

# **Intellectual Property Policy**

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#### 1 Introduction

The Framework and Guidance on the Management of Intellectual Property in the NHS<sup>1</sup> and the Health and Social Care Act<sup>2</sup> encourages NHS Trusts to capture innovations that could lead to new or improved products, interventions and services and to develop innovative organisations.

# 2 Why we need this policy

#### 2.1 Purpose

This Policy provides an outline for the effective identification, protection, and management, of innovations and any associated Intellectual Property (IP).

#### 2.2 Objectives

This Policy also includes information on who to contact if you have an innovation that you think may need protecting, or if you require general advice regarding IP arising as a result of your work at The Trust.

It also provides guidance on revenue sharing between The Trust and the originator of the innovation.

## 3 Scope

#### 3.1 Who this policy applies to

Tees, Esk and Wear Valleys NHS Foundation Trust (The Trust) recognises that its workforce, from any discipline or activity, can generate new ideas, innovative solutions to problems, or better ways of working, all of which may lead to improvements in NHS services. This can arise from both research activities, occupational activities, and other types of work carried out by the group comprising the following ("The Workforce of The Trust"): -

- (i) Students, both part time and full time, working within The Trust but not employed by The Trust ("Non-Trust Employees");
- (ii) Students, both part time and full time, employed by The Trust ("Trust Employees");
- (iii) Clinical staff, both part time and full time, employed by The Trust ("Trust Employees");
- (iv) Clinical staff, both part time and full time, working within The Trust but not employed by The Trust ("Non-Trust Employees");
- (v) Research staff, both part time and full time, employed by The Trust ("Trust Employees");
- (vi) Research staff, both part time and full time, working within The Trust but not employed by The Trust ("Non-Trust Employees");

- (vii) Non-clinical staff, both part time and full time, employed by The Trust ("Trust Employees");
- (viii) Non-clinical staff, both part time and full time, working within The Trust but not employed by The Trust ("Non-Trust Employees"); and
- (ix) Non-clinical individuals working within The Trust but not employed by The Trust ("Non-Trust Employees"),

This includes people who used to be but who are no longer in The Workforce of The Trust, as appropriate.

These types of innovations can lead to the creation of Intellectual Property (IP). IP represents a valuable asset to both The Trust and the NHS as a whole, and it is important that it is managed appropriately.

The law surrounding IP can be complicated and you should contact the R&D Department at The Trust, who are nominated to be responsible for IP management locally, at the earliest opportunity, to discuss IP protection in more detail. The R&D Department can be contacted at tewv.researchanddevelopment@nhs.net.



Do not reveal your innovation in any way to any third party (e.g. friends, family, associates, colleagues or companies) before seeking advice. Disclosure of an innovation, even by word of mouth, could seriously limit its value to patients, the innovator, and The Trust.

#### 3.2 Roles and responsibilities

Role	Responsibility
The Workforce of The Trust	• Have an obligation to inform the R&D Department at The Trust about identified or potential IP resulting from their clinical, and/or non-clinical, and/or study related, and/or research activities, and must not, under any circumstances, publish or disclose, assign, licence, give, or otherwise trade in, IP, without the agreement of The Trust.
R&D Department	<ul> <li>Facilitate the setting up of appropriate Collaborative Research Agreements with research partners</li> </ul>
	• Provide advice in relation to, and facilitate, Confidentiality Agreements
	<ul> <li>Manage the strategy for the identification, protection, and commercialisation, of new innovations</li> </ul>
	<ul> <li>Facilitate discussions regarding revenue sharing between The Trust and the originator of the innovation, on a project by project basis</li> </ul>
	<ul> <li>Obtain input from legal advisors, patent attorneys, and Trust Board, as required</li> </ul>

# 4 Intellectual property (IP)

IP can be defined as the product of intellectual or creative activity in the form of novel ideas, innovation or the results of research and development, which can be given legal recognition of ownership through IP rights such as patents, copyright, design rights, trademarks or know-how (see Appendix 1).

By means of example, the following categories of IP can be relevant to the NHS: -

Category	Protection	Examples
Functional inventions	Patents	New medical devices, software systems
Written work	Copyright	Computer software, patient leaflets, training booklets, journal articles
Products having a specific shape and configuration	Registered and unregistered design rights	New medical devices
Brand names	Trade marks	Trust logo, product names
Occupational knowledge	Know-how and trade secrets	Surgical techniques

# 5 Ownership of intellectual property (IP)

It is common for the innovator / author / creator to own the IP associated with their work. However, this position can be changed by a number of factors, in particular IP generated during employment.

For The Workforce of The Trust generating IP as a result of their work or study whilst working at The Trust, the legal position in terms of ownership of that IP is to be decided on a case by case basis and in accordance with Section 39 of The UK Patents Act 1977 (as amended), The Copyrights Designs and Patents Act 1988 and The Registered Designs Act 1949, as appropriate, according to the type of IP generated.

However, by means of example, it is often the case that IP created by Trust Employees whilst they are employed by The Trust is owned in the first instance by The Trust. In order to decide whether IP generated by a Trust Employee whilst they are employed by The Trust is owned by The Trust, a number of criteria are taken into consideration, such as, whether or not the IP was generated in the course of their normal duties, whether or not they had a special obligation to further the interests of The Trust, and whether the IP was as a result of duties specifically assigned to them.

There is legal case law for helping to decide who owns IP created by Trust Employees in their 'spare time' where it relates to the work for which that person is employed.

Accordingly, The Workforce of The Trust should not assume that they are the first owners of any IP created and they should instead seek advice from the R&D Department.

Although it is common for IP generated by Trust Employees to be owned by The Trust, this is not always the case. For example, where work, such as research, is carried out on behalf of a sponsor, the contract with the sponsor may provide that the IP associated with the results will be owned by the sponsor. It is the policy of The Trust that, wherever possible, contracts undertaken by Trust Employees should clarify that first ownership of IP generated by Trust Employees in the course of their employment should in the first instance subsist with The Trust. Trust Employees must take account of this when discussing proposals with sponsors, and should take advice from the R&D Department before concluding any negotiations.

Non-Trust Employees are not employees of The Trust for the purposes of IP and therefore in most cases, unless there is an agreement to the contrary, such as a contract with a sponsor for example, the Non-Trust Employees themselves, or their employer, will be the first owners of any IP generated as a result of their work or study at The Trust. However, the general rule is that, to be considered as the rightful first owner of the IP generated as a result of their work or study at The Trust, the Non-Trust Employee will need to have demonstrated some independent thought and inventive input leading to the creation of the idea, innovation etc... It is to be appreciated that if the IP generated resulted from the inventive input of the Non-Trust Employee's work colleagues, whom themselves are Trust Employees for example, The Trust may actually be the sole first owner of the IP.

In the event that The Trust decides not to exploit the IP owned by them and generated by a Trust Employee, the Trust Employee may then be provided with the opportunity to exploit the IP themselves by means of the execution of an assignment of the IP from The Trust to the Trust Employee.

It is to be appreciated that, should a Trust Employee leave The Trust then the rights associated with any IP belonging to The Trust that was created when the Trust Employee was still employed by The Trust, shall remain with The Trust, unless there is an agreement otherwise.

In view of the above, it is therefore important that The Workforce of The Trust discloses all IP that they think may have been generated as a result of their work or study whilst working or studying at The Trust and seeks advice as appropriate from the R&D Department.

# 6 Collaborative projects

It is to be appreciated that IP can belong to more than one legal entity (for example, The Trust and a Non Trust Employee, jointly) if the IP was generated as a result of collaborative effort between parties.

Accordingly, if work or research is conducted by a Trust Employee in partnership with another organisation, a formal agreement stating ownership of generated IP is required. The R&D Department has overall responsibility within The Trust for developing IP sharing agreements and collaboration agreements with collaborating institutions.

### 7 Disputes of ownership

If the ownership of IP is disputed, dated written records relating to the IP in question will be assessed to establish the innovator(s) and their proportionate contribution. If such material is not available, the R&D Department will make a final decision, taking advice from third party advisors such as The Academic Health Science Network for the North East and North Cumbria Limited, if required.

### 8 Infringements of IP

The Workforce of The Trust will take appropriate steps to avoid infringement of third party IP and will notify the R&D Department if they do become aware of any potential infringements.

#### 9 Decisions of commercialisation

The R&D Department, in consultation with the innovator and other specialists where necessary, will decide on the potential for an innovation to be commercialised. Criteria such as the potential market, the likelihood of success, and the scope for protection of the innovation, will be considered.

The R&D Department can agree on a case-by-case basis to grant permission to other NHS partners or collaborators to have free or discounted access to the IP, where the wider public interest for this is demonstrated.

### **10 Contract negotiations**

Any IP that is licensed, assigned, or otherwise transferred to another organisation, will be negotiated in the best interests of The Trust with the assistance of professional advisers, where necessary.

### **11 Revenue sharing with innovators**

The Trust encourages full participation of The Workforce of The Trust in the creation and potential commercialisation of IP. The policy of The Trust is to reward Trust Employees who have contributed substantially to the generation of IP which subsequently provides revenue through commercialisation. The sharing of revenue will be determined by The Trust at its discretion. Where more than one originator of the innovation is involved, the distribution of revenue will be decided based upon principles of percentage of creative contribution.

### **12 Publications**

It is the policy of The Trust to actively encourage Trust Employees to publish their work and The Trust will not normally object to an individual's right to be named as an author of copyright material. *However*, if IP is to be commercialised, all potential IP needs to be kept confidential until a decision has been made regarding whether to protect it.

Advice should be sought from the R&D Department before publicly disclosing any potential IP, for example, by means of scientific papers, posters at conferences, publication of abstracts, chapters in books, and any other verbal or written communication.

# 13 Record keeping

It is important for staff working on projects which can generate IP to keep written and dated records of their activities and results.



It is also imperative that all correspondence, including emails, 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 for R&D.

The Trust nominated person responsible for IP management is also 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 Department. It is also their responsibility to keep safe any important original documents relating to IP, such as Confidentiality Agreements.

## 14 How this policy will be implemented

• This policy will be published on the intranet and external website of The Trust.

#### 14.1 Training needs analysis

Staff/Professional Group	Type of Training	Duration	Frequency of Training
ALL	Individual	Bespoke per training need	As required

## 15 How the implementation of this policy will be monitored

Auditable Standard/Key Performance Indicators	Frequency/Method/Person Responsible	Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group).
1	Monitored on case by case basis by R&D Department	

### **16 References**

1. Department of Health (2002) *The NHS as an Innovative Organisation. A Framework and Guidance on the Management of Intellectual Property in the NHS.* Accessed from: <a href="http://www.nic.nhs.uk/Pages/NHSIPGuidance.aspx">http://www.nic.nhs.uk/Pages/NHSIPGuidance.aspx</a>

2. Department of Health (2001) The Health and Social Care Act. Accessed from: <u>http://www.legislation.gov.uk/ukpga/2001/15/contents</u>

## **17 Document control**

Date of approval:	25 September 2019				
Next review date:	25 September 2022				
This document replaces:	CORP-0058-v3 Intellectual Property Policy				
Lead:	Name	Title			
	Sarah Daniel	R&D Manager			
Members of working party:	Name	Title			
	Victoria Christie	Intellectual Property and Contracts Manager, Academic Health Science Network North East and North Cumbria			
This document has been	Name	Title			
agreed and accepted by: (Director)	Joe Reilly	Clinical Director for Research and Development			
This document was approved	Name of committee/group	Date			
by:	Research Governance Group	06 June 2019			
This document was ratified by:	Name of committee/group	Date			
	EMT	25 September 2019			
An equality analysis was completed on this document on:	June 2019				

#### Change record

Version	Date	Amendment details	Status
V3	Nov 2017	Removed reference to Research Governance Framework	Published
V4	June 2019	<b>Purpose section</b> updated to incorporate innovations pathway	Approved pending ratification
		Who this applies to section expanded to describe innovation activity and include new groups of Trust and non-Trust employees. Informs to contact R&D on individual case by case basis as law can be complicated	
		Intellectual property Definitions and categories with examples provided	
		<b>Roles and responsibilities</b> Section updated to include wording from the innovation pathway i.e. identification and commercialisation.	
		<b>New section included</b> Ownership, collaborative projects and disputes of ownership	

### Appendix 1 – Overview of IP

This Appendix includes a very brief overview on some aspects of IP. It should be noted that the law surrounding IP can be complicated and The Workforce of The Trust are advised to contact the R&D Department for The Trust at the earliest opportunity to discuss IP in further detail, when required.

#### 1.1 COPYRIGHT

Copyright covers for example, written information (such as leaflets, articles, assessment tools and training packs), databases, computer software and films/videos. Copyright is achieved automatically when the work is created. However, it is advisable to attach a statement to the work, in order to discourage infringement, such as:

© [Owner] [Year of Creation]. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner.

#### **1.2 PATENTS**

Patents can be used to protect inventions that embody a new idea that is capable of being made or used by industry, such as devices, processes or methods. 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 published anywhere in the world prior to the filing date of the patent application. Publication can include journals, the internet, discussion at meetings and poster presentations.

#### **1.3 UNREGISTERED DESIGN RIGHTS**

Unregistered Design Rights are directly associated with appearance. The right can protect external features but it only provides protection against copying of features of shape and configuration.

#### **1.4 REGISTERED DESIGN RIGHTS**

In some new products, the novelty lies not in the functionality or concept of a new idea, but in their appearance. Registered design rights usually cover commercial objects with a unique or aesthetic appearance.

#### 1.5 TRADEMARKS

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. Trade marks can be very valuable in keeping a product as a market leader.

#### 1.6 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 it could 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 Confidentiality Agreement. This may be a reciprocal agreement whereby confidential information is both disclosed and received, and it can be obtained from the R&D Department. Moreover, know-how can be bought and sold like any other form of IP and it can persist indefinitely, as long as it remains a secret.

#### 1.7 CONFIDENTIALITY AGREEMENTS

This is a reciprocal agreement whereby confidential information is both disclosed and received. It may be obtained from the R&D Department at The Trust.

### Appendix 2 - Equality Analysis Screening Form

#### Please note; The Equality Analysis Policy and Equality Analysis Guidance can be found on InTouch on the policies page

Name of Service area, Directorate/Department i.e. substance misuse, corporate, finance etc.	Research and Development, Medical Directorate				
Name of responsible person and job title	Sarah Daniel, R&D Manager				
Name of working party, to include any other individuals, agencies or groups involved in this analysis	Research Governance Group				
Policy (document/service) name	Intellectual Propert	y			
Is the area being assessed a	Policy/Strategy	х	Service/Business plan	Project	
	Procedure/Guidance Code of			Code of practice	
	Other – Please sta	te			
Geographical area covered	Trustwide				
Aims and objectives	<ul> <li>The Intellectual Property policy provides an outline for the effective management of IP. It has information on who to contact if any staff member has an invention that may need protecting, or if they require general advice on IP arising as a result of their work.</li> <li>The aims are to: <ul> <li>Identify and protect innovations and IP likely to be created from activities generated within TEWV;</li> </ul> </li> </ul>				
	<ul> <li>Set a framework and programme for the development of IP management for The Trust to assert its rights over IP owned by The Trust;</li> <li>Provide guidance on revenue sharing between the Trust and the innovator.</li> </ul>				

Start date of Equality Analysis Screening (This is the date you are asked to write or review the document/service etc.)	March 2019
End date of Equality Analysis Screening (This is when you have completed the equality analysis and it is ready to go to EMT to be approved)	June 2019

#### You must contact the EDHR team if you identify a negative impact. Please ring Sarah Jay on 0191 3336267/3046

1.	Who does the Policy, Service,	Function, Strategy,	Code of practice, Guid	dance, Project or Busi	ness plan benefit?
	,	, · · · · , · · · · · · · · · · · · · ·			

The policy will benefit any staff member who has an innovation they would like to develop by providing support and guidance in taking that idea forward. Service users and carers may benefit from any innovation that is developed to improve their care, health or well-being. Some innovations may have a beneficial impact on staff groups e.g. new ways of working, development of technologies or devices that positively impact on staff workload. The Trust and individual staff members may benefit financially if the innovation is marketable.

2. Will the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan impact negatively on any of the protected characteristic groups below?

Race (including Gypsy and Traveller)	No	<b>Disability</b> (includes physical, learning, mental health, sensory and medical disabilities)	No	Sex (Men, women and gender neutral etc.)	No
Gender reassignment (Transgender and gender identity)	No	<b>Sexual Orientation</b> (Lesbian, Gay, Bisexual and Heterosexual etc.)	No	Age (includes, young people, older people – people of all ages)	No
Religion or Belief (includes faith groups, atheism and philosophical belief's)	No	Pregnancy and Maternity (includes pregnancy, women who are breastfeeding and women on maternity leave)	No	Marriage and Civil Partnership (includes opposite and same sex couples who are married or civil partners)	No

Yes - Please describe anticipated negative impact/s

**No** – Please describe any positive impacts/s

The policy has been developed to ensure intellectual property is managed effectively as any innovation has the potential to make a positive impact on the lives of service users, carers and staff, regardless of the protected groups individuals may identify with.

3. Have you considered other sources of information such as; legislation, code nice guidelines, CQC reports or feedback etc.? If 'No', why not?	es of practice, best practice,	Yes x		No				
<ul> <li>Sources of Information may include:</li> <li>Feedback from equality bodies, Care Quality Commission, Equality and Human Rights Commission, etc.</li> <li>Investigation findings</li> <li>Trust Strategic Direction</li> <li>Data collection/analysis</li> <li>National Guidance/Reports</li> <li>Staff grievances</li> <li>Media</li> <li>Community Consultation/Consultation/Consultation</li> <li>Research</li> <li>Other (Please state below)</li> </ul>								
<ol> <li>Have you engaged or consulted with service users, carers, staff and other stakeholders including people from the following protected groups?: Race, Disability, Gender, Gender reassignment (Trans), Sexual Orientation (LGB), Religion or Belief, Age, Pregnancy and Maternity or Marriage and Civil Partnership</li> </ol>								
Yes – Please describe the engagement and involvement that has taken place								
Discussions with Research involved PPI members and approval at Research G	overnance group included se	rvice use	ers					
No – Please describe future plans that you may have to engage and involve people from different groups								
The policy exists to guide all staff members through the IP process and wouldn't exclude people from any protected group.								
During any 'product' development phase, it would be necessary to engage those service users, carers, staff and stakeholders which the innovation may have an impact on. This would include people from protected groups as appropriate.								

5. As part of this equality analysis have any training needs/service needs been identified?							
No	Please describe the identified training needs/service needs below						
A training need has been identified for;							
Trust staff		No	No Service users No Contractors or other ou agencies		Contractors or other outsid agencies	e	No
Make sure that you have checked the information and that you are comfortable that additional evidence can provided if you are required to do so							
The completed EA has been signed off by:							
You the Policy owner/manager:						Date:	
Type name: Sarah Daniel, R&D Manager						June 2019	
Your reporting (line) manager:							
Type name: Prof Joe Reilly, Clinical Director Research and Development						Date:	
						June 2019	
If you need further advice or information on equality analysis, the EDHR team host surgeries to support you in this process, to book on and							
find out more please call: 0191 3336267/3046							