

INTELLECTUAL PROPERTY POLICY

| | |
|--|--|
| Approved By: | Policy and Guideline Committee |
| Original Approval Date: | 22 October 2010 |
| Latest Approval Date: | 20 January 2023 |
| Trust Reference: | B35/2010 |
| Version: | 6 |
| Supersedes: | Version 5 - December 2021 |
| Author / Originator(s): | Tim Skelton, Research and Innovation Chief Operating Officer |
| Name of Responsible Committee/Individual: | UHL Medical Director |
| Latest Review Date | 20 January 2023 – Policy and Guideline Committee |
| Next Review Date: | April 2026 |

CONTENTS

| Section | | Page |
|---------|---|------|
| 1 | Introduction | 4 |
| 2 | Policy Aims | 4 |
| 3 | Policy Scope | 5 |
| 4 | Definitions | 6 |
| 5 | Roles and Responsibilities | 6 |
| 6 | Policy Statements and Procedures 6.1 General 6.2 Disputes of Ownership 6.3 What happens to revenue the Trust receives from IP? 6.4 Publications 6.5 Confidentiality 6.6 Intellectual Property Management structure 6.7 Exploitation of Intellectual Property | 8 |
| 7 | Education and Training | 13 |
| 8 | Process for Monitoring Compliance | 13 |
| 9 | Equality Impact Assessment | 14 |
| 10 | Supporting References, Evidence Base and Related Policies | 14 |
| 11 | Process for Version Control, Document Archiving and Review | 15 |

| Appendices | | Page |
|------------|----------------------------------|------|
| 1 | Intellectual Property Protection | 11 |

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

September 2021 review of version 3: Main changes relate to the Introduction and background which have been updated. The Trust now uses a different provider for IP advice – Medipex. The declaration of IP and the process have been changed to reflect changes in R&I workforce.

August 2022 review of version 4: Main changes are a change from use of ‘employee’ to ‘staff’ and clarification that the revenue sharing policy as stated applies to inventions, whereas other types of IP are dealt with on a case-by-case basis.

January 2023 review of version 5: We revised the IP policy in light of feedback on previous version received from UHL colleagues. We have consulted with UHL legal team and externally with CAPSTICKS, and conducted a limited national review for the most current legal position around IP ownership. We believe that the revised document

reflects the most current legal position and that of our close partner University of Leicester and that of other NHS trusts. We have harmonised the revenue share section to reflect that of University of Leicester and also revised the revenue share to better incentivise potential inventors in UHL.

KEY WORDS

'Intellectual Property', 'Patents', 'Copyright', 'Revenue Sharing', 'Commercialisation', 'Invention', 'Innovation'

1 INTRODUCTION

NHS policy frameworks and guidelines supported by relevant legislation including the Health and Social Care Act 2001 (see section 10 below) place a duty on the Trust to protect and exploit intellectual property generated by its employees in the course of their normal duties for the benefit of patient care, staff and the wider health care community.

The NHS recognises the need to develop as an organisation which has innovation at the core of its business, developing new products and service innovations for better health care delivery. Innovation occurs naturally in the normal course of employment at all levels throughout the NHS.

The innovation may be a novel treatment, device, new drug, data, software, training program or a new management system. Most innovations are best implemented by making them freely available through normal knowledge management processes once they have demonstrated a quantifiable health service gain. However, some innovations can only be realised through commercial development; for these innovations, professional management of the associated Intellectual Property (IP) is crucial.

The NHS recognises that the protection of IP facilitates rather than impedes the uptake of innovations with commercial potential. All of these considerations made it desirable for the Trust to develop this policy, which outlines how the Trust with the aid of specialist organisations within the NHS will protect and manage the IP created by its employees for the improvement of healthcare while ensuring that any revenue generated is shared equitably with the employees creating the IP.

Background

In 2002 the Department of Health (as it was then) published a Framework and Guidance on the Management of Intellectual Property in the NHS. The Framework and Guidance builds on the previous 1998 policy published in the Health Service Circular HSC 1998/106, which dealt with the management of IP arising from Research and Development (R&D) funded in whole or in part from the NHS R&D Budget. The Framework and Guidance extended the 1998 policy to include IP generated by all NHS employees involved in healthcare delivery. As a result of this, IP generated from any source is now recognised by the NHS as an asset of value which should be managed in the best interests of NHS patients, employees and society as a whole.

All NHS Trusts are required to ensure that IP arising within their trusts is managed within the given Framework and according to the provisions of Section 5 of the Health and Social Care Act 2001. Under the 1998 policy, Trusts already have the power to generate income through commercial exploitation of IP. The Health and Social Care Act is aimed at supporting the delivery of the NHS Plan, and is intended to enable Trusts, subject to the approval of a

business case, to take a shareholding in spin-out companies set up as a vehicle to exploit IP provided that it does not interfere with its functions or obligations under NHS contracts.

Income generated by successful commercial exploitation of IP arising from the Trust will be retained by the Trust and shared with inventors as set out below.

Trusts are advised by the Department of Health to appoint at least one organisation to provide high quality IP management advice on their behalf.

2 POLICY AIMS

- 2.1. The 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.
- 2.2. 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 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 (as detailed in Section 6.7.4).

3 POLICY SCOPE

This policy extends to the following staff categories:-

- 3.1. All staff that are full or part time employees of the Trust
- 3.2. 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). 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.
- 3.3. Staff who have a part-time Trust contract and who are self-employed or otherwise employed part-time.
- 3.4. Trust employees who 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.

- 3.5. Trainee professionals hosted by the Trust who generate IP during the course of their training.
- 3.6. Staff who generate IP outside normal working hours and / or away from the place of work, where the IP relates to their area and nature of their employment duties within the Trust.
- 3.7. 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.
- 3.8. Contractors whose contracts require them to adhere to the Trust's policies and procedures.

4 DEFINITIONS

- 4.1. **Intellectual property** is defined as products of intellectual or creative activity in the form of novel ideas, innovation or research and development (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, trade marks or know-how (see Appendix 1).
- 4.2. **An inventor** is defined as the person or one of the persons without whose intellectual contribution the development would not have taken place.
- 4.3. **Distributable 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, and IP management/exploitation costs.

5 ROLES AND RESPONSIBILITIES

- 5.1. **The Director of Research & Innovation (R&I)** via the R&I has overall responsibility for managing IP assigned to the Trust. The medical Director is the UHL Board executive lead for IP.
- 5.2. **R&I** are responsible for:
 - a) Managing and protecting IP for the Trust.

- b) Maintaining a register of all the IP owned by the Trust.
- c) Keeping safe any important original documents, such as confidentiality disclosure agreements, relating to IP. It is advisable that the members of staff concerned with the project should also retain copies of these documents.
- d) If work / research is conducted by an employee in partnership with another organisation, a formal agreement stating ownership (or sharing) of generated IP is required. The R&I will have primary responsibility for developing IP sharing agreements with collaborating institutions.

5.3. **All employees** must follow the staff procedures set out in this document.

5.4. **Staff** have an obligation **to inform** the Trust via the R&I Department 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. This may be done directly to the R&I Department via the R&I Contracts and IP Manager, or the The Research and Enterprise Division (RED) team at the University of Leicester, using the contact details that are at the end of this policy.

Staff are required to declare any patents and other intellectual property rights as per the Trust's policy titled 'Managing conflicts of interest in the NHS' (including gifts and hospitality). Declarations should be made to the Trust's dedicated mailbox declarationsofinterest@uhl-tr.nhs.uk.

Copyright protects any literary or artistic work which is original, and arises automatically, but employees should include a copyright notice on any text, source code, design etc. which they have created. This should take the form of © University Hospitals of Leicester NHS Trust [YEAR OF CREATION]. A copy of the copyright document should be sent to R&I.

5.5. **Staff** have an obligation **to keep written, dated records** of their activities and results. This is especially important for patent application purposes in the USA, since the USA has a policy of 'first to invent' rather than the 'first to file' rule in the UK. When exploiting IP it is imperative that all correspondence, including e-mails, telephone conversations and meetings are logged to provide a detailed account of any discussions relating to the IP. This is in accordance with clinical governance, research governance and good clinical practice guidelines.

5.6. **Staff** have an obligation **to keep confidential** any information relating to their research, and to only disclose it under a Non-disclosure Agreement, until such time as R&I have confirmed that it is not patentable.

- 5.7. **Staff** must not enter negotiations with third parties about ownership of IP without involving R&I.
- 5.8. **Staff** entering into joint research with third parties must consider IP ownership at as early a stage as possible; preferably, before any research begins. With R&I's help, they must agree a contract with the third party or parties stating (a) who owns the IP, (b) who will manage it and how costs are to be met, and (c) how any benefit is to be shared. It is generally advisable for one organisation to be given exclusive rights to exploit the jointly owned IP, granting a licence to the other owners, and agreeing to use best endeavours to exploit the IP.
- 5.9. **Staff** must give all necessary assistance to the Trust in protecting and enforcing IP rights. This duty may apply after the staff member has left the Trust.
- 5.10. The RED team at the University of Leicester will provide advice on and assistance with the protection and exploitation of valuable IP.

6 POLICY STATEMENTS AND PROCEDURES

6.1. General

- a) If a member of the staff (an employee) of the Trust creates or generates any intellectual property (for example, an invention, information/results, a database, source code or a new design) in the course of performing their duties, generally the rights in that intellectual property belong to the Trust.
- b) In addition, if any other person working for or within the Trust creates or generates intellectual property while working for the Trust, the normal rule which the Trust will apply is that rights belong to the Trust. This is intended to apply to consultants, visiting research students and other categories of non-employed staff. In practice, in each case the position is also likely to be affected by the contract under which the work is being carried out, or relevant research contracts.
- c) In each case, this includes activities carried out wholly or partly under Trust auspices. It also includes activities using Trust facilities, and works carried out during time for which the member of staff receives financial reward or

remission of duties or responsibilities from or through the Trust, for example where they are given time off to write a book.

- d) In any case, it may also be important that the Trust own the rights, as the Trust may have entered obligations with third parties in relation to the intellectual property rights. It is important that the rights initially belong to the Trust so that it can comply with those obligations.
- e) In cases where the intellectual property does not belong to the Trust, but has been generated by use of, or access to, Trust resources, this must not be exploited without prior written consent from the Trust. The Trust will not unreasonably withhold consent but may, in its discretion, require a reasonable reward reflecting the contribution made from its resources.

6.2. Disputes regarding Ownership

If the ownership of IP is disputed, dated written records relating to the IP in question will be assessed by the Director of R&I or their nominated deputy 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 independent professional legal advice if necessary and seeking, where necessary, the approval of the Chairman.

6.3. What happens to Revenue the Trust receives from IP?

To encourage staff to contribute to the generation of IP, the Trust operates a reward scheme for staff creating or generating IP which subsequently becomes commercialised. Revenue from patents will generally be shared between the Trust and the inventor according to the Trust's revenue sharing policy, the current version of which is set out in Section 6.7.4.

In cases where there are a number of inventors, the income allocated will be divided between them. In all cases, the shared revenue will be net of any protection and exploitation costs incurred by, or on behalf of, the Trust.

6.4. Publications

- a) Prior publication, before the date of filing an application to register intellectual property, must be avoided at all costs because any non-confidential disclosure before the date of filing a patent or design application can invalidate the application.

- b) It is the Trust's policy to actively encourage employees to publish their work and the Trust will not normally object to an employee's 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.
- c) Advice must be sought from R&I before publicly disclosing any work, where there is a possibility that IP will need to be protected.

6.5. Confidentiality

Any IP with the potential to be exploited must not be disclosed to anyone outside the Trust (including presenting papers or posters at conferences, abstracts, chapters in books and any other verbal or written communication), until IP advice has been sought from R&I. IP cannot normally be protected (especially in the case of filing patents) once disclosure has occurred, no matter how informal. Prior to any disclosure a Confidentiality Agreement should be signed between the Trust and third party to govern information transfer. The Trust approved confidentiality agreement is available from R&I. Signature on behalf of the Trust must be arranged by R&I.

6.6. Intellectual Property Management Structure

- a) The Contracts Manager in R&I is the initial contact point for advice and can provide details of the support available for the management of IP.
- b) Any employee wishing to discuss the protection of any idea or other form of IP should discuss the matter with R&I at the earliest opportunity and, in any event, before disclosure of the idea to any party outside the Trust either orally or in writing. Care must also be applied not to disclose internally except to those who are directly related to the generation of the IP or providing requisite professional advice. 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 that they are reported through the correct channels. All employees should be aware of the importance of avoiding improper disclosure of their invention.
- c) Employees should keep accurate and dated laboratory notebooks/research files 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.

- d) The R&I department maintains a register of all IP rights owned by the Trust which have been licensed or assigned to a third party where an employee/staff member 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 and Social Care on request.

6.7. Exploitation of Intellectual Property

6.7.1. IP Audits and Evaluations

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

6.7.2. Decisions on Exploitation

- a) It is the role of R&I, in consultation with the inventor and other specialist staff, including employees of Medipex, 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.
- b) 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 R&I. Employees are expected to co-operate with those charged by the Trust to execute its management responsibilities.
- c) The Trust may, at its absolute discretion, decide that the IP is best exploited through a spin-out company. A spin-out company can be defined as a new, small, company formed to exploit IP developed during the course of an individual's employment in a larger organisation.
- d) 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 discussion and co-operation with the employee and the Trust and with those responsible for setting up the company.

- e) Where the Trust chooses not to exploit IP arising from the work of Trust employees/staff members, it will assign the IP back to the inventor, who may wish to pursue its further development.

6.7.3. 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 professional advisors.

6.7.4. Revenue-Sharing with Inventors

- a) The Trust wishes to encourage full participation of staff in the creation and commercial exploitation of IP. The policy will, therefore, be to reward staff who have contributed substantially to the generation of patentable IP, which has subsequently provided revenue through exploitation. Such revenue will be shared between R&I (on behalf of the Trust), and the inventors. In all cases, the shared revenue will be net of any protection and exploitation costs (e.g. patent costs, or revenue due to third parties). A table showing the split revenue is referenced in 6.7.4 (d) below.
- b) Currently, the net income received from IP by the Trust will be distributed to the employee/staff member who is the inventor of the IP. In cases where several employees have been involved in the generation of IP, the proportion of the income allocated to inventors will be divided between them on the basis of the relative inventive contributions or intellectual effort. It is at the discretion of the inventor(s) to agree this share of income with others if appropriate.
- c) Please note that the Secretary of State may step in and insist the revenue (if excessive) is used elsewhere in the NHS.
- d)

| Cumulative Income | Inventor(s) | Trust |
|-------------------|-------------|-------|
| Up to £10k | 80% | 20% |
| Next £20k | 75% | 25% |
| Next £100k | 60% | 40% |
| Next £200k | 50% | 50% |

| | | |
|------------|-----|-----|
| Over £250k | 30% | 70% |
|------------|-----|-----|

6.7.5. 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. However, the Trust will normally assign to the author its 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. The Trust, in doing so, reserves the right to itself, at no cost, reproduce and use these publications for its own non-commercial purposes, including teaching and research. The Trust does not assign copyright to the author in, without limitation:

- (i) course or training materials;
- (ii) patient information;
- (iii) software programs;
- (iv) designs, specifications or other works which may be necessary to protect rights in commercially exploitable IP.

As noted above (under paragraph 5.4), [employees should include a copyright notice on any text, source code, design etc. which may be valuable. This should take the form of © University Hospitals of Leicester NHS Trust \[YEAR OF CREATION\]. A copy of the copyright document should be sent to R&I.](#)

7 EDUCATION AND TRAINING

There is no specific training for this policy, advice regarding IP and this policy can be sought from the R&D Department

8 PROCESS FOR MONITORING COMPLIANCE

Scope:

All innovation projects reported to R&D Department
 Research projects processed by the R&D Department

| Element to be monitored | Lead | Tool | Frequency | Reporting arrangements | Lead(s) for acting on recommendations |
|-------------------------|------|------|-----------|------------------------|---------------------------------------|
|-------------------------|------|------|-----------|------------------------|---------------------------------------|

| | | | | | |
|--|--|---------------------|-------------|--------------------------------------|-----------------------------|
| *IP/Innovation projects reported to R&I and /or Medipex | R&I Chief Operating Officer | IP Audit by Medipex | Annual | R&I Executive Trust Board (annually) | R&I Chief Operating Officer |
| *Staff working on projects that generate IP keep written, dated records of their findings and activities | R&I Chief Operating Officer | IP Log | Monthly | | |
| *When exploiting IP is all correspondence logged? | | E-mail audit | As Required | | |
| *Are confidentiality agreements signed to govern information transfer prior to any disclosure | | Audit R&I | Annually | | |

9 EQUALITY IMPACT ASSESSMENT

- 9.1. The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
- 9.2. As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

10 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

Relevant NHS documents (published by the Department of Health and Social Care):

- [HSC 1998/106: Policy framework for the management of intellectual property within the NHS arising from research and development](#) (published on 6 July 1998). By virtue of this NHS circular, NHS Trusts are obliged to put in place arrangements for the protection of intellectual property.

- *Handling inventions and other intellectual property: a guide for NHS researchers* (published on 1 July 1998). The purpose of this document is “to raise awareness amongst researchers involved in R&D funded by the NHS as to the potential value of intellectual property arising from their work and of the issues involved in its exploitation.”
- *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* (published in 1998).
- *The NHS as an innovative organisation: a framework and guidance on the management of intellectual property in the NHS* – was added to the list of “supporting booklets” in 2002. This extended the 1998 policy to include IP generated by all NHS employees involved in healthcare delivery.
- *Health and Social Care Act 2001*

11 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

This document will be uploaded onto SharePoint and available for access by Staff through INsite. It will be stored and archived through this system.

This Policy will be reviewed and updated every 3 years by the Director of R&I.

12 CONTACTS

Chirag Sonrat
 IP & Contracts Manager
 R&I Department
 Leicester General Hospital
 Gwendolen Road
 Leicester LE5 4PW
Email: chirag.sonrat@uhl-tr.nhs.uk
Telephone: 07977 371363

The Research and Enterprise Division (RED) University of Leicester
Email: red@le.ac.uk
Telephone: 0116 252 2437

INTELLECTUAL PROPERTY PROTECTION

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

1 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:

*“©University Hospitals of Leicester NHS Trust, [YEAR of CREATION]. All rights reserved.
Not to be
reproduced in whole or in part without the permission of the copyright owner.”*

2 Patents

Patents can be used to protect inventions that embody a new idea and are capable of being made or used by industry (such as devices, processes or methods of operation). Exclusions from this include methods of treatment of the human / animal body by surgery or therapy, or methods of diagnosis. An invention must not have been made public anywhere in the world prior to the patent filing date (including journals, the internet, meetings, posters, etc.) and must not be obvious, compared to what is already known to someone who is experienced in the relevant field.

3 Design Rights

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

3.1 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).

3.2. 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.

4 Trade marks

A trade mark 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 trade mark 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.

5 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 or be a list of clients.

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 R&I Department.

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".