Intellectual Property Policy

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Reference number	WHHT: R003
Document type	Policy
Version	6.1
Author's name & job title	Fiona Smith – Associate Director, R&D
Department/Speciality	Research and Development
Division	Corporate
Reviewed by	Research & Development Steering Group
Review date	09/02/2023
Approved by PGRG	22/02/23
Ratified by QSG	27/02/23
Next review date	09/02/2026
Target audience	Research & Development
Search terms	'Intellectual', Property', 'Policy'
Previous document name (if different)	

Contribution List
Key individuals involved in developing this version of the document

Name	Designation
Fiona Smith	Associate Director of R&D

Change of History

Version	Date	Author	Reason for change
1	Feb 2006	Fiona Smith	New
2	Sept 2008	Fiona Smith	Review
2.1	Sept 2011	Fiona Smith	Review
3	Aug 2012	Fiona Smith	Updated guidance from NHS Innovations East
4	Sept 2015	Fiona Smith	Formal review
5	Oct 2017	Fiona Smith	Formal review
6	Oct 2019	Fiona Smith	Formal review
7	Feb 2023	Fiona Smith	Formal review

Abbreviations and Acronyms

Abbreviations and Acronyms	Description
MDT	Multidisciplinary Team
PGRG	Policy & Guideline Review Group
QSG	Quality & Safety Group

Contents

1. Introduction

Recent NHS policy frameworks and guidelines supported by the Health and Social Care Act 2001 place a duty on the Trust to protect and commercialise 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 material 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 whilst ensuring that any revenue generated is shared equitably with the employees creating the IP.

1.1 Background

In 2002, the Department of Health 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 and Primary Care 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 commercialisation 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 commercialise IP provided that it does not interfere with its functions or obligations under NHS contracts.

Income generated by successful commercialisation of IP arising from the Trust will be retained by the Trust and shared with inventors.

1.2 Aim

The aims of the Trust's Intellectual Property Policy are:

- to clarify the IP ownership and management arrangements adopted by the Trust
- to ensure the NHS/Trust benefits from IP arising from NHS funded activity
- to encourage staff/researchers to consider the relevance of their work (whether R&D or not)
- to enhance IP identification and management
- to promote commercialisation, where appropriate

2. Objectives

The overriding objective of the Policy is to promote the use of research results and other knowledge generated within the Trust to benefit a wider community, and if possible to obtain a commercial benefit to the Trust in doing so.

3. Definitions

Intellectual Property (IP)	IP can be described as the novel or previously un-described tangible output of any intellectual and creative activity. It can arise in the form of ideas, inventions, discoveries, software, digital platforms, research material, know-how & expertise, designs and images. Like physical propriety it can be bought, sold or licensed and must be adequately protected. IP property rights are protected by law and enable to owner to control the IP and be rewarded for its use.
IP Lead	The individual within the Trust able to advise and liaise with external IP advice.

4. Scope

What the Policy covers:

4.1 Invisible value

The Trust generates valuable information and intellectual property in many of its activities.

4.2 Objectives

The aim of the Trust is to promote wide and effective use of such information and ideas generated within the Trust, if possible with a commercial return to the Trust which it can reinvest in its activities; and to that end to identify valuable information and rights, to secure appropriate protection, and to promote use; and to educate those involved in the value and opportunities which may arise.

4.3 Application

Intellectual property provides the basis for protecting information, ideas and developments: from new drugs or methods of diagnosis, to papers, manuals and forms; from software and collections of data to new procedures. It arises from research, but also in day to day activities in the Trust. Examples are rights in inventions, copyright in papers, books, or collections of information and data and in software, rights in designs, and trade and brand names used by the Trust.

4.4 Who owns it
In general, intellectual property rights generated by those working in the Trust in the course of their work, belongs to the Trust. In relation to some types of work, such as academic books, the Trust may transfer its rights to the person involved.

4.5 Third party contracts
In some cases there will be contractual arrangements under which the arising intellectual property belongs to a third party. Normally, unless a third party in the private sector meets the full cost of any research or development, the Trust will expect to retain an interest in the intellectual property. Staff should ensure they are familiar with any relevant third party contract, so as to meet any requirements in relation to reporting and protection of intellectual property.

4.6 Thinking "intellectual property"
All those working in the Trust should consider whether any developments, ideas or results they or their colleagues generate or information or data they collect, could be used to benefit others, especially outside the Trust. If so they should review this with the person to whom they report, or the Trust's IP Lead.

4.7 Protection
If such material is potentially valuable, those in the Trust should ensure that they report this, with appropriate details, to the person they report to, or to the Trust's IP Lead, so that appropriate steps can be taken to protect any relevant intellectual property. Until appropriate protection is obtained, those who know of the material should avoid doing anything which might damage its value (and in particular disclosing information without protection), as long as this can be achieved while doing their job.

4.8 Publication and disclosure
Publication and dissemination of relevant ideas and information is important. However, unless the appropriate steps are taken in advance, disclosure to others outside the Trust may invalidate any protection. Staff involved should therefore not disclose information to anyone outside the Trust without considering whether it is valuable, or whether disclosure could be damaging to the Trust, and if so, permitting the Trust to put in place appropriate protection. This may be in the form of confidentiality agreements, copyright notices, or, in suitable cases, patent protection - if in doubt, you should consult the person to whom you report or the Trust's IP Lead.

4.9 Evaluation
The Trust's IP Lead will consider, in conjunction with you, the value of the material, what steps can be taken to promote the wider beneficial use of any material, and whether commercialisation is appropriate; what steps are appropriate to take to protect the material. The Trust's IP Lead may review this with a panel of advisors.

4.10 Commercialisation
If appropriate the Trust's IP Lead will advise on what steps should be taken to promote wider dissemination, and/or prepare a plan to implement suitable commercialisation, and will report the conclusions to you. The Trust will not normally be willing to undertake significant risks in the course of commercialisation and where commercialisation is possible, the Trust will look to a third party to assume such risks.

4.11 Sharing the benefits
If revenue arises for the Trust from commercialisation of any material, after accounting for any costs it has incurred the Trust will share a part of the benefit with you in accordance with the current revenue sharing policy.

4.12 Additional assistance
Those involved should provide such assistance as the Trust's IP Lead requests to help protect and permit commercialisation of relevant material. In some cases they may be required to sign documents relating to rights in the material.

4.13 Own development
If the Trust concludes that it is not appropriate for it to be involved in commercialisation, unless there are reasonable grounds for it not doing so, it will allow you to take steps to commercialise the results yourself. The Trust may need to maintain some control, in order to protect its interests or the interests of patients.

4.14 The Trust's name
The Trust's name and brands are valuable assets of the Trust. It is important that they are not damaged by inappropriate use, and at the same time that the Trust can be promoted by use of its name in the right circumstances. Any use of the Trust's name in relation to any publication or other publicity should be cleared with the Trust's IP Lead in advance, and advice obtained on how the name may be used.

4.15 Records and Administration
The Trust will maintain an administrative procedure for handling the matters set out above, and will maintain records of developments, ideas, and other information reported under this policy. In addition, so far as is relevant, the Trust will implement the terms of this policy in contracts of employment for staff, and in relation to research and other contracts with third parties.

5. Responsibilities
The Associate Director, R&D will have primary responsibility for agreeing IP sharing agreements with collaborating institutions.

6. Procedure

6.1 Intellectual Property
Intellectual Property is the novel or previously un-described tangible output of intellectual and creative activity. IP can arise in the form of ideas, inventions, discoveries, software, digital platforms, research material, know-how and expertise, designs and images. Like physical property, it can be bought, sold or licensed to others.
Intellectual property rights (IPR) are rights which are protected by law, and which enable the owner to control the IP and be rewarded for its use, encouraging further innovation.

The main intellectual property rights are:

Patents (for inventions, covering for example new diagnostic tests or surgical equipment, new drugs, and new processes and equipment). A patentable invention is a product or process which is new (or novel), involves an inventive step, and is capable of industrial application. Patents must be registered to be effective. Publication of results before seeking patent protection may be fatal to the protection of the invention. An invention must not be obvious development, compared to what is already known to someone who

is experienced in the relevant field. Where there is a possibility of patent protection being obtained this should be reported to the Trust's IP Lead as soon as possible.

Copyright (for written works, drawings, photographs, sound recordings, and works such as computer software and collections of data, written or computer based protocols, forms, clinical guidelines and website content). Copyright arises automatically in most cases. However, it is desirable to ensure that documents or other works which may be covered by copyright contain appropriate notices, such as: "© [Name] NHS Trust 20[22]. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner."

Designs (covering the shape and configuration of articles, such as equipment and tools). Designs rights can be registered or unregistered and give protection in the UK or in the EU. If there is the possibility of design protection advice should be sought from the Trust's IP Lead.

Confidentiality (which can apply to any information). 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 on a new method of treatment or diagnostic. Confidentiality is generally protected by written agreements. In all cases, the "know-how" will only retain its value if it is managed effectively. All commercialisation partners, business partners and collaborators should be bound by conditions of confidentiality through a Non Disclosure Agreement (NDA), also referred to as a Confidentially Agreement (CDA). Such an agreement should only be signed by an appropriate, authorised representative of the Trust, so that the risk from disclosure can be assessed and suitable records kept.

Trademarks (Brands) such as the Trust name and stylised logos (e.g. the blue and white 'NHS' logo), brands used by the Trust or a name given to a new digital health platform. Trade marks can be registered or unregistered; however it is more effective to register a trade mark.

6.2 Ownership of Intellectual Property

Generally, if a member of the staff (an employee) of the Trust creates or generates any intellectual property, including inventions and information and results in the course of performing their duties, the rights in that intellectual property belong to the Trust (subject to some statutory exceptions).

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.

In each case this includes activities carried out wholly or partly under Trust auspices. It also includes activities using Trust facilities, and work 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.

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.

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 commercialised 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.

6.3 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 generated will be shared with the Trust and the inventor(s) according to an agreed revenue sharing policy, the current version of which is set out in Appendix 1.

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 commercialisation costs (such as IP or legal costs; financial obligations to funders; or management fees due to third party advisors) incurred by or on behalf of the Trust.

6.4 Copyright
Although copyright of any work produced by an employee in the course of normal employment belongs to the Trust, the Trust will normally grant to the author a royalty free licence to the copyright of any work published in a recognised scientific, technical, professional or management journal or book and will not claim a share of any income derived from such works. The Trust will not grant such a licence for materials created by a member of staff during the course of and related to their employment, which are on the following non-exhaustive list:

- Course or training materials
- Patient information
- Software programmes
- Designs, specification or other works which may be necessary to protect rights in commercially valuable Intellectual Property.

The Trust will respect the moral rights of its employees as authors in copyright materials if asserted by notification to R&D, with the exception to any materials related to computer programs, the design of a typeface or any computer generated work, in standing with the Copyright, Designs and Patents Act 1988 (Commencement No. 6) Order 1990.

6.5 Who And What Does This Policy Cover?
All staff that are full or part-time employees of the Trust, trainee professionals hosted by the Trust and agency staff contract by the Trust where the IP generated relates to their area of employment by the Trust, whether it was created during the course of a working day, or outside normal working hours and/or away from the place of work. This includes:

Staff with contracts of employment with the Trust whose payroll costs are partially or fully funded by another party (e.g. medical charity, Government Department or commercial sponsor), unless the contract between the Trust and that party gives ownership of the IP to that party.

Trainee professionals employed by the Trust (e.g. specialist registrars) hosted by the Trust who generate IP during the course of their training.

Staff employed part-time by the Trust who are self employed or otherwise employed part-time. Where IP is generated during the non-Trust employment but involves use of or access to Trust resources, 6.2 (paragraph 5) above will apply.

Trust staff seconded to another organisation or employees of another organisation (e.g. a university) hosted by the Trust under contract subject to the terms defined in the contract between the Trust and that organisation.

Independent providers of services who generate IP from research funded by the NHS are required to inform the Trust and share the benefits of its commercialisation. Where IP is assigned to the Trust, the independent service provider will benefit under the revenue sharing scheme of the Trust.

Collaborative projects - if work/research is conducted by a Trust employee in partnership with another organisation, a formal agreement setting out ownership (or sharing) of generated IP is required. R&D will have primary responsibility for agreeing IP sharing agreements with collaborating institutions.

6.6 Students and Other Non-Employees of the Trust
Students, where they are not employees of the Trust, are required to sign a confidentiality agreement which provides that the student disclose details of any inventions to the Trust and assign the rights to the Trust on request. Similar provisions will apply to other researchers at the Trust who are neither staff nor students e.g. Senior Research Fellows and other emeritus staff.

6.7 What If The Trust Is Not Interested In My IP?
When IP is generated, and the Trust chooses not to further the development or commercialisaton of such IP for whatever reason, the IP will be assigned to the inventor on request who may wish to pursue its further development independently.

6.8 Ownership Disputes
If the ownership of IP is disputed, dated written records relating to the IP in question will be assessed by the RDSG with professional help to establish the ownership of the IP, the inventor(s) and their proportionate contribution as appropriate.

6.9 Employees' Obligations
From time to time an employee may generate IP which may have value in the delivery of better patient care. All employees who may have created any form of intellectual property are required to bring it to the immediate attention of the Trust IP Lead, who will provide first level advice and engage the services of outside advisors as appropriate.

Disclosure to persons outside of the Trust (other than under explicit terms of confidentiality) may invalidate any subsequent attempt to gain IP rights and significantly diminish both potential commercial value and benefits accruing to both the Trust and the inventor. It is essential therefore that all ideas and developments are not generally discussed and are reported instead through the correct channels.

All employees should treat as confidential and not disclose to any third party any research results or other confidential information relating to IP developments without prior written approval of the Trust's IP Lead. If there is any uncertainty as to the sensitivity or confidentiality of the information, the employee should consult with the Trust IP Lead prior to any disclosure.

Employees must not, under any circumstances, disclose before protection, sell, assign, licence, give or otherwise trade in IP without the Trust's written agreement.

6.10 Record Keeping

You are reminded of the importance of keeping accurate and dated notebooks so that, in the event of similar intellectual property being generated elsewhere, ownership of the invention can be proved. Such notebooks can be important when applying for patents in the USA and also for identifying know-how.

In addition, a record will be kept of the date and time on which an employee reports to the IP Lead that he or she is the inventor of a creative product.

6.11 Working with Others

Before negotiating or entering into any contract or other arrangement which addresses intellectual property or the rights in results or developments, it should be reviewed with the Trust's IP Lead. The Trust's IP Lead must give written approval to any such contract before it is signed and should be consulted as early as possible when such an arrangement is being considered.

6.12 How Will The Trust Manage IP?

Any employee wishing to discuss the protection of any idea or other form of intellectual property should inform the IP Lead at the earliest opportunity and, in any event, before disclosure of the idea (whether orally or in writing) to any party outside the Trust.

The IP Lead will be the initial contact point for advice and can provide details of the support available for the management of IP.

The Trust is the vehicle for holding patents and other intellectual property, but is free at its absolute discretion to engage another party (e.g. an independent company) to protect, develop and commercialise its intellectual property on its behalf.

6.13 Commercialisation

In each case reported to the Trust's IP Lead, the Trust's IP Lead will consider what form of protection is suitable and appropriate for the results or developments.

The Trust has specific arrangements in place for the commercialisation of intellectual property therefore you should not take any steps to commercialise Trust intellectual property without the specific approval of the Trust Board.

The Trust may at its absolute discretion decide that the IP is best commercialised through a spin-out company; in such a case the Trust may take shares in that company and there may also be opportunity for the employee who created the relevant IP to take shares and/or otherwise participate in the spin out company. Setting up a spin out company is a complex procedure which may require consent of the Department of Health and Social Care. Details of the procedures to be followed are set out in the Framework and Guidance document at https://www.england.nhs.uk/ourwork/innovation/.

6.14 IP Audit

There is no formal obligation to capture IP through a process of technology audit. The Trust may however employ an auditing process to identify and evaluate IP and otherwise assist in its commercialisation.

6.15 Assistance

Those involved in creating or generating intellectual property, or results or developments, may be asked to assist by providing further information which helps the Trust to protect or to arrange commercialisation of it. For example you may be asked to sign formal transfer documents.

6.16 Administration and Management

Training: The Trust will take steps to promote understanding by those working in the Trust of the issues arising under this policy, in particular the value and protection for intellectual property, and how to identify this.

Records and Administration: The Trust's IP Lead will maintain an administrative procedure for handling the matters set out above, and will maintain records of developments, ideas, and other information reported under this policy. In addition, so far as relevant, the Trust will implement the terms of this policy in contracts of employment for staff, and in relation to research and other contracts with third parties.

6.17 Trust Intellectual Property Contacts

IP Lead:	Associate Director, R&D
External business consultant:	Health Enterprise East, please contact R&D office for details

7. Monitoring & Compliance

1	Following local and national policies and guidelines, what key elements require monitoring?	List elements to be monitored	a. Records of innovations identified and resulting actions held in R&D office
2	Who will lead/be accountable for monitoring?	Lead title and/or MDT	Research & Development Steering Group (RDSG)
3	Describe how the key elements will be monitored?	List tools to evidence compliance	a. Project Review b. Annual R&D Review c. Audit plans for Trust Sponsored projects d. Annual Report submitted to Trust Board e. Involvement in external/internal audit/inspection
4	How frequently will each element be monitored?	List frequency of monitoring for each element	a. As required
5	Explain the protocols for escalation in the event of problems?	List the processes of escalation	a. RDSG to People, Education and Research Committee (PERC) and Quality and Safety Group (Q&S)
6	Which Committee/ Panel/ Group will reports go to?	List the Committee/Panel/ Group/Peer Review that the reports will go to	a. RDSG b. PERC c. Q&S
7	Explain how the policy/guideline will be disseminated within the Trust?	List ways identifying how this document will be shared and how it will be recorded that appropriate staff have been	a. Intranet b. Researcher discussions

		made aware of the document and where to find it	

8. Safeguarding

Does this document have any impact on safeguarding issues for adults and/or children? n/a

9. Patient & Carer Involvement

Reference any group/individual patient/carer involvement in developing this document n/a

10. References

For further information regarding policies mentioned in this document, please contact the R&D department.

10.1 Research and Development Office Contact Details:

Watford General Hospital R&D Office
Telephone: 01923 217854
Email: westherts.rdapplications@nhs.net
Website: https://www.westhertshospitals.nhs.uk/randd/default.asp

11. Related Policies and Guidelines

R&D SOP's - http://wghintra01/Copy%20of%20policies/srchReturns_withID.asp

12. Equality Impact Statement (EIA)

What is an equality impact assessment?

There are many benefits in conducting an equality impact assessment (EIA) prior to making business decisions about policies, clinical guidelines or any other work that may potentially impact on a wide range of people with protected characteristics. Equality impact assessments should not be seen as an afterthought once decisions have already been made.

Benefits:

- Improved capacity to consider equality, diversity and inclusion as part of business management
- Reduced costs as a result of not having to revisit a policy/project
- Take into account a diverse range of views and needs
- Enhanced reputation as a Trust that is seen to understand and respond positively and proactively to diversity.

Whatever approach you take to an equality impact assessment, case law has established that you should keep an accurate, dated, written record of the steps you have taken to analyse the impact on equality. This will help you to check whether you are complying with the duty and it will be useful if your decisions are challenged.

When completing an equality impact assessment you should consider:

- Treating a person worse than someone else because of a protected characteristic (known as direct discrimination)
- Putting in place a rule or way of doing things that has a worse impact on someone with a protected characteristic than someone without one, when this cannot be objectively justified (known as indirect discrimination)
- Treating a disabled person unfavourably because of something connected with their disability when this cannot be justified (known as discrimination arising from disability)
- Failing to make reasonable adjustments for disabled people.

Equality impact assessment process
Stage 1 (Screening)

This stage provides an opportunity to explore whether the policy decision may have a negative, neutral or positive impact on different groups of people.

- If yes, use the ‘comments’ column to describe what this impact could be.

- If no, outline how have you arrived at this conclusion.

- If unsure use the ‘comments’ column to describe what you need to do to find out.

Stage 2 (Full Assessment)
This should be carried out in compliance with policy HR028 Equality & Human Rights Policy.

Does this policy/guideline affect one group less or more favourably than another on the basis of:				
				Comments
1	Age (younger people & children& older people)		no	
2	Gender (men & women)		no	
3	Race (include gypsies and travellers)		no	
4	Disability (LD, hearing/visual impairment, physical disability, mental illness)		no	
5	Religion/Belief		no	
6	Sexual Orientation (Gay, Lesbian, Bisexual)		no	
7	Gender Re-assignment		no	
8	Marriage & Civil Partnership		no	
9	Pregnancy & Maternity		no	
	Is there any evidence that some groups maybe affected differently?		no	
	Could this document have an impact on other groups not covered by a protected characteristic? (e.g.: low wage earners or carers)		no	
x	If '**NO IMPACT'** is identified for any of the above protected characteristics then no further action is required.			
	If '**YES IMPACT**' is identified a full impact assessment should be carried out in compliance with HR028 Equality & Human Rights Policy and linked to this document			

Any other comments:
Please use this box to add any additional comments relevant to the assessment

Assessment completed by:	*Name and designation*	Date completed:	02/02/2023

If you have any queries or concerns about completing the EIA form, contact the Trust's Inclusion & Diversity Team at WestHerts.Inclusion@nhs.net

Appendix 1

Revenue sharing table

The shared revenue will be net of any IP protection and commercialisation costs incurred by or on behalf of the Trust.

Net revenue	Inventor(s)	Department	Trust
First £10K	80%	10%	10%
Next £40K	75%	12.5%	12.5%
Next £200K	50%	25%	25%
Over £250K	35%	32.5%	32.5%