University Hospital of North Staffordshire NHS
NHS Trust

Policy No. G03
Intellectual Property

The following personnel have direct roles and responsibilities in the implementation of this policy:

- **All Trust Staff**

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Ratified By:	**Executive Committee**
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Specialist Forum Approved By:	**Quality and Safety Forum**
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Trust Contact:	**Research and Development Manager**
Executive Lead:	**Director of Research and Development**

Version Control Schedule

Final Version	Issue Date	Comments
1	December 2005	Policy developed
2	June 2007	Policy reviewed and approved by the LNC and Executive Committee
3	June 2010	Policy reviewed and approved
4	February 2013	Policy reviewed and no changes made

Statement on Trust Policies

Staff Side and Trade Unions
The University Hospital of North Staffordshire NHS Trust is committed to ensuring that, as far as is reasonably practicable, the way in which we provide services to the public and the way in which we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds.

Equality and Diversity
The University Hospital of North Staffordshire aims to promote equality and diversity and value the benefits this brings. It is our aim to ensure that all staff feel valued and have a fair and equitable quality of working life.

Equality Impact Assessment
The organisation aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. The Equality Impact Assessment tool is designed to help you consider the needs and assess the impact of your policy.

Information Governance
Any Trust policy which impacts on or involves the use and disclosure of personal information (patient or employee) must make reference to and ensure that the content of the policy is comparable with the relevant statutory or legal requirement and ethical standards

Data Protection Act 1998 and the NHS Confidentiality Code of Practice
The Data Protection Act (DPA) provides a framework which governs the processing of information that identifies living individuals. Processing includes holding, obtaining, recording, using and disclosing of information and the Act applies to all forms of media, including paper and images. It applies to confidential patient information but is far wider in its scope, e.g. it also covers staff personnel records. The DPA provides a legal gateway and timetable for the disclosure of personal information to the data subject (e.g. health record to a patient, staff file to an employee).

Whilst the DPA applies to both patient and employee information, the Confidentiality Code of Practice (COP) applies only to patient information. The COP incorporates the requirements of the DPA and other relevant legislation together with the recommendations of the Caldicott report and medical ethical considerations, in some cases extending statutory requirements and provides detailed specific guidance.

Freedom of Information Act 2000
The Freedom of Information Act 2000 (FOIA) is an Act which makes legal provision and creates a legal gateway and timetable for the disclosure, to the public, of the **majority** of corporate information held (but not necessarily created) by this Trust. The Trust has a legal responsibility to proactively provide a large amount of information to the public and to pro-actively respond to specific requests for information. Information will not be disclosed when the Trust can claim legal exemption. Any non-disclosure must be conveyed in writing; quoting the relevant exemption together with signposting to internal and external methods of compliant. Locally, guidance on the DPA, FOIA and COP can be obtained from the Information Governance Manager or the Caldicott Guardian.

Mental Capacity Act
Any Trust policy which may affect a person who may lack capacity should comply with the requirements of the Mental Capacity Act 2005 (MCA)

The MCA and its associated Code of Practice provides the framework for making decisions on behalf of individuals who lack the mental capacity to do these acts or make these decisions for themselves. Everyone working with and/or caring for adults who lack capacity, whether they are dealing with everyday matters or life-changing events in the lives of people who lack capacity must

comply with the Act.

In a day to day context mental capacity includes making decisions or taking actions affecting daily life – when to get up, what to wear, what to eat etc. In a legal context it refers to a person's ability to do something, including making a decision, which may have legal consequences for the person lacking capacity, or for other people.

The Code provides guidance to all those working with and/or caring for adults who lack capacity, including family members, professionals and carers. It describes their responsibilities when acting or making decisions with, or on behalf of, individuals who lack the capacity to do this for themselves. In particular, it focuses on those who will have a duty of care to a person lacking capacity and explains how the legal rules set out in the Act will work in practice.

The Health Act: Code of Practice for the Prevention and Control of Health Care Associated Infections

The purpose of the Code is to help NHS bodies plan and implement how they can prevent and control HCAI. It sets out criteria by which managers of NHS organisations are to ensure that patients are cared for in a clean, safe environment, where the risk of HCAI is kept as low as possible. Failure to observe the Code may either result in an Improvement Notice being issued by the Care Quality Commission, or in the Trust being reported for significant failings and placed on 'Special Measures'.

The Code relates to healthcare provided by all NHS bodies. Each NHS body is expected to have systems in place sufficient to comply with the relevant provisions of the Code, so as to minimise the risk of HCAI to patients, staff and visitors.

The Trust Board must have an agreement outlining its collective responsibility for minimising the risks of infection and the general means by which it prevents and controls such risks.

Effective prevention and control of HCAI must be embedded into everyday practice and applied consistently by all staff.

Human Rights

The Trust is committed to the principles contained in the Human Rights Act. We aim to ensure that our employment policies protect the rights and interests of our staff and ensure that they are treated in a fair, dignified and equitable way when employed at the Trust.

Sustainable Development

University Hospital North Staffordshire NHS Trust recognises the impact that its operations have on the environment as well as the strong link between sustainability, climate change and health. The trust is committed to continual improvement in minimising the impact of activities on the environment and expects all members of staff to play their part in achieving this goal and in particular to work towards a 10% carbon reduction by 2015. The Green Aware Campaign is designed to support you to do this. All trust policy should embed sustainability and refer to our Sustainable Development Management Plan where relevant. Further information and guidance can be obtained from the Trust Sustainability Manager.

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1. INTRODUCTION

All employees of the University Hospital of North Staffordshire have the potential to generate significant valuable Intellectual Property (IP) from both within and outside research and development activities. In some cases it will be necessary to protect this IP, to ensure that it benefits the health of our patients, the interests of the innovator and the financial position of the Trust.

Intellectual property can be defined as the product of intellectual or creative activity in the form of novel ideas, innovation or research and development (R&D). Like most commodities IP has the potential to be exploited through licensing or sale.

Acquiring legal recognition in the form of intellectual property rights (IPR) is an important part of protecting the exploitation process. IPR can be held as a patent, design, copyright, trade mark, database or as confidential "know-how". These IPR types are defined further in Appendix B.

Given the potential value of IP to the NHS, it is essential that the Trust instigate a policy to facilitate its protection. The NHS executive has adopted a Policy Framework for the management of intellectual property within the NHS (HSC1998/106) which will ensure that IP is owned and exploited in the best interests of the NHS. The NHS Policy framework and guidelines place a duty on the Trust to audit, protect and exploit its intellectual property (IP) and it is the Trusts intention to be at the forefront of these initiatives.

2. POLICY STATEMENT

University Hospital of North Staffordshire is committed to supporting and facilitating staff in the development and implementation of innovations. This policy sets out the basic principles that underpin the development of innovations within the Trust.

3. SCOPE

All staff that are full or part time employees of the Trust including staff that hold an honorary contract.

Staff with Trust 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 the Trust and that party assigns ownership of any IP to that party.

Trainee professionals hosted by the Trust who generate IP during the course of their training.

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 IP agreed between the Trust and that organisation.

4. DEFINITIONS

Where it is appropriate "Trust" is used as meaning the University Hospital of North Staffordshire NHS Trust

"Net Revenue" means all revenue after deduction of registration fees, sponsors' deductions, legal and other direct costs.

5. RESPONSIBILITIES

It is the responsibility of the R&D Manager to manage and protect IP for the Trust. For information and advice on any matter regarding IP and its protection please speak to your IP Lead.

Employees should at the earliest opportunity, inform the Trust (via the R&D Manager) about identified or potential IP arising from their activities and should not unilaterally sell, assign, license, give or otherwise trade the IP since this is likely to compromise it's subsequent value. A guide to IP and its protection can be obtained from the R&D Office.

Any IP with the potential to be exploited must not be disclosed to anyone outside the Trust (including presenting papers or posters at conferences, abstracts, chapters in books and any other verbal or written communication) wherever possible until IP advice has been sought from your R&D Manager. IP cannot normally be protected (especially in the case of filing patents) once prior informal disclosure has occurred.

The Trust is not obligated to seek protection for IP in all cases. Protection will be sought where a viable commercial case is demonstrated.

If the Trust, following advice from the R&D manager, decides that exploitation of any IP is no longer financially commercial it may choose to abandon its exploitation of that IP. In this event, the IP ownership would revert to the originating employee on the date that the Trust makes written confirmation that it no longer wishes to exploit this particular IP.

It is the Trusts policy to actively encourage employees to publish their work and the Trust will not normally object to an employees' right to be named as an author of copyright material. 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 R&D Manager before publicly disclosing work.

Despite the statutory provision whereby the copyright in any work produced by an employee in the course of employment belongs to the employer, the Trust normally grants the originator a free licence to the copyright in any work to be published in a recognised scientific, technical, professional, management journal or book.

In dealing with an external organisation, it is not always possible to ensure all contact is through the R & D Office. When staff are contacted directly by a third party company, it is important to keep full records, including copies of all correspondence and notes of telephone conversations and meetings, and to supply these to the R & D Office in order to provide detailed accounts of the progress of discussions relating to any Intellectual Property. All records and notes must show the relevant date(s) and action(s) agreed.

It is essential that staff working on projects which generate IP keep written, dated records of their activities and results. This is especially significant for subsequent patent applications in the US, since precedence is awarded to the first to invent, rather than the first to file the patent. It is imperative that all correspondence, including emails, telephone conversations and meetings are logged to provide a detailed account of any discussions relating to the IP. Besides maintaining optimum clinical practice, this diligence is in accordance with clinical and research governance guidelines.

The R&D Lead is 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 Office. Records will also be kept of arrangements entered into by the Trust for the protection and subsequent use of the Intellectual Property, including any disclosures made to a third party.

It is the responsibility of the R&D office to ensure that the originator of any IP is kept fully informed as to progress in relation to its protection, exploitation and commercialisation. This will be done through regular correspondence and meetings.

Audits or "I.P. Surgeries" will be periodically carried out by or on behalf of the Trust. This process is essential to identify potential IP arising from R&D and to ensure that the correct action is taken to protect any IP that may later be exploited.

Further information on ownership of IP, decisions of exploitation, potential disputes and revenue-sharing with inventors please refer to Appendix A.

6. EDUCATION AND TRAINING

IP issues will be included in general R&D training initiatives as and when these take place in the Trust. All new employees with an interest in R&D will have the intellectual property policy and procedures brought to their attention.

All training should be recorded within the personal staff record, ideally within ESR.

7. MONITORING AND REVIEW

This policy will be reviewed in three years by the R&D Committee and in consultation with the West Midlands NHS IP Hub. On going monitoring of the policy will be the responsibility of the R&D Manager.

APPENDIX A

OWNERSHIP OF IP

In cases where the employee was engaged in a research capacity, ownership of IP generated within that research rests with the Trust that employed the person at the time that the IP was originated.

Any intellectual property produced outside the scope of their normal working duties as defined in their job plan/job description will belong to the employee. This distinction is in legal accordance with the Patents Act 1977 and the Copyright, Designs and Patents Act 1988.

IP exploitation is an expensive and time consuming process. When a member of staff assigns IP to the Trust by choice or due to originating in normal duties as defined in their job plan/job description, this financial and logistic commitment is taken up on their behalf. The originator is entitled to receive recompense in the form of a share of the derived net revenue detailed in section 7.4.

If work or research is conducted by an employee in partnership with another organisation, a formal agreement stating ownership (or sharing) of generated IP is required. The R&D Manager will have primary responsibility for developing IP sharing agreements with collaborating institutions and the employee.

If the relative ownership of IP 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 Chief Executive Officer of the Trust will make a final decision, taking professional advice as necessary.

Wherever possible, commercially funded research contracts should provide for the Trust to hold the resulting Intellectual Property to enable it to benefit from its exploitation.

In pricing commercially funded research contracts, regard must always be given to the value of the resulting Intellectual Property and the rights to the Intellectual Property which are granted to the sponsor, as well as the value of existing background Intellectual Property (especially software or patented inventions) which may be used in furtherance of the research project.

Further information about protecting and exploiting IP can be obtained from the R&D Office. See also Appendix B.

DECISIONS OF EXPLOITATION

Any IP that is licensed, sold or otherwise transferred to another organisation will be negotiated in the best interests of the Trust by professional advisers. In the case of IP assigned to the Trust, it is the role of the R&D Office, in consultation with other specialists (e.g. the local IP Hub, patent agents, legal representatives), to advise the Trusts on the potential for an idea/invention to be exploited.

Intellectual Property management decisions such as whether to patent or license reside with the Trust Board but may be delegated to the R&D Lead for UK patents and to the Director of R&D and Chief Executive for all other patent applications. The Trust is the vehicle for holding patents and other Intellectual Property, but is empowered to engage another organisation to exploit its Intellectual Property on its behalf.

In cases where the Trust declines to proceed with the exploitation of an opportunity, ownership of the IP will be reassigned by the Trust back to the inventor. Decisions on whether the Trust will exploit an opportunity will be taken by the Trust within 1 month of the idea being disclosed to the R&D Office.

All commercial exploitation activity is co-ordinated by the R & D Office of the Trust. Members of staff who are the originators of Intellectual Property are reasonably expected to co-operate with those responsible for its exploitation so that the maximum possible benefit is obtained.

Staff are reminded that no steps should be taken to exploit Intellectual Property that has been assigned to the Trust without the approval of the Trust Board.

DISPUTES

Any dispute which arises under this policy may be referred to the Trust's Executive Board for resolution. In the case where the Chief Executive is the inventor any dispute will be referred to the Trust Chairman. For Medical staff any disputes will be referred to the Medical Director for resolution through the normal job plan appeal mechanism.

In the event that the dispute remains unresolved after 28 days of reference to the Trust's Chief Executive then either party may ask the Strategic Health Authority or some other impartial third party, as agreed between those in dispute, for assistance in the mediation and resolution of this dispute.

If there should be a failure to resolve this dispute following the above processes then the matter may be referred to the Department of Health's decision to be final and binding on all parties.

REVENUE-SHARING WITH INVENTORS

The Trust wishes to encourage full participation of employees in the creation and commercial exploitation of IP.

The policy will reward staff that have contributed substantially to the generation of IP which has subsequently provided exploitation revenue. Such revenue will be shared between the Trust and the inventor according to the revenue sharing formula (see below).

In cases where several staff have been involved in generating the IP, the proportion of income allocated to inventors will be divided between them on the basis of relative inventive contributions. In all cases the shared revenue will be the Net Revenue of any protection and exploitation costs (e.g. patent costs). Cessation of employment, under normal circumstances, will not affect an inventor's right to receive a share of revenue.

Revenue Sharing Agreement

The Cumulative Net Income received by the Trust will be shared as follows:

Cumulative Net Income	Inventor	Clinical Division / Operational Units	Trust*
0-£1K	100%	-	-
>£1K- £6K	80%	10%	10%
>£6K- £11K	60%	20%	20%
£11K +	50%	25%	25%

* The proportion of this sum which is allocated to funding R&D activities or direct NHS care will be agreed on a case by case basis at the R&D Committee and approved by the Trust Board.

Net income refers to the income remaining after recovery of all development costs, patenting and other out of pocket costs incurred by the Trust in identifying, protecting and exploiting the Intellectual Property.

Where there is a contractual agreement with a funding sponsor to share the revenue from successful exploitation of Intellectual Property arising from research funded by that sponsor, the Cumulative Net Income to the Trust is the income from exploitation remaining after deduction of the sponsor's share.

APPENDIX B

INTELLECTUAL PROPERTY PROTECTION

This appendix includes a very brief overview on some aspects of IP protection. It must be noted that the law is complicated and members of staff are advised to contact their R&D Manager at the earliest opportunity to discuss more detailed information on IP protection.

i.Copyright

Copyright covers written information (such as leaflets, articles, assessment tools and training packs), databases, computer software and films/videos, which can all be protected by copyright. Copyright is achieved automatically, when the IP is created. However, it is advisable to attach a statement for additional protection, such as:

© Copyright (Name of Legal entity owning the I.P., 2005). All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner.

ii. Patents

Patents can be used to protect inventions that embody a new idea and are capable of being manufactured or used by industry (such as devices, processes or methods of operation). Examples of exclusions would be methods of treatment of the human/animal body by surgery or therapy, or diagnostic methods. An invention must not have been made public anywhere in the world prior to the patent filing date (journals, internet, meetings, posters, etc.) and must not be an obvious development, with regard to what is already common knowledge to someone who is experienced in the relevant field.

iii. Design rights

Design Rights protect against deliberate copying of the shape or configuration of an article. Design Right may exist in addition to other forms of protection such as Patent, Copyright or Registered Design.

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

v. 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.

vi. 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.

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.

vii. 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.

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 Confidential Disclosure Agreement (CDA). This may be a reciprocal agreement whereby confidential information is both disclosed and received. A CDA may be obtained from your R&D Office.

Know-how and confidential information can be bought, sold and licensed like any other form of IP and persist indefinitely, as long as they remain "secret".

APPENDIX C

REFERENCES AND FURTHER READING

The Management of Intellectual Property within the NHS arising from Research and Development. Available on the following webpage in pdf format:
www.doh.gov.uk/nhsexec/iprdocs.htm

This includes:

- Policy framework for the management of intellectual property within the NHS arising from research & development HSC1988/106.

- Handling inventions and other Intellectual Property: A Guide for NHS Researchers.

- The Management of Intellectual Property and Related Matters: An Introductory Handbook for R&D Managers and Advisers

- Person responsible for Policy (IP Lead): Research and Development (R&D) Manager