incurred by the Trust in identifying, protecting and exploiting the Intellectual Property.

Where there is a contractual agreement with a funding sponsor to share the revenue from successful exploitation of Intellectual Property arising from research funded by that sponsor, the Cumulative Net Income to the Trust is the income from exploitation remaining after deduction of the sponsor's share.

8 MONITORING AND COMPLIANCE

IP activity will form part of the R&D Annual Report.

9 References

Leeds Teaching Hospitals NHS Trust Policy on Intellectual Property
<http://www.leedsth.nhs.uk/research/intellectual-property/>

Managing Intellectual Property, MIDTECH

10 Policy Review

This policy will be reviewed every two years, or sooner, if there is a significant policy change. The next review date is December 2022.

11 Background

Consultation

Consultation will take place with the Divisional Directors, Executive Management Team, Associate Medical Directors.

Approval process

Approval will be sought through the Clinical Governance Group.

Equality requirements

No adverse equality requirements have been identified.

Financial risk assessment

No adverse financial requirements have been identified.

APPENDIX A

INTELLECTUAL PROPERTY PROTECTION

This appendix includes a very brief overview on some aspects of IP protection. It must be noted that the law is complicated and members of staff are advised to contact the Company Secretary at the earliest opportunity to discuss more detailed information on IP protection.

i. COPYRIGHT

Copyright covers written information (such as leaflets, articles, assessment tools and training packs), databases, computer software and films/videos, which can all be protected by copyright. Copyright is achieved automatically, when the IP is created. However, it is advisable to attach a statement for additional protection, such as:

© Copyright Worcestershire Acute Hospitals NHS Trust, 2014. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner.

ii. PATENTS

Patents can be used to protect inventions that embody a new idea and are capable of being manufactured or used by industry (such as devices, processes or methods of operation). Examples of exclusions would be methods of treatment of the human/animal body by surgery or therapy, or diagnostic methods. An invention must not have been made public anywhere in the world prior to the patent filing date (journals, internet, meetings, posters, etc.) and must not be an obvious development, with regard to what is already common knowledge to someone who is experienced in the relevant field.

iii. DESIGN RIGHTS

Design Rights protect against deliberate copying of the shape or configuration of an article. Design Right may exist in addition to other forms of protection such as Patent, Copyright or Registered Design.

iv. UNREGISTERED DESIGN RIGHTS

Unregistered Design Rights are not directly associated with appearance. The right can protect internal and external features but only gives protection against copying of features of shape and configuration (e.g. physical design of computer chips, engineering components and architectural drawings).

v. REGISTERED DESIGN RIGHTS

In some new products, the novelty lies not in a new idea or principle but in their appearance. Registered Design Rights usually cover commercial objects with a unique or aesthetic appearance.

vi. TRADEMARKS

A trademark is a sign or symbol that is used to distinguish a product or service from that produced or supplied by another business. It could be the design of a label or the shape of a product's packaging (for example, the Coca-Cola bottle). The term "sign" includes logos, slogans, words, colours and 3-D shapes.

Registering a trademark protects the owner from competitors also trying to use that image to promote their own products. Trademarks can be very valuable in keeping that product as a market leader.

vii. KNOW-HOW

Confidential information or "Know-how" is information which may be commercially or technically valuable and which is regarded as secret. It may, for example, include information on industrial processes.

In all cases, the "know-how" will only retain its value if it is managed effectively. All exploitation partners, business partners and collaborators should be bound by conditions of confidentiality through a Confidential Disclosure Agreement (CDA). This may be a reciprocal agreement whereby confidential information is both disclosed and received. A CDA may be obtained from the Company Secretary.

Know-how and confidential information can be bought, sold and licensed like any other form of IP and persist indefinitely, as long as they remain "secret".

Appendix B

PROCESS GOVERNING CREATION OF A SPIN-OUT COMPANY

For each spin-out company, a Local IP advisory group (“the Group”) is established comprising;

- Director of Resources (or designated deputy)
 - Company Secretary
 - Medical Director (or designated deputy)
 - Associate Medical Director for Research and Development
 - Non-executive Board member
 - Member from the health local research network
- The Group will take responsibility for ensuring that due process is followed and that the Board is informed of progress and any key risk issues.
 - The Group has responsibility for ensuring the Trust Board/Chairman is advised when the creation of a spin-out company and purchase of shares is being considered for their approval. Where venture capital provides an opportunity for investment a rapid decision may be required for the creation of the spin-out company and Trust shareholding. If a decision is required outside the Trust Board meetings, the Group will instigate a ‘Trust Board Chairman’s Action’¹ and, if approved this will be reported to the Board at their next meeting. The Chair of the Group has delegated authority to sign the Shareholders Agreement and assign IPR. The Group is required to document risk assessments and will consider the need for additional legal advice at appropriate stages.
 - Periodically a spin out company may need to seek additional or new capital which may require changing the shareholding of the Trust. The Group will evaluate all such requests and document its conclusions and recommendations. The Chair of the Group has delegated authority to sign any new or revised Shareholders Agreements following approval by the Trust Board.
 - Key documentation includes:-

Articles of Association - The Articles of Association contains the internal regulations and bye-laws covering procedure, shares, meetings, directors and other administrative issues and is commonly based on Table A taken from the Companies Act.

Memorandum of Association – The Memorandum of Association is the first constitutional document of a company containing fundamentals such as the name, the company’s objects and powers, and its original share capital.

Shareholders Agreement – This is a legal documentation signed as a deed of trust by all parties that is used where two or more parties wish to carry on business together as a limited company (limited by shares) and wish to regulate the relationship between shareholders, and determine actions in the event of deadlock. It sets out what restrictions there may be on share dealing (buying & selling), warranties and liabilities and who the directors are.

Assignment of IP - It is normal practice to, either transfer the ownership or licence of the rights to the IP (patents, ‘know-how’ and access to data) in to the company. Generally, this

¹ Please see Trust Standing Orders, paragraph 5.3 (Emergency Powers and Urgent Decisions)

is the major asset around which external investors would be prepared to invest. Usually the patents are assigned ownership passes to the company and its shareholders, but occasionally a licence is used.

- The Group will ensure that the process followed is in accordance with the DH Framework document and other documentation, and will review the need for additional external, legal, advice throughout the process.

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
2	Is there any evidence that some groups are affected differently?	No	
3	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
4	Is the impact of the policy/guidance likely to be negative?	No	
5	If so can the impact be avoided?	N/A	
6	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7	Can we reduce the impact by taking different action?	N/A	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1	Does the implementation of this document require any additional Capital resources	No
2	Does the implementation of this document require additional revenue	No
3	Does the implementation of this document require additional manpower	No
4	Does the implementation of this document release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	No