

Cheshire and Wirral Partnership

NHS Foundation Trust

Document level: Trustwide (TW) Code: CG6 Issue number: 1

Intellectual Property (IP) Policy

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Type of document	Policy
Target audience	All CWP Staff
Document purpose	In order to ensure that innovation is spread throughout the Trust, to maximise the potential benefits to service users and the general population and the wealth of the Trust, it is necessary to protect the Trust's Intellectual Property and either disseminate freely or commercialise the Intellectual Property, as appropriate. To ensure that Trust staff understand how CWP can support innovation and to inform staff of the protocols surrounding the development and rewards associated with new Intellectual Property.

Approving meeting	Quality Committee	Date 4-Mar-15
Implementation date	March 2015	

CWP docu	iments to be read in conjunction with
<u>HR6</u>	Mandatory Employee Learning (MEL) policy

Document change his	istory	
What is different?	New document	
Appendices / electronic forms	New document	
What is the impact of change?	New document	

Training requirements	No

Implications	Financial resource implications	No
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Ex	External 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'.			
2.	Department of Health, 2000, 'The NHS Plan 2000, A Plan for Investment, A Plan for reform'.			

Equality Impact Assessment (EIA) - Initial assessment	Yes/No	Comments
Does this document affect one group less or more favourably than	another or	the basis of:
- Race	No	
- Ethnic origins (including gypsies and travellers)	No	
- Nationality	No	

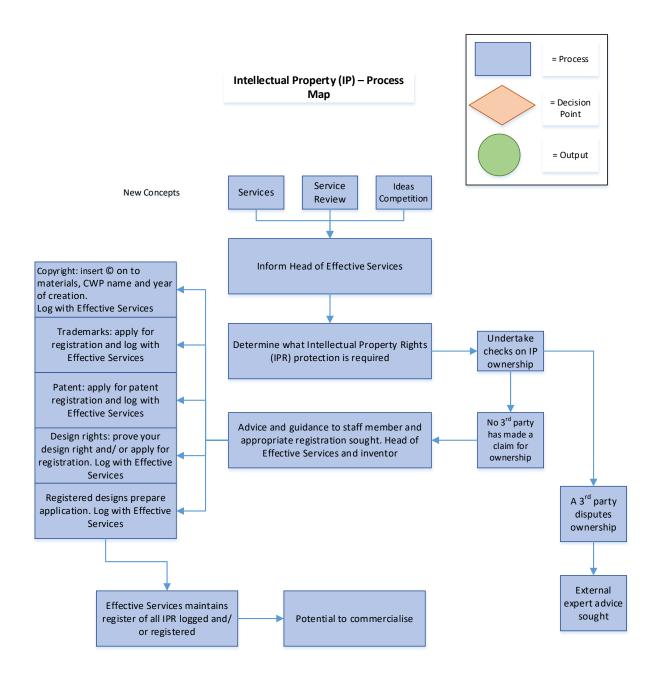
Equality Impact Assessment (EIA) - Initial assessment	Yes/No	Comments
- Gender	No	
- Culture	No	
- Religion or belief	No	
- Sexual orientation including lesbian, gay and bisexual people	No	
- Age	No	
 Disability - learning disabilities, physical disability, sensory impairment and mental health problems 	No	
Is there any evidence that some groups are affected differently?	No	
If you have identified potential discrimination, are there any exception	ons valid,	legal and/or justifiable?
Is the impact of the document likely to be negative?	No	
 If so can the impact be avoided? 	N/A	
- What alternatives are there to achieving the document without the impact?	N/A	
- Can we reduce the impact by taking different action?	N/A	
Where an adverse or negative impact on equality group(s) has been identified during the initial screening process a full EIA assessment should be conducted.		
If you have identified a potential discriminatory impact of this procedural document, please refer it to the human resource department together with any suggestions as to the action required to avoid / reduce this impact. For advice in respect of answering the above questions, please contact the human resource department.		
Was a full impact assessment required?	No	
What is the level of impact?	Low	

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Quick reference flowchart

For quick reference the guide below is a summary of actions required.



1.1 Introduction to this Intellectual Property policy

Since 2001, management of intellectual property (IP) has been a requirement of all NHS organisations carrying out research to comply with the Research Governance Framework.

In 2002, the Department of Health (DH) expanded on the existing guidance on management of innovation and IP⁻ The main points being that: IP from patient care as well as from R&D should be managed as an asset; statutory changes have occurred allowing NHS Foundation Trusts to form or invest in spin-out companies to facilitate income generation. With 'generating wealth for better health' as its theme, the framework and guidance encouraged the NHS to develop innovations that can lead to new products, improved interventions and better services for health and social care. It supports the delivery of the NHS Plan.

On 1 April 2013 NHS Improving Quality was established to bring together the wealth of knowledge, expertise and experience of a number of NHS improvement organisations. NHS Improving Quality is a new kind of NHS organisation. A national body, it plays a key role in helping to transform the NHS, helping create the conditions and momentum for change at an unprecedented scale and pace.

In 2014 The NHS established 15 Academic Health Science Networks. (AHSN) These networks support local NHS Services find the research and informatics, services, education and training they need to be Innovative. CWP is serviced by the North West Coast AHSN.

This document outlines a policy for the effective management of IP based on the guidance discussed above. It gives a brief definition of what IP is, with information on who to contact if you have an invention/idea/innovation that you think may need protecting or if you require general advice on IP arising from your work.

1.2 What is IP and Why This Policy Is Required

Intellectual property (IP) can be defined as products of innovative and intellectual or creative activity and can include inventions, industrial processes, software, data, written work, designs and images. IP can be given legal recognition of ownership through intellectual property rights (IPR) such as patents, copyright, design rights, trade marks or know-how. Certain IPR arise automatically and do not need to be registered, whilst others are required to be registered before they are valid. The status and validity of IP and IPR can vary depending on the country in question. Protection of IP by IPR facilitates rather than hinders the uptake of innovation.

In an NHS organisation, IP can arise from innovative activity associated with both Research and Development (R&D) and day to day service provision and healthcare delivery. This IP aids in the improvement of health care services provided by the NHS. In order to ensure that such innovation is spread throughout the NHS to maximise the potential benefits to the general population and the wealth of the nation, it is necessary to protect this IP and either disseminate freely or commercialise the IP as appropriate.

Examples of intellectual property that may be developed in the NHS include: training manuals, clinical guidelines, book and journal articles, PowerPoint presentations, inventions, new or improved designs, devices, equipment, new uses for existing drugs, diagnostic tests, and new treatments.

1.3 Ownership of IPR

Ownership of IPR generated by Trust employees will, in general terms, rest with the Trust first, unless agreed otherwise as per 1.3.1, 1.3.2, 1.3.3 and 1.3.4. This applies to all intellectual property produced by Trust employees in the course of their normal duties or employment. IP developed by an employee outside the course of their employment will usually belong to the employee. This is in accordance with the Patents Act 1977 and the Copyright, Designs and Patents Act 1988. However, IPR ownership can

vary according to the circumstances under which the IP was generated and can depend on factors such as the scope of the employment activities, whether the member of staff is an employee or contractor and other terms of the contract of employment. Therefore, in addition to this policy, members of CWP staff should also thoroughly read their employment contracts for details regarding ownership of IPR arising during the course of their employment with CWP and any notification obligations of the employee.

1.3.1 Joint/Honorary appointments/trainees

If staff are jointly employed by more than one organisation (e.g. Trust and University), or have an honorary contract with another organisation, or are employed by one organisation but hosted by another (e.g. specialist registrars), then an agreement should be in place between the two organisations stating who will own any IP generated by that person before work begins.

1.3.2 Externally funded work

If IP is generated by a Trust employee through work that is funded by an external body (e.g. a research project funded by a medical charity) then it is possible that the funding agreement includes a statement regarding IPR ownership such that the funding body may own the IPR instead of the Trust.

1.3.3 Commissioned work

If the Trust commissions work by a third party supplier who is not a Trust employee (e.g. the development of a database by a software company), then the Trust will not necessarily own the IPR generated by the work. If the intention is that the Trust should own the IPR, it is very important that the contract with the supplier includes provision for the third party to transfer and assign IPR in the output of the work. If the intention is that the supplier should retain the IPR, then the contract should include licence provisions which clearly set out the scope of what the Trust can or cannot do with the work.

1.3.4 Collaborative projects

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 Head of Effective Services will have primary responsibility for developing IP sharing agreements with collaborating institutions.

1.4 Disputes of ownership

If the ownership of IPR 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 Head of Effective Services will follow the Innovation Policy process map and if all negotiation fails, then the Chief Executive Officer of the Trust will make a Trust decision, taking professional advice if necessary.

1.5 Assignment of IP

The Trust may sometimes choose not to exploit IP arising from the work of Trust employees. As a result, exceptionally and in its sole and absolute discretion (subject to no outstanding claims such as from a funding body), the Trust may consider assigning the IPR back to the inventor(s) who may wish to pursue its further development. In return for any such assignment, the inventor(s) may be required to pay a percentage of any income generated with the Trust, with the details of the percentage share and the payment terms, to be agreed between the Trust and the inventor prior to the assignment.

2.0 Persons covered by this policy

a) All staff that are full or part time employees of the Trust.

- b) Staff with Trust contracts of employment whose payroll costs are partially or wholly funded by another party (e.g. medical charity, government department) unless the contract between the Trust and that party assigns ownership of any IPR to that party.
- c) Trainee professionals (e.g. specialist registrars) hosted by the Trust who generate IP during the course of their training.
- d) 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.
- e) 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 IPR agreed between the Trust and that organisation.
- f) Staff with joint or honorary contracts with another organisation (e.g. University).

2.1 Staff obligations

Employees have an obligation to inform the Trust via The Head of Effective Services about identified or potential material IP (including inventions and innovative ideas of potential significance) resulting from their activities and must not, under any circumstances, sell, assign, license, give or otherwise trade any IPR (whether or not material) without the Trust's agreement.

3.0 IP management structure

It is the responsibility of the Chief Executive to manage and protect IP for the Trust and this responsibility has been delegated to the Head of Effective Services.

The first point of contact for information and advice on any matter regarding IP and its protection is the Head of Effective Services.

3.1 Budget for IP management and protection

The Trust has a budget to fund initial protection (e.g. patent) and development of IP, if the IP appears to have real potential to benefit healthcare, improve services and/or save the NHS money. The budget will be managed by The Head of Effective Services and directed by the Business Development & Innovation Sub-Committee (BDISC)

Funding for protecting IP, developing and trialing prototypes may also be gained from applying to external funding bodies (e.g., Department of Health) and/or by working with commercial partners.

4.0 Innovation Competition

BDISC will initiate an Innovation Competition three times per annum to support the generation of new ideas across the Trust. The Ideas generated will be assessed by The Innovation Panel which reports to BDISC. Funding may be allocated from the Innovation Budget to support the further development of ideas.

Although the competition will be run three times each year, any innovative idea can be submitted to the Effective Services Department using the <u>innovation&ideas@cwp.nhs.uk</u> e mail address

5.0 Exploitation of intellectual property

5.1 IP audits

An audit involve Effective Services meeting with staff to discuss his/her work and to identify any IP that could improve health directly or indirectly and/or save the NHS money and/or generate income for the NHS. Auditing is essential to ensure the correct action is taken to protect any IP that may later be exploited and to identify potential routes for exploitation such as free dissemination or commercialisation.

5.2 Confidentiality

To maximize the potential benefits of IP, it is often necessary to keep the details confidential in the first instance. Indeed, for some types of IP (e.g. patents) the Trust's rights will depend upon confidentiality having been carefully preserved. Maintaining confidentiality also allows development work to be carried out without alerting competitors to its existence and increases the chances of a company being interested in investing time and resources to its development.

If information needs to be shared with another person/organisation (e.g. to gain advice or funding), then the information can be kept confidential if the person/organisation is asked to sign a Non-Disclosure Agreement (NDA) before the details of the IP are disclosed to them. The Head of Effective Services can arrange for an NDA to be prepared if required. The NDA will be signed on behalf of the Trust by The Head of Effective Services who is authorised by the Chief Executive to sign such documents on behalf of the Trust.

5.3 Decisions on exploitation

The Head of Effective Services, in consultation with the inventor and other specialists (e.g. Academic Health Science Network AHSN), and BDISC will decide on the potential for an idea/invention to be exploited and the best route of exploitation. Often this will be through disseminating the idea throughout the NHS either freely or with a nominal charge to cover costs. Other cases will benefit the NHS more effectively and/or be easier to adopt into widespread use by developing the idea as a commercial product. In strong cases, the information reported should effectively demonstrate the potential market and the likelihood of success of the venture. In these instances, the Trust will explore commercialisation of the IP such as by licensing the IPR to a company in return for a royalty or by assignment of the IPR to a spin-out company in return for a stake in the company.

5.4 Contract negotiations

Any IPR that is licensed, sold or otherwise transferred to another organisation will be negotiated in the best interests of the Trust by professional advisers (e.g. Trust solicitors). Wherever possible the Trust will maintain a license to use the IP for training purposes and the contract will ensure that the Trust retains such a right to use the IP for such training purposes.

5.5 Revenue-Sharing with inventors

CWP acknowledges the work that employees contribute to innovation and will support the inventors of new systems and products. This support will include; enabling the staff member to take the time to develop innovation within their CWP employment and where appropriate, the provision of financial support to purchase equipment and materials to support its production.

Should an innovation lead to an exceptionally successful and profitable product for the Trust, the Trust may, (in its sole discretion) consider providing an incentive to the inventor with the details of any percentage share and the payment terms being in the sole discretion of the Trust.

APPENDIX 1 – TYPES OF IPR AND HOW THEY ARE PROTECTED:

1. INTELLECTUAL PROPERTY AND ITS PROTECTION

This appendix includes a very brief overview of some types of IP and how they may be protected. In general, registering an IPR offers greater protection for the owner.

More than one type of protection could be linked to a single product; eg you could

- Register the name and logo as a trade mark
- Protect a product's unique shape as a registered design
- Patent a completely new working part
- Use copyright to protect drawings of the product

It must be noted that the law is complicated and members of staff are advised to contact The Head of Effective Services at the earliest opportunity to discuss more detailed information on IP protection.

1.1 COPYRIGHT

Copyright can protect written information (such as letters, leaflets, assessment tools, and training packs) and electronic material (such as databases, software, film and video). Although copyright protection arises automatically as soon as the IP is created, it is advisable to attach the following statement to the work for the purposes of alerting users to the protected status of the works: "Copyright© CWP NHS Foundation Trust (+ year work was created). All rights reserved. Not to be reproduced in whole or in part without prior permission from the copyright owner".

1.2 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 treatment methods (surgical or therapeutic) and methods of diagnosis. An invention must not have been made public anywhere in the world (including journals, the internet, posters, meetings etc.) prior to the patent filing date and must not be obvious, compared to what is already known to someone who is experienced in the relevant field. Patents are capable of being registered by filing an application for a patent with the Intellectual Property Office and typically last for 20 years in most countries.

1.3 DESIGN RIGHTS

Design Rights protect against deliberate copying of the shape or configuration of an article and may exist in addition to other forms of IP protection such as Patent, Copyright or Registered Design rights. There are two types of design right: an unregistered design gives a right against copying (protection in the UK for 10 years) whilst a registered design provides a legal monopoly which means that the owner can prevent another party form using the right without permission, and can last for up to 25 years (they must be renewed every 5 years).

1.3.1

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 drawings of computer chips, engineering components and architectural drawings).

1.3.2

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.

1.4 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. There are two types of trademark - registered and unregistered. 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. Trademarks which are capable of being registered, can, once registered, benefit from registration lasting for 10 years (which can be renewed). The goodwill in unregistered trademarks is also capable of being protected by the law of passing off but proving a right to protection, in this way, is more difficult and so registration is preferable, wherever possible.

1.5 CONFIDENTIALITY AND KNOW-HOW

Confidential Information is information which is confidential in nature, having the necessary quality of confidence and disclosed in circumstances importing an obligation of confidence. Almost any type of information can be the subject of confidential information, and can apply to both commercial information and personal information.

Know-how is a type of confidential information, which is information which may be commercially or technically valuable and which is regarded as secret. It may include, for example client lists or 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 Non-Disclosure Agreement (NDA). This may be a reciprocal agreement whereby confidential information is both disclosed and received. A NDA may be obtained from The Head of Effective Services. Whilst, strictly speaking, Know-how and confidential information are not forms of IP, they can be bought, sold and licensed like other forms of IP and can persist indefinitely.

APPENDIX 2 STAFF PROCEDURES

2.1 PUBLICATIONS It is the Trust's protocol 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 the work. However, if intellectual property is to be exploited, all work needs to be kept confidential until it is correctly protected. Advice should be sought from The Head of Effective Services before publicly disclosing any work.

2.2 CONFIDENTIALITY Any IP with the potential to be exploited must not be disclosed to anyone outside the Trust (including presenting papers at conferences, abstracts, chapters in books and any other verbal or written communication), until IP advice has been sought from The Head of Effective Services.

2.3 RECORD KEEPING It is important for staff working on projects which generate IP, to keep written, dated records of their activities and results. This is especially important for patent application purposes in the US, since the US has a protocol 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 for R&D. The Head of Effective Services is responsible for maintaining a register of all the IP owned by the Trust, including the date and time it was reported. It is also their responsibility to keep safe any important original documents, such as confidentiality agreements, relating to IP. It is advisable that key members of staff concerned should also retain copies of these documents.