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Staff involved in development: <i>Job titles only</i>	Senior R&D Manager
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
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Key Points of this Document

- This policy aims to ensure that the Trust is in a position to identify and exploit any intellectual property (IP) that it generates and that all IP is managed efficiently and effectively.

1 Background

- 1.1 The NHS recognises that staff, from any discipline or activity, can generate new ideas, innovative solutions to problems, inventions or better ways of working which may lead to improvements in the delivery of healthcare.
- 1.2 To ensure that this potential is recognised, published Framework and Guidance on the management of Intellectual Property in the NHSⁱ, supported by changes to the law, enable NHS organisations to take appropriate steps to ensure that the services, expertise and knowledge base are put to maximum use.
- 1.3 The NHS Planⁱⁱ recognises the need for the NHS to develop as an innovative organisation. It commits the NHS to ensuring that innovations are identified and developed in the interests of patients and society as a whole. New technologies should lead to new products, improved interventions and services for health and social care.
- 1.4 Section 5 of the Health and Social Care Act 2001ⁱⁱⁱ empowers NHS Trusts (and therefore employees of NHS Trusts), to participate in spin-out companies established for the purposes of income generation.
- 1.5 A Policy Framework^{iv} for the management of IP arising from research has been in existence since 1998, with the management of intellectual property arising from research and development (R&D) being a contractual requirement for Trusts in receipt of NHS R&D Support Funding.
- 1.6 The Research Governance Framework for Health and Social Care^v states that the protection and exploitation of intellectual property is one of the responsibilities of a high quality organisation undertaking R&D and that agreements should be in place with NHS employees and research partners about ownership, exploitation and income from any IP arising from research.
- 1.7 The current Framework and Guidance extends the requirement of NHS Trusts to identify and exploit innovation arising from the full spectrum of NHS activity i.e. patient care, education and training, administrative and support functions, as well as R&D. An essential aim of wider-Government strategy^{vi} is to capture and exploit innovations for the benefit of the UK economy.

2 Aims

- 2.1 To encourage and enable staff to participate in the generation of IP as part of its commitment to deliver the best possible patient care through innovation and improvement.
- 2.2 To ensure that innovation and associated IP arising within Papworth Hospital NHS Foundation Trust is appropriately protected and exploited for the purposes of income generation and the benefit of NHS patients and employees.
- 2.3 To ensure that IP is managed in accordance with Department of Health guidance.

3 Policy

- 3.1 **DEFINITION:** Any novel or previously un-described tangible output of intellectual or creative activity can legitimately be described as IP. It has an owner, it can be bought, sold or licensed and must be adequately protected in order to ensure its appropriate development and ultimate use or exploitation. IP can include inventions, industrial processes, software, data, written work, designs and images.

The most common types of IP are:

- Inventions, each embodying a new idea capable of being made or used by industry and involving a non-obvious inventive step (*There are a number of excluded classes, such as mathematical algorithms, methods of treatment of the human or animal body by surgery or therapy, or methods of diagnosis*)
- Literary and artistic works, films, videos, records, broadcasts and typographical arrangements, including computer software
- Designs and design drawings, mainly of aesthetic objects
- Engineering components, architectural drawings, etc
- Product brand names, company logos, etc
- Trade secrets, background techniques.

Exploited can mean anything from dissemination throughout the Trust, or the NHS, to commercial exploitation in order to access wider markets and other healthcare systems.

- 3.2 **IP RIGHTS:** Intellectual property rights define the legally protected rights that enable owners of IP to exert monopoly control over exploitation of these rights, usually with commercial exploitation in mind. They give the right to stop others exploiting this property, sometimes for a fixed period.

The most common types of IP rights are:

- **Patents** for inventions, processes, gadgets, equipment, *etc.*
- **Copyright** for works, media, *etc.*
- **Registered Design Rights** for designs, features of appearance, *etc.*
- **Unregistered Design Rights** for engineering components, architectural drawings, *etc.*
- **Trade Marks** for names, signs, logos, *etc.*
- **Know-How/Confidential Disclosure Agreement** for information, secrets, techniques, *etc.*

3.3 Ownership of IP

- 3.3.1 As a general rule, in accordance with the Patents Act 1977 and Copyright, Designs and Patents Act 1988, ownership of IP created by any person in the course of performing their normal duties during his or her employment rests with the employer unless their agreement is otherwise. Any activities outside the normal duties of the employee that generate IP belong to that employee.

Therefore, IP generated by Trust employees in the normal course of business, including inventions, information and data, generally belongs to the Trust. This includes IP created when the employee was not technically employed (e.g. outside normal working hours), except when the IP is not connected with the employment, as the employee would not have been able to develop the IP if it were not for the use of or access to the work environment. This includes IP developed from background IP, by input from professional colleagues, and with the use of technology or data connected with employment.

While the Trust owns such IP, as recognition and reward for creative energy and innovation the Trust will usually grant employees who create commercially exploitative IP a majority share in revenue received from that IP.

- 3.3.2 In cases where IP is generated by students or employees working for the Trust with employment contracts funded partially or wholly by third parties (e.g. a university, a medical charity or a commercial organisation), the IP normally belongs to the Trust, unless the contract between the Trust and third party organisation dictates otherwise. In cases where IP does not belong to the Trust, but has been generated by use of or access to Trust resources, the IP must not be exploited without prior written consent from the Trust. In such circumstances the Trust would normally expect to receive a share of any revenue derived from exploitation and these would be set out in a formal agreement with the other party.
- 3.3.3 **COPYRIGHT** - Statute provides that copyright in any work produced for the Trust by an employee in the normal course of employment belongs to the employer. The Trust 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. The Trust does not assign any of its other copyright to the author including, without limit:
- (i) Course or training materials or patient information leaflets produced by an employee in the course of employment for the Trust and which are produced, used or disseminated within or outside the Trust
 - (ii) Any software program generated by an employee in the normal course of their employment
 - (iii) Any designs, specification or other works which may be necessary to protect rights in commercially exploitable IP.
- 3.3.4 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 judgement.

3.4 Procedures for Trust Staff

- 3.4.1 The Trust has appointed an IP Lead to act as first point of contact for information and advice on any matters regarding IP created utilising Trust resources.
- 3.4.2 Trust staff should discuss new innovations with the IP lead at the earliest opportunity and, in any event, before disclosure of the idea to any party outside the Trust either orally or in writing. Prior public disclosure (other than under explicit terms of confidentiality or to another employee of the Trust) may invalidate any subsequent patent application and diminish both potential commercial value and benefits accruing to the Trust and the inventor.
- 3.4.3 Once such potential IP has been identified, it is important to keep full records, (including copies of all correspondence, notes of telephone conversations, and meetings) in order to provide detailed accounts of the progress of discussions relating to IP. All records and notes must show the relevant dates and actions agreed.
- 3.4.4 Trust staff must not make any attempt to sell, license or otherwise commercially exploit IP owned by the Trust without approval from the Trust.
- 3.4.5 The Trust makes use of an adviser organisation to provide high quality advice on its behalf. The adviser organisation for the Trust is Health Enterprise East (HEE). The

IP Lead will facilitate access to HEE.

HEE is the NHS innovation hub for the East of England. It is a non-profit-making organisation set up to manage and exploit IP generated by NHS staff for the benefit of patients and the wider health care community.

- 3.4.6 As recognition and reward for creative energy and innovation the Trust will usually grant employees who create commercially exploitable IP a majority share in revenue received from that IP.

The Trust's principle of commercial exploitation is that should it be deemed that the IP is likely to generate income that outweighs the costs and risks of development, the employee will provide technical (but not financial) support for the IP he or she has generated, whilst the Trust in conjunction with specialist IP organisations and other third parties as required will provide the management and financial support required to exploit the IP.

The table below provides an illustration of how revenue from the successful commercial exploitation of IP might be shared between the employee(s) as inventors of the IP and the Trust.† Actual revenue share will be determined on a case by case basis using the table as a guide. Revenue share arrangements for amounts over £500,000 will be individually negotiated.

Residual Income[†]	Inventor(s)	Trust[‡]
<i>First £10,000</i>	90%	10%
<i>Next £40,000</i>	80%	20%
<i>Next £200,000</i>	70%	30%
<i>Next £250,000</i>	60%	40%
<i>Over £500,000</i>	<i>To be negotiated</i>	

† Residual income is revenue after the deduction of exploitation costs

‡ To be apportioned between the inventors department, R&D and central Trust funds

- 3.4.7 The Trust IP Lead will work with the employee in developing grant applications, research protocols and research related employment and financial issues to address ownership and exploitation of potential IP.
- 3.4.8 The Trust recognises that commercialisation of IP generated by the Trust will not always be appropriate and other priorities such as improving care for the maximum number of patients and providing cost-savings should be considered. Where the IP has no commercial value but has the potential to improve healthcare and/or reduce NHS expenditure, the IP Lead in conjunction with Adviser organisations (and other third parties as required) will determine the most appropriate course of action.

In cases where the Trust chooses not to further the exploitation of IP, in most cases, the IP will be assigned to the member of staff generating that IP at their request so that they may exploit the IP independently of the NHS.

- 3.4.9 The Trust through the IP lead maintains a register of all IP rights owned by the Trust which have been licensed or assigned to a third party where an employee is a named inventor or originator.

3.5 Identification of IP

- 3.5.1 The Trust will assist staff with the identification of IP by increasing awareness about innovation is, how it originates and how to bring it to the attention of the IP Lead.
- 3.5.2 Staff will be encouraged to identify and report all activities that might generate IP from their particular duties within the Trust.
- 3.5.3 In some circumstances, the Trust in conjunction with the adviser organisation will conduct technology audits in order to recognise IP generated by the Trust that might otherwise never be identified.

Further Document Information

Approved by: <i>Management/Clinical Directorate Group</i>	Research and Development Directorate						
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Ratified by Board of Directors/ Committee of the Board of Directors	N/A						
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This document supports: <i>Standards and legislation</i>	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. Research Governance Framework for Health and Social Care (2005)						
Key related documents:	Trust Research Policy Research and Development Standard Operating Procedures entitled: Archiving Protocol Trial closure and end of trial reporting Trust Policy DN48 Case Note Retention & Disposal of Patient Records						
Equality Impact Assessment: Does this document impact on any of the following groups? If YES , state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.							
Groups:	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No:	NO	NO	NO	NO	NO	NO	NO
Positive/Negative:	Negative	Negative	Negative	Negative	Negative	Negative	Negative

- i The NHS as an innovative organisation: a framework and guidance on the management of Intellectual Property in the NHS. 2002. www.nic.nhs.uk . (National Innovation Centre)
- ii 'THE NHS PLAN 2000' A PLAN FOR INVESTMENT A PLAN TO REFORM. 2001
- iii 'HEALTH AND SOCIAL CARE ACT 2001'. 2001
- iv HSC 1998/106 'POLICY FRAMEWORK FOR THE MANAGEMENT OF INTELLECTUAL PROPERTY WITHIN THE NHS ARISING FROM RESEARCH AND DEVELOPMENT'
- The management of Intellectual Property and related matters: an introductory handbook for R & D managers and advisers in NHS Trusts and independent providers of NHS services. NHS Executive. 1998.
 - Handling inventions and other Intellectual Property: a guide for researchers. NHS Executive. 1998.

v 'Research Governance Framework for Health and Social Care' Department of Health. 2001
vi 'CREATING KNOWLEDGE CREATING WEALTH: REALISING THE ECONOMIC POTENTIAL OF PUBLIC SECTOR RESEARCH ESTABLISHMENTS'; *BAKER REPORT (TREASURY)*

- www.nisw.co.uk (NHS Innovations South west)
- www.nic.nhs.uk (NHS National Innovation Centre)
- www.ipo.gov.uk (UK Intellectual Property Office)