



*Coastal West Sussex
Clinical Commissioning Group*

Intellectual Property Rights Policy

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For more information on the status of this policy, please contact:	
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Intellectual Property Rights

1. Introduction

The NHS is an organisation that has innovation at the heart of its services. In the NHS, innovation occurs in the delivery of patient care, in the education and training of employees and in R&D programmes. Innovation occurs naturally in the normal course of employment.

In September 2002 the Department of Health (DH) published new guidance on the management of Intellectual Property (IP) in the NHS which superseded the previous policy framework published in 1998. The 2002 guidance sets out how NHS organisations can contribute to the development of the NHS as an innovative organisation by capturing new technologies, such as novel treatments, devices, drugs, data, software, training materials, or management systems, and by ensuring that those inventions which can contribute towards improving the health service are appropriately developed, exploited and disseminated.

There are various forms of legal protection for Intellectual Property, including patents, copyright, design rights, and trademarks.

Coastal West Sussex Clinical Commissioning Group (CWS CCG) is required to ensure that Intellectual Property (IP) arising in the organisation is managed within the 2002 Framework and Guidance. The Guidance contains model management arrangements and employment conditions which will contribute towards developing the CWS CCG's arrangements for managing IP for the benefit of NHS employees and patients.

2. Purpose/ Scope

This policy is to encourage and enable an employee to participate in the generation of IP as part of its commitment to encourage innovation and to deliver the best possible patient care. Sometimes an improvement to patient care can only come about by the protection of the IP rather than by immediate widespread dissemination. The policy is to maintain a balance between the legitimate needs of CWS CCG to protect its interests and the provision of a creative environment for employees in which to work

Employee in this context means:

- a) All staff that are full or part time employees of CWS CCG.
- b) Staff with CWS CCG contracts of employment whose payroll costs are partially or wholly funded by another party (e.g. medical charity, a government

department) unless the contract between CWS CCG and that party assigns ownership of any IP to that party.

c) Staff who have honorary CWS CCG contracts with substantive employment elsewhere e.g. University academic otherwise employed part-time.

d) Where IP is generated during this non-CWS CCG employment, which is within the specialist area of the CWS CCG employment, CWS CCG owns the IP. Flexibility will be exercised where the non CWS CCG employment gives a greater opportunity for IP to arise.

e) Trainee professionals hosted by CWS CCG who generate IP during the course of their training.

f) 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 CWS CCG.

g) CCG staff seconded to another organisation or employees of another organisation hosted by the CCG under contract are subject to the arrangements for the ownership of IP agreed between the CCG and that organisation.

3. Definitions

Intellectual property can be defined as products of intellectual or creative activity in the form of novel ideas, innovation or research and development which can be given legal recognition of ownership through intellectual property rights.

Intellectual Property Rights (IPR) are a commodity that can be bought or sold. It may be useful to set out examples of IP in the following format:

Category	Protection Method	Examples
Inventions	Patents	New medical device, medical substance
Literary works	Copyright	Computer software, patient leaflet, journal article
Designs, drawings	Design rights	Medical illustration
Trade secrets	Know-how, knowledge	Surgical technique

4. Roles and Responsibilities

The Chief of Development and Transformation acts as CWS CCG Lead for IP.

5. Ownership

The ownership of IP arising from activities undertaken jointly with another organisation, e.g. a university, will be assigned to either of the employing

organisations by agreement, unless subject to prior agreement with a third party external organisation. The proportion of IP contributed by each party will be agreed by discussion between the parties as early in the process as possible.

IP generated by an employee acting outside the normal course of their NHS duties and not directly related to the work of the CCG will be owned by the employee subject to the terms of employment set out in this document.

CWS CCG recognises that from time to time, during the normal course of employment, an employee may generate IP which may have value in the delivery of better patient care. Under the Copyright, Designs and Patent Act 1988, CWS CCG legally owns IP which arises in, or could reasonably be expected to arise from, the course of the normal duties of an employee, including R&D, delivery of patient care, and education and training, and/or using CWS CCG facilities, unless such intellectual property is subject to a formal agreement between CWS CCG and an external funding organisation. Such ownership remains with CWS CCG upon the departure of the employee.

6. IP Management Arrangements

Responsibilities of employees

All employees have an obligation to report to the Lead for IP the existence of any intellectual property as defined in Section 3 of this policy. The Lead for IP will then assist the inventor in providing sufficient information on which a commercial assessment can be made.

Any employee wishing to discuss the protection of any idea or other form of IP should discuss the matter with the Lead for IP at the earliest opportunity and, in any event, before disclosure of the idea to any party outside the CWS CCG either orally or in writing. Inventors are obliged to maintain confidentiality until such time as CWS CCG has made a decision on whether to exploit their idea or technology or up to the point at which protection is in place. Prior public disclosure (other than under explicit terms of confidentiality or to another employee of CWS CCG) may invalidate any subsequent application for legal protection (e.g. patent) and diminish both potential commercial value and benefits accruing to CWS CCG and the inventor. Disclosure to CWS CCG's R&D office or NHS Innovations South East shall not be viewed as a public disclosure.

It is essential therefore that ideas and inventions are not generally discussed and are reported instead through the correct channels. Written consent must be obtained from CWS CCG's Lead for IP and any third party external organisation prior to publication of any aspect of the innovative idea or technology in question.

All employees should be aware of the Importance of avoiding improper disclosure of their inventions.

Public disclosure could, for example, include any of the following: written article whether official or not; poster presentation; oral presentation; an abstract or conversations/correspondence without a confidential agreement.

Employees should take no steps to exploit any CWS CCG IP without the specific approval of the Relevant Executive. Employees are expected to co-operate with those charged by CWS CCG to execute its management responsibilities.

Employees should maintain clear and dated documentation, or a research log, during the development of an idea or technology as this may be required as supporting evidence for any patent application.

Employees are obliged to seek advice on IP issues from CWS CCG's Lead for IP before entering into any negotiation with a third party concerning research. All contracts for the provision of such services by CWS CCG or its employees must include clauses covering intellectual property arrangements. This remains the case even if IP is to be solely owned by the sponsoring company or institution initiating the research.

Upon leaving CWS CCG, it is incumbent upon inventors to maintain contact with the CWS CCG IP Lead. All obligations of confidentiality associated with the intellectual property will remain.

7. Recording and assessment of IP

CWS CCG Lead for IP will keep a record of the date and time on which an employee reports a new creative product. Once the IP has been registered with CWS CCG, CWS CCG's Lead for IP will discuss next steps with the inventor.

CWS CCG will make reasonable endeavours to assess any innovative idea or technology within three months of its having been brought in writing to the attention of CWS CCG's Lead for IP.

CWS CCG may consult on a confidential basis with appropriate experts in the field of the intellectual property in question in order to assist with assessment of the innovation and its commercial potential.

CWS CCG is supported in the identification, management and exploitation of IP by NHS Innovations South East (NISE). NISE is one of a national network of Innovation Hubs that provide specialist IP assistance to NHS organisations

CWS CCG undertakes to make decisions on which form of IPR protection to take, e.g. registration of a design, copyright, trademark or domain name, or filing of a patent, on the basis of appropriateness/fitness for purpose as well as with regard to the implications for financial return to CWS CCG and inventor.

8. Protection and exploitation of IP

Where it is decided to seek exploitation of CWS CCG intellectual property, discussions between interested parties will be held to determine the appropriate action to be taken. This may include one or more of the following:

- The retention of confidentiality and strict avoidance of prior disclosure
- The filing of a patent application in the name of CWS CCG, with the inventor as named inventor
- The filing of an application to register for copyright in the name of CWS CCG where necessary e.g. USA (not required in UK where copyright is automatic)
- The identification of potential licensees
- The assignment of rights to CWS CCG or to a third party
- The formation of a company to exploit the technology

CWS CCG undertakes to involve the inventor throughout the protection/exploitation process as part of a project team and to take on board his/her ideas and wishes as far as possible. The inventor shall provide reasonable assistance in the exploitation process by, for example, providing information promptly upon request, attending meetings with potential licensees and advising on further development.

All arrangements and commitments involving CWS CCG with regard to the potential exploitation of an innovative idea or technology must be made via the CWS CCG Lead for IP.

For those innovative projects which are judged to have potential for commercial exploitation, CWS CCG undertakes to provide access to specialist advice on IPR protection and exploitation, including:

- negotiation and drafting of contracts with commercial partners and the preparation of confidentiality agreements
- patent search and application procedures
- licensing assignment/agreements
- advice on market research and finance
- development of a business plan

CWS CCG will re-examine its involvement in any project on a periodic basis and reserves the right to cease its involvement at any point, in which case ownership of intellectual property rights shall be re-negotiated.

CWS CCG may decide to waive its right to own its intellectual property and assign ownership to the employee, with the full costs of this being borne by the assignee (including all patent costs, legal assignment costs and management costs).

CWS CCG will pay for patent search and application fees (wholly or partly with commercial partners) and other costs relating to the processing of an application. These costs will have first call on any income relating to the project. CWS CCG reserves the right to withdraw support at any time during the patenting process. In this instance ownership of intellectual property rights shall be re-negotiated.

Annual patent reviews will be undertaken to decide whether or not it is viable for the CWS CCG to renew a patent. If the patent is not considered viable, CWS CCG is at liberty to cease its involvement with the project in which case ownership of intellectual property rights shall be re-negotiated. CWS CCG must inform interested parties with sufficient time for them to maintain the patent before expiry.

CWS CCG will defend granted patents and at its discretion pursue infringers. Inventors should be aware that the cost of any such action may be a call on potential royalty income.

9. Non-exploitation of IP by CWS CCG

If CWS CCG decides not to apply for patent or other legal protection in respect of any invention which belongs to the institution by virtue of section 39 of the Patents Act, the employee concerned will be notified in writing of that decision as soon as is reasonably practicable. Ownership of IPR will then be ceded to the inventor. In this case CWS CCG has no obligation to meet costs associated with IPR protection or exploitation.

If, following such a decision by CWS CCG, the employee concerned wishes to apply for patent or other protection or otherwise exploit the relevant IP, he/she must first inform CWS CCG's Lead for IP. The relevant employee will be notified of any objection to his/her proposed action. The sole ground for such objection being that the exploitation of the invention would involve or result in the disclosure to third parties of trade secrets or other confidential information belonging to CWS CCG and/or its patients and that such disclosure might damage the interests of CWS CCG.

Where CWS CCG does object, the employee must undertake, in consideration of the payment of compensation, not to proceed to apply for patent of the invention concerned nor to assist any other person to do so nor to otherwise exploit the intellectual property. The calculation of compensation will have regard to the factors set out in section 41 of the Patents Act.

CWS CCG maintains a register of all IP rights owned by CWS CCG which have been licensed or assigned to a third party where an employee is a named inventor or originator. Details of these IP rights and the income they generate will be given to the Department of Health from time to time on request.

10. Revenue Sharing

CWS CCG believes that revenue sharing with the inventor/s encourages the development of new ideas and inventions and their commercialisation and exploitation.

The revenue from successful licensing, whether a lump sum or royalties, from option, licence or assignment agreements is:

- (a) first subject to repayment of external patenting (filing, searching etc) and legal costs;
- (b) if appropriate, subject also to the NHS Innovations South East management fee.

Net Revenue	Inventor(s) %	Inventor's department %	CWS CCG %
Up to £50,000	75	12.5	12.5
£50k to £500k	37.5	31.25	31.25
Over £500k	12.5	43.75	43.75

The inventor's share of net revenue is a discretionary gift by CWS CCG which is intended to continue for the inventor's lifetime or the term of the licence agreement.

The normal NHS approach is to allow revenue sharing during the inventor's lifetime. After the inventor's death CWS CCG will permit revenues to the inventor's estate where CWS CCG continues to benefit from royalties.

It is at the discretion of the inventor(s) to agree to share the inventor's share of the income with others if appropriate.

CWS CCG will agree with any external organisations or partners, which contribute to generation of IP, as to how revenue will be shared between the eligible parties.

11. Special Conditions Concerning Copyright

Statute provides that copyright in any work produced for CWS CCG by an employee in the normal course of employment belongs to the employer. CWS CCG will normally assign to the author copyright in a work intended for publication in a professional or academic journal or electronically, and waive any claim it may have to benefits arising from the publication. CWS CCG however reserves the right to itself to reproduce and use these publications at no cost for its own non-commercial purposes, including for research and training. CWS CCG does not assign any of its other copyright to the author including, without limit:

(a) course or training materials or patient information leaflets produced by an employee in the course of employment for CWS CCG and which are produced, used or disseminated within or outside CWS CCG

(b) any software program generated by an employee in the normal course of their employment;

(c) any designs, specification or other works which may be necessary to protect rights in commercially exploitable IP.

Students are required to disclose full details of any intellectual property they generate that is related to their employment activities within CWS CCG. They are required to assign ownership of any intellectual property rights to CWS CCG if requested. In consideration for this, CWS CCG will treat students on a par to employees for the purposes of commercial exploitation of the intellectual property.

The assignment of copyright will apply to books as well as to academic articles.

Where more than one person or organisation is working together, the ownership must be agreed in writing and at the start of the collaboration.

12. Disputes

Any dispute arising from this Policy shall (subject to the rights of CWS CCG and the inventor under the Patents Act 1997) be referred to an independent expert. If the Executive, acting on behalf of CWS CCG, and the inventor are unable to agree upon the identity of the expert within thirty (30) days, the expert shall be appointed by the President of the Law Society. The decision of the expert shall be final and binding upon the CWS CCG and the inventor, and shall include a determination of the apportionment of the costs and expenses payable by each of them.

13. Communication and Implementation

This policy will be available to all staff via the intranet.

14. Monitoring Compliance

Compliance with this policy will be monitored by the Chief of Development and Transformation as the Lead for IP.

15. Review

This policy should be reviewed every two years, or sooner should relevant legislation change.

16. Equality Impact Assessment

The CCG recognises the diversity of the local community and those in its employment. The organisation aims to provide a safe environment free from discrimination and a place where all individuals are treated fairly, with dignity and appropriately to their need. This policy is therefore subject to an Equality Impact Assessment checklist which can be found in Appendix A of this policy.

17. References

- 1. The NHS as an Innovative Organisation. A Framework and Guidance on the Management of Intellectual Property in the NHS. Department of Health, 2002.*
- 2. The Management of Intellectual Property and Related Matters.*
- 3. NHS Executive, 1998. Handling Inventions and other Intellectual Property: A Guide for NHS Researchers. NHS Executive, 1998.*

Appendix A- Equality Impact Assessment Template

1	Does the policy /guidance affect one group less or more favourably than another on the basis of:	Yes/No	Comments
	Race	No	
	Ethnic Origin	No	
	Nationality	No	
	Gender	No	
	Culture	No	
	Religion or belief	No	
	Sexual orientation including lesbian gay and bi-sexual people.	No	
	Age	No	
	Disability (e.g. physical, sensory or learning)	No	
	Mental Health	No	
	2 Is there any evidence that some groups are affected differently?	No	
	3 If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
	4 Is the impact of the policy/guidance likely to be negative?	No	
	5 If so can the impact be avoided?	N/A	
	6 What alternatives are there to achieving the policy/guidance without the impact?	No	