

CPFT Intellectual Property (IP) Management Policy

Author	Research and Development
Sponsor	Chief Medical Officer
Responsible committee/individual	Quality and Compliance Executive
Ratified by	Quality and Safety Committee
Consultation & Approval: (committee/Groups which signed off the policy, including date)	Clinical Effectiveness Executive Group 5 th June 2024 Research and Development Committee 17 th December 2024
This document replaces:	2.1
Date ratified	14/01/2025
Date issued	14/01/2025
Review date	14/01/2027
Version	2.2
Policy Number:	CP06
Purpose of the Policy	To set out the background and direction the Trust will take to ensure that innovation and associated intellectual property (IP) arising in the organisation is managed and disseminated according to national guidance
If developed in partnership with another agency, ratification details of the relevant agency	N/A
Policy in-line with national guidelines:	Framework and Guidance on the Management of Intellectual Property in the NHS and Section 5 of the Health and Social Care Act 2001



Signed on behalf of the Trust:

Steve Grange, Chief Executive Officer

Elizabeth House, Fulbourn Hospital, Fulbourn, Cambs CB21 5EF Phone: 01223 726789

Version Control Page

Version	Date	Author	Comments
1.0	02/04/2009	Natercia Godinho	Policy developed and ratified by Quality and Healthcare Governance Committee
2.0	15/03/2015	Mary Kasanicki/ Rachel Kyd	Updated 'Duties' (Section 3.3); Ownership and Recognition clause (Section 6). Commercial exploitation of IP (Section 7.2.4)
2.1	27/6/2018	Mary Kasanicki/ Jane Gaffa	Updated ratification committees
2.2	02/05/2024	Stephen Kelleher/ Kate Jones/ Mary-Beth Sherwood	Update to section 9.2 Adviser organisations by removal of reference to HEE 9.2.2 and throughout document.

Policy Circulation Information

Notification of policy release: All recipients; Staff Notice Board; Intranet;	
Key words to be used in DtGP search	Intellectual property, IP

CQC Standards	
Other Quality Standards	

Contents

Section		Page
1	Introduction	4
2	Purpose	4
3	Scope	4
4	Definitions	4
5	Duties	4
6	Innovation and intellectual property	5
7	Intellectual property rights	5
8	Ownership and recognition of intellectual property	6
9	Intellectual property management	7
10	Operational procedures	10
11	Contacts	11
12	Education and training requirements	11
13	Monitoring compliance	12
14	Links to other documents	12
15	References and Acknowledgements	12
16	Equality Impact Assessment	13

1 Introduction

This document sets out the general background and direction the Trust will take to ensure that innovation and associated intellectual property (IP) arising in the organisation is managed and disseminated according to the Framework and Guidance on the Management of Intellectual Property in the NHS and Section 5 of the *Health and Social Care Act 2001* as amended from time to time.

2 Purpose

The policy will seek to ensure that the Trust is in a position to identify, protect, exploit and disseminate any IP that it generates and that all IP is managed efficiently and effectively.

3 Scope

Trust wide

4 Definitions

The meanings of terms are defined within the body of this policy.

5 Duties

5.1 All employees

All Trust employees are responsible for providing true and accurate information on the innovation being reported.

5.2 R&D manager

Responsible for holding regular meetings with the Adviser Organisations and review progress made on the development and exploitation of IP innovation reported.

5.3 Biomedical Research Centre (BRC) IP manager

The Trust works with the Cambridge University Hospital's Biomedical Research Centre IP Manager to identify, protect, manage and exploit intellectual property rights arising from research that is funded either wholly or in part by the mental health stream of the BRC. The IP Manager should be the first point of contact for information and advice regarding IP which is created using BRC funded staff or facilities.

5.4 Cambridge Enterprise and Health Enterprise East

Please refer to Section 9.

6 Innovation and intellectual property

The novel or previously undescribed tangible output of any intellectual activity can legitimately be described as innovation. It may for example be:

- a novel treatment
- a new diagnostic
- a device
- a new drug or its new use
- use of data
- software
- training material or patient information leaflets
- treatment protocol
- a new management system.

There is always IP associated with innovation.

Under the terms of the convention establishing the World Intellectual Property Organisation (WIPO), Stockholm 1967, IP was defined as:

'the rights relating to:

- literary, artistic and scientific works;
- performances of performing artists, phonographs and broadcasts;
- inventions in all fields of human endeavour;
- scientific discoveries;
- industrial designs;
- trademarks;
- service marks and commercial names and designations;
- and all other rights resulting from intellectual activity in the industrial, scientific, literary and artistic fields.'

IP has an owner, it can be bought, sold or licensed and should be adequately protected. The owner of IP can control and be rewarded for its use. IP generated by all NHS bodies through all their activities is now recognised as an asset of value which should be used in the best interests of the NHS and the country as a whole by those best able to do so.

In this document, innovations which need to be developed commercially are called inventions and the employee responsible for the innovation is called inventor. The owner of the IP may or may not be the inventor.

7 Intellectual property rights

Intellectual property rights define the legally protected rights that enable owners of items of IP to exert monopoly control over the exploitation of these rights, usually with commercial gain in mind. They give the right to stop others exploiting this property, sometimes for a fixed period, sometimes indefinitely. The principal forms of these rights are:

- patents
- copyrights
- design rights
- trademarks
- know-how.

8 Ownership and recognition of intellectual property

From Framework and Guidance on the Management of Intellectual Property in the NHS (section 3.11):

'In the absence of express contractual provision, ownership of IP is determined by statute. Generally speaking, under statute an employer will be the owner of IP generated by an employee in the course of employment or normal duties unless the employer and employee have agreed otherwise. Such an agreement does not have to be in writing and can have arisen through custom and practice. Any agreed custom and practice should ideally be reflected in writing in the contract of employment. Where there are no contrary agreements then this should be stated expressly in the contract. However, for patentable inventions there are additional conditions which must be met in order for the employer to own the rights to the invention. Not only must the invention be made in the course of normal duties, or in the course of duties falling outside the normal duties but specifically assigned to the employee, but it must also have been reasonably expected that an invention may result from such duties. In addition, when looking at patentable inventions, the employer not the employee will be the owner where the invention is made by the employee in the course of duties which, because of their nature and particular responsibilities, imposed on the employee a special obligation to further the interests of the employer NHS body.'

Although the Intellectual property rights created by employees vests in Trust, a confirmatory assignment of IP to the Trust is required as evidence to potential investors. The Trust will not proceed with the exploitation of the IP until such confirmatory assignment has been made.

In addition to employees whose payroll costs are met entirely by the NHS, there are many who hold joint appointments where part of their payroll costs are partially or totally funded by another party (e.g. a university, a medical charity, a commercial sponsor). Sometimes the Trust uses its own funds to support an employee in a university (e.g. through distinction awards) with the employee holding a university contract. Normally the employer holding the employment contract would own the IP with a commitment to share the benefit (eg royalties) with the other party.

Where research is conducted by an employee in collaboration with other organisation(s), the project should not start until a written collaboration agreement defining ownership of any arising IP is in place. Negotiation and conclusion of such agreement is the responsibility of the R&D legal team with advice from the project team and adviser organisations.

Factors which affect sharing of benefits, include consideration of the source of funding for the post and the resources used to support the post including the use of NHS patients. For such employees holding an NHS contract, the model employment conditions for dealing with IP owned by the NHS would be appropriate if agreed with the other party. It is appropriate that revenue sharing and income streams in relation to work resulting from joint appointees be agreed

by the joint employers. Factors to be taken into consideration in agreeing these include:

- proportion of funding and other resources from each party, including access to NHS facilities and equipment and involvement of patients
- IP management resources provided by each party
- ownership of background IP and contribution to foreground IP
- the Department of Health's attitude to access to essential medicines in the developing world.

These considerations mean that although ownership of IP may reside with one party (University or Trust) the revenue derived from commercialising the IP may be split between the Trust, University and other funders depending on the exact circumstances.

9 Intellectual property management

9.1 Background

The Framework and Guidance on the Management of Intellectual Property in the NHS came into effect from 9 September 2002, when Section 5 of the *Health and Social Care Act 2001* came into force.

The aim of the guidance is to establish within NHS Trusts, Primary Care Trusts and Independent Providers of NHS Services a structure for managing innovation to benefit NHS patients and employees. This forms part of the NHS Plan which commits the NHS to ensuring that new technologies are identified and developed in the interests of NHS patients and society; leading to new products, improved interventions and services.

The guidance recognises that most innovations are best implemented by making them widely disseminated, but some may only be realised through commercial development and for these, professional management of IP is crucial. Section 5 of the Act also allows the Secretary of State and NHS Trusts to form or invest in companies in order to facilitate income generation.

9.2 Adviser organisations

The Framework and Guidance on the Management of Intellectual Property in the NHS advises NHS bodies to contract with an organisation to provide high quality advice on its behalf and to act as adviser. The adviser organisations for the Trust are:

- Cambridge Enterprise (CE) and

9.2.1 Cambridge Enterprise (CE)

CE provides a service for all University of Cambridge staff working on the Cambridge Biomedical Campus.

Cambridge Enterprise is a wholly owned subsidiary of University of Cambridge responsible for commercialisation of intellectual property on behalf of the University.

Cambridge Enterprise shall be lead project manager for any intellectual property, which has been created by University employees, whether or not Trust employees were also involved in their creation.

In order to facilitate the work of the adviser organisation, the Trust has an identified lead person (R&D manager) to act as a bridge between employees and the adviser organisation.

9.2.2 Responsibilities of the adviser organisations

CE will assess all innovations generated by staff (NHS or University) on the Cambridge Biomedical Campus and will provide support in:

1. identifying IP of potential value, through audit and other means
2. assessing potential value of IP
3. determining ownership of IP
4. determining whether identified IP should be protected
5. determining what type of protection is sought, if any
6. arranging such protection
7. determining the best route to market for any technology
8. negotiating and concluding suitable agreements for commercialisation of technology
9. using reasonable endeavours to successfully exploit technology via formation of a new company, licensing or other agreements.

9.2.3 Commercial exploitation of intellectual property

Identified IP, however it arises, would be evaluated by the adviser organisation to determine whether exploitation, commercial or otherwise, is appropriate.

If the IP has commercial potential, part of this evaluation is to resolve the question of ownership. In evaluating whether to follow a commercial route, the adviser organisation will carry out a risk appraisal including the costs of exploiting the IP, the expected value to the NHS and the financial return.

When income is generated by commercial exploitation of IP there will be costs incurred by the adviser organisation in obtaining this income. The Trust has a contractual agreement with CE which defines the proportion of this income which the adviser organisation will receive as its commission and the balance (the residual income) which will be due to the Trust. The Trust would normally meet costs of identification of IP, initial patent protection and training.

Section 5 of the *Health and Social Care Act 2001* authorises Trusts to form or participate in the formation of companies and to invest in companies for income generation purposes. In particular, this enables them to participate fully in companies established to exploit Trust IP, including acquiring shares. In accordance with the regulation for three star Trusts, 'business cases will still be required for such companies, although they will not be subject to approval by the Secretary of State.'

There are two circumstances in which it may be appropriate to establish companies for the exploitation of NHS IP.

1. The first is where the company is intended to grow in value or act as a route to market (commonly called a spin-out company and limited by shares).
2. The second is where the company is not intended to make a profit and uses its available income and property only for its objects (normally a company limited by guarantee).

Cambridge Enterprise will be the Trust adviser for formation of companies set up to commercialise Trust IP. The Trust and the employee inventor will be eligible to own an equity share in the company. The size of the shareholding will be decided on a case by case basis, taking in to account the contributions of all the parties and other funders.

9.2.4 Revenue sharing

The most usual route to commercial exploitation is through licensing. Income from successful commercial exploitation of IP, through sale or licensing of IP, through dividends or sale of shares, will normally be received by the Trust. In achieving this income, the Trust and the adviser organisation may have incurred expenditure for patent or legal work. This expenditure will be recovered as a first charge on the income. The net income, after deduction of these costs, will then be shared between CE as appropriate, and the Trust responsible for generating the IP. CE will receive 20% of the net income.

As an incentive to employees, the Trust will grant its employees and respective departments an interest in revenues arising from the successful exploitation of specific IP. The standard division of the revenues received by the Trust, after deduction of agreed costs and the share to CE shall be:

- one third to the inventor(s)
- one third to his/her clinical department
- one third to the Trust.

However, where third parties have funded work or provided resources, or where there are co-inventors from other institutions, there may be an obligation for the Trust to also share any revenue with those parties. In particular, the standard division of revenues received by the Trust, after deduction of agreed costs and the share to CE from successful commercial exploitation of IP resulting from an invention coming from research or other work funded by CPFT charities shall be:

- one third to the inventor(s)
- one third to his/her clinical department
- one third to the charity.

These terms may be subject to review where there is deviation from normal practices. In particular, and in accordance with the provisions of the Framework and Guidance on the Management of Intellectual Property in the NHS which

states that “Successful exploitation of IP is often derived from R&D undertaken collaboratively with universities. NHS bodies for whom this is likely to arise should take care in setting their reward structures to ensure, as far as possible, that their employees have sharing arrangements similar to those of employees in their collaborating university”, the R&D Manager will at his discretion in such cases agree an appropriate fee sharing structure with the inventors.

Revenues allocated to the Trust are to cover the cost of legal fees in relation to Addenbrooke’s IP development and for exploitation of new inventions. Where the exploitation of IP results in the formation of a company, the equity division will be decided on a case by case basis. Any revenue in this context will be distributed after the Trust has recovered all direct costs and/or support for patent and legal services to protect IP and negotiate commercial contracts.

In the event that the Trust and its employees cannot agree on issues of IP management (i.e. revenue share, ownership of intellectual property etc), a panel of experts will be set up to provide independent judgment.

9.2.5 Dissemination

IP that is a ‘good practice’ innovation, which has no commercial value but has the potential to improve health and to save expenditure by the NHS, should be evaluated locally and disseminated freely when appropriate.

10 Operational procedures

Two levels of advice and support are available to employees:

1. The R&D manager (see contacts section below) will provide a first level of advice and information on IP policy and procedure and will facilitate access to Cambridge Enterprise and Health Enterprise East.
2. CE will assess all innovations generated by staff (NHS or University) on the Cambridge Biomedical Campus and will provide support as identified in responsibilities of the adviser organisations above.

10.1 Communicating ideas

10.1.1 University staff

The first step for University staff holding an NHS honorary contract with an idea that may have commercial potential is to fill in an invention disclosure form;

<http://www.enterprise.cam.ac.uk/our-services/academics-researchers-and-students/commercialise-your-research/disclose-an-invention/>

This form is the same for all inventions, regardless of their origin or funding. CE is also happy to give advice on matters relating to IP and how research can be applied to the commercial sector. The form provides a straightforward way of supplying the information needed by CE to start assessing the patentability and commercial opportunity of an invention.

Signed forms have to be returned by **post** (only) to the address in the contacts section below.

CE will acknowledge receipt of the form within one working day, and a technology transfer professional will be allocated to the case in less than a week.

CE is also available for a confidential discussion of the commercial potential of an idea or invention.

Note: Non-confidential disclosure of inventions to other people or organisations can damage or destroy the possibility of obtaining patent rights. CE can advise on this. For this reason, CE recommends that the invention disclosure form is **not** transmitted by email.

10.2 Continuing prosecution and maintenance

On further investigation of the commercial prospects of an invention, it may become apparent that the cost of commercialisation outweigh the benefits. The R&D Manager on advise from the appropriate Advisor Organisation will make the decision as to whether the Trust and the Advisor Organisation will continue to pay the costs of patent prosecution and maintenance. In specific instances the Trust may decide not to pursue its intellectual property rights (IPR) and may assign ownership of the intellectual property to the relevant inventors (assignees) with their agreement, the costs of such assignment to be borne by the assignee. In such cases, the assignees may pursue and exploit the relevant IP in their own time and without utilising Trust facilities and resources.

11 Contacts

11.1 Senior R&D manager

Research and Development Department
Addenbrooke's Hospital
Box 277
Hills Road
Cambridge, CB2 0QQ

Telephone: +44 (0)1223 217418

Email: stephen.kelleher@cpft.nhs.uk / r&d@cpft.nhs.uk

11.2 Cambridge Enterprise Ltd

Cambridge Enterprise Limited
University of Cambridge
Hauser Forum
3 Charles Babbage Road
Cambridge CB3 0GT

Telephone: +44 (0)1223 760339

Email: enquiries@enterprise.cam.ac.uk

12 Education and Training Requirements

This document does not require any specific education or training for implementation, but has been reviewed and advised by the CPFT solicitor

13 Monitoring Compliance

This policy does not require monitoring as such. The policy will be reviewed after two years to ensure that it is up to date and relevant, or earlier if new processes are introduced for intellectual property.

14 Links to other documents

There are no other Trust policies that related to this document

15 References and Acknowledgements

Department of Health. Framework and Guidance on the Management of Intellectual Property in the NHS.

Department of Health. *Health and Social Care Act 2001*

Department of Health. An introductory handbook for R&D managers and advisers: *The management of intellectual property and related matters*. London. 1998

Department of Health. *Handling inventions and other intellectual property*. London. 1998

Equality Analysis Form

Name of Proposal - policy, strategy, function, service being assessed:	CPFT Intellectual Property (IP) Policy
Is this a new or existing policy, practice or change to a service?	Existing policy with updates
Directorate, Department / Service:	CPFT Wide
Details of the person completing this impact assessment form. Name, Job Title, Telephone / Extension:	Mike Garwood, Research and Development Contracts Manager 01223 219467
Those involved in the assessment:	Due to the indirect nature of this policy, no other persons were involved.
Date:	3 October 2024

What are the intended outcomes of this work)? (Include outline of objectives and function aims)	To ensure that innovation and associated IP arising in the organisation is managed and disseminated according to national guidance.
Who will be affected? (e.g. staff, patients, service users etc.)	Directly, staff employed by CPFT will be affected, with the intention they will be incentivised to innovate. Indirectly, the underlying intention is to facilitate medical advances and patient benefit.
What are the desired outcomes?	The aim of the policy is to protect staff and CPFT corporately when IP is developed during working time, to ensure such IP is protected and appropriately commercially exploited to promote improvements in patient care and patient benefit.

<p>What does this policy, function, process link to in terms of wider Business plans and objectives?</p>	<p>This links to</p> <ul style="list-style-type: none"> - the one of the four Trust priorities in the three year strategy 2023-26, 3. <i>A system leader in innovation and research.</i> - One of the six workstreams in the improvement programme, 5. <i>Enhance the care we deliver with pioneering innovations and research.</i> <p>This also links to Framework and Guidance on the Management of Intellectual Property in the NHS and Section of the Health and Social Care Act 2001 (income generation)</p>

Evidence considered

When looking at the impact on the equality groups, you must consider the following points in accordance with General Duty of the Equality Act 2010:

In summary, those subject to the Equality Duty must have due regard to the need to:

- eliminate unlawful discrimination, harassment and victimisation;
- advance equality of opportunity between different groups; and
- foster good relations between different groups

Consider how your assessment has been able to demonstrate Positive Impact, Negative / Adverse Impact or Neutral Impact?

<p>What evidence have you considered? <i>List the main sources of data, research and other sources of evidence This can include national research, surveys, reports, research interviews, focus groups, pilot activity evaluations etc.</i></p>
<p>Disability <i>Consider and detail on attitudinal, physical and social barriers.</i> Neutral impact. A web search on this topic (Intellectual property and disability) shows considerable discussion as to how IP rights can sometimes act as a barrier to people with this protected characteristic. This occurs where IP might prevent material being replicated in an accessible manner, and legislation aims to address this. This policy would cause no such barriers, or any other identifiable barriers to people with this protected characteristic.</p>
<p>Sex <i>Consider and detail on men and women (potential to link to carers below).</i> Neutral impact. There is no evidence that this would adversely impact people based on this protected characteristic. For the staff involved, UK government research “Gender Profiles in UK Patenting”¹, states “<i>Although historical analysis reveals ever-increasing levels of female patenting, the growth rate is slow and the absolute numbers are still very low. The world of patenting remains male-dominated and even in 2015 there is a clear gender disparity with</i></p>

¹ [Gender Profiles in UK Patenting - An analysis of female inventorship \(publishing.service.gov.uk\)](https://publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/431117/gender_profiles_in_uk_patenting.pdf)

88% of all GB patent applications coming from all-male inventors, rising to almost 96% when mixed teams are considered”.

This demonstrates an underlying demographic trend in relation to equality in IP development. Based on the Trusts Equality Diversity & Inclusion Strategy 2019-2024², in the staff groups “Add Prof Scientific and technical” and “Medical and Dental” a large majority of the staff are identified as female, and so the aspects of this policy designed to promote the development of IP by this staff group could potentially provide a positive impact the above identified national issue. However, the effect of this would be very difficult to measure and so it is concluded that the impact will be neutral.

Race *Consider and detail on difference ethnic groups, nationalities, Roma gypsies, Irish travellers, language barriers. See Trust website for the Patient and Carer Race Equality Framework for more information on how to identify potential impacts for racialised communities.* [Patient and Carer Race Equality Framework | CPFT NHS Trust](#)

Neutral impact. There are no aspects of the policy that would directly or indirectly act as a barrier to access the same opportunities, or discriminate in any way, based on this protected characteristic.

Age *Consider and detail across age ranges on old and younger people. This can include safeguarding, consent and child welfare.*

Neutral impact. There is no particular evidence that in the context of the Trust, that IP developments, or the impact on them, will favour any particular age group. The policy is entirely neutral as to what parts of CPFT patient services such innovations may arise and IP may equally be to be expected to be developed by younger staff members undertaking training and research study, as equally from older, more senior or experienced staff leaders engaged in research. Thus, there are no aspects of the policy that would directly or indirectly act as a barrier, or discriminate in any way, based on this protected characteristic.

Gender reassignment (including transgender) *Consider and detail on transgender and transsexual people. This can include issues such as privacy of data and harassment.*

Neutral impact. There are no aspects of the policy that would directly or indirectly act as a barrier to access the same opportunities, or discriminate in any way, based on this protected characteristic.

Sexual orientation *Consider and detail on heterosexual people as well as lesbian, gay and bi-sexual people.*

Neutral impact. There are no aspects of the policy that would directly or indirectly act as a barrier to access the same opportunities, or discriminate in any way, based on this protected characteristic.

Religion or belief *Consider and detail on people with different religions, beliefs or no belief.*

Neutral impact. There are no aspects of the policy that would directly or indirectly act as a barrier to access the same opportunities, or discriminate in any way, based on this protected characteristic.

Pregnancy and maternity *Consider and detail on working arrangements, part-time working, infant caring responsibilities.*

Neutral impact. People with this protected characteristic can face barriers, for example, if they are engaged in research and have a break in the continuity of their employment. The

² [download.cfm \(cpft.nhs.uk\)](#)

<p>policy should not adversely affect individuals in these circumstances, who should still receive the corresponding benefit from their IP development, for example, continue to receive any agreed revenue sharing.</p>
<p>Carers Consider and detail on part-time working, shift-patterns, general caring responsibilities, protected characteristics of the carer themselves and if this makes seeking help from services more challenging. Neutral impact. People with this characteristic might be expected to have barriers to gaining recognition for their work, if they work part time, and it is important that their contribution to any research and development is recognised, for example, by the recognition that any IP may be developed as a collaboration and several people might be its inventor.</p>
<p>Other identified groups Consider and detail and include the source of any evidence on different socio-economic groups, area inequality, income, resident status (migrants) and other groups experiencing disadvantage and barriers to access. Neutral impact. Due to the intangible nature of the subject matter of this policy, no other groups could be identified as particularly affected.</p>

Engagement and involvement

<p>Have you consulted on the proposal? If so with whom? If not why not? Due to the intangible and abstract nature of the subject matter of this policy, it has only been consulted on amongst relevant members of the R & D workforce</p>
<p>How have you engaged stakeholders in gathering evidence or testing the evidence available?</p>
<p>For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:</p>

Action planning for improvement:

<p>Outline key actions based on any gaps, challenges, and opportunities you have identified and will be addressed through consultation or further research.</p>			
Category	Actions required to address gaps and issue/s	Target date	Person responsible and their division
Gaps and Challenges	None		
Monitoring, evaluating & reviewing	None		
Signed off by EDI Team	<p>Name: Approved by Sue Rampal, Equality and Diversity Lead</p>		<p>Date: 20/11/24</p>