

## **Intellectual Property (IP), Revenue Sharing & Equity Policy**

Effective Date: April 2011

Review Date: April 2012

### **1. Introduction**

This policy is in line with and follows the current framework and guidance published by the Department of Health<sup>1</sup>. It relates to additional powers given to “NHS bodies” under section 5 of the Health and Social Care Act 2012<sup>2</sup>, which allows them to form or invest in companies and permits NHS organisations to partake in the generation of income. The exploitation of Intellectual Property falls within the Trust’s scope of income generation.

It has been recognised that advances in health and social care are sometimes required to be exploited commercially if they are to be made widely available<sup>3</sup>.

A policy framework for the management of intellectual property arising from R&D in the NHS has been in existence since 1998<sup>4</sup> which encourages NHS organisations and their staff to identify, protect and exploit their intellectual property.

The current framework and guidance<sup>1</sup> extends the scope to cover the full spectrum of NHS activities (e.g. patient care, education and training, administration and support functions) and not just R&D.

The NHS Plan 2010-2015<sup>5</sup> states the continuing importance of developing the NHS as an innovative organisation, especially in the challenging economic environment. This will not only lead to improved health outcomes but also contribute to the wider economy and nation’s wealth.

This policy aims to outline the importance of intellectual property and its proper management within The Newcastle upon Tyne Hospitals NHS Foundation Trust (the Trust) and provides guidance to achieve this.

The policy supersedes any previous policy held by the Trust and will be effective for any new commercial agreements signed after 1<sup>st</sup> April 2011.

#### **1.1 Intellectual Property**

Intellectual property is the tangible result of intellectual or creative activity such as novel ideas, knowledge and innovation. Intellectual property can be legally protected (intellectual property rights) through the use of patents, copyrights, design rights, trademarks or non-disclosure agreements (see Appendix 1).

Intellectual property can be bought, sold or licensed and must be adequately protected in the interests of both owners and inventors to prevent another party infringing on their intellectual property rights.

## 1.2 Disclosure

IP cannot normally be protected (especially in the case of filing patents) once prior disclosure has occurred, including through: presenting papers, posters, abstracts, chapters in books and verbal and written communications. Any IP with the potential to be exploited must not be disclosed to anyone outside the Trust without prior consent.

The purposeful disclosure of commercially sensitive material, including ideas which may be protected and exploited in the future contravenes the principles set out in this policy.

Please see Appendix 3 for more information on publication.

## 2. Ownership of IP

The Patents Act 1997<sup>6</sup> and the Copyright, Designs and Patents Act 1988<sup>7</sup> state that, in the majority of cases, the ownership of IP rests with the employing organisation. In accordance with this, the Trust reserves its right to own all intellectual property created by its employees during the course of their normal working duties.

### 2.1 Collaborative Research Projects

The Trust and its employees often work in partnership with external partners or organisations. Where this is the case, a formal agreement stating the ownership or sharing of any IP generated within the project is required. The Trust's Chief Operating Officer, or nominated person(s), will have the responsibility for developing IP sharing agreements with collaborating institutions. You should consult with the Assistant Director of Enterprise and Development for advice before entering into a joint project with another organisation which may involve the generation of IP.

The Trust and the University realise that collaborative research projects involving staff from both institutions, or staff operating on honorary contracts, may generate intellectual property. The two institutions have therefore aligned their IP policies to give common revenue or equity shares to inventors.

Should commercially exploitable IP arise from collaborative research projects, you should inform the Joint Research Office (JRO) in the first instance. If the project is non-research related you should inform your directorate manager or the Trust's Assistant Director of Enterprise and Development.

## 2.2 Dispute of Ownership

If the ownership of IP is disputed, then any documentation and written records relating to the IP in question will be reviewed to establish the inventor(s) proportionate contributions (see Appendix 3 for the importance of written records). The Chief Executive Officer of the Trust will make the final decision if an amicable solution cannot be reached, taking professional advice if required.

### 3. Persons Covered by this Policy

- i. All staff that are full or part time Trust employees, including employees on honorary contracts<sup>i</sup> (paid or not) and/or are self-employed, agency, or locum staff.
- ii. Staff with a Trust contact of employment whose payroll costs are *partially* or *wholly* funded by another party (e.g. medical charity, government) unless the contract between the Trust and that party assigns ownership of the IP to that party.
- iii. Trust staff seconded to another organisation or employees of another organisation seconded in to the Trust who are under contract. Normally, the IP will be in the ownership of the employees substantive employer.
- iv. Staff who generate IP outside of their normal working hours and/or away from the workplace, where the IP relates to their specialist area of employment within the Trust, the Trust shall own the IP.
- v. Trainee professionals or students hosted by the Trust who generate IP during the course of their training at the Trust.

### 4. IP Management Structure

It is the responsibility of the Chief Operating Officer or their nominated person(s) to manage and protect IP for the Trust. For information on any matter regarding IP and its protection please speak to the Assistant Director of Enterprise and Development.

The Trust, on occasion, may utilise the services of external technology transfer organisations or independent patent agents for the exploitation and/or protection of IP. This may involve up front costs or a share of the eventual revenues being agreed with that organisation.

Please see Appendix 2 for the Trust's IP commercialisation pathway.

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<sup>i</sup> The close relationship which the Trust has developed with Newcastle University has led to a number of jointly employed staff or staff on honorary contracts in either organisation. These include: medical, dental, research and non-medical/non-research honorary contracts. These employees are covered as stipulated in their contract of employment.

#### 4.1 Staff Obligations

Employees have an obligation to inform the Trust Management (either through their directorate manager or by informing the Assistant Director of Enterprise and Development) regarding identified or potential IP resulting from their activities and must not, under any circumstances, sell, assign, license, give or otherwise trade IP without the Trust's formal written agreement.

Any employee found to be involved in the unauthorised exploitation of IP on the Trust's behalf, or for their personal gain, may face disciplinary action.

See Appendix 2 and 3 for further guidance on staff procedures.

#### 4.2 Decisions on Exploitation

The decision of whether to exploit an idea/invention and how best to exploit it (i.e. licence or spin out) will be taken by the Trust Investment Committee or the Joint Business Executive (JBE) for joint projects. Decisions on whether to exploit IP will be based on the ability to demonstrate market potential and the likelihood of success of the venture.

Where or when the Trust chooses not to exploit IP, exploitation rights may be granted to the inventor, or other party, at the Trusts discretion.

#### 4.3 Contract Negotiations

Any IP that is licensed, sold or otherwise transferred to another organisation will be negotiated in the best interests of the Trust by the Trust's nominated officer. Such nomination will be made by the Chief Operating Officer of the Trust.

Employees will not under any circumstance, being the inventor or otherwise, enter into commercial negotiations regarding the Trust's IP with external organisations without the prior consent and authority of the Trust's Chief Operating Officer.

### 5. Revenue & Equity Sharing

The Trust believes that it is important to actively encourage employee innovation in the work place, especially where it significantly enhances patient care and contributes to the overall productivity of the Trust. The Trust's policy will be to reward staff [*lead inventor(s)*<sup>ii</sup>] and departments who have had the initial original idea that results in commercially valuable intellectual property being generated and subsequently exploited.

The Trust does not expect to share revenues or equity with those individuals employed by the Trust whose everyday role it is to then develop those ideas into products. The

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<sup>ii</sup> A lead inventor is defined as the person(s) who had the original novel idea. A lead inventor is not somebody who then goes on to make that idea a reality (i.e. a developer).

activity of new product development is expected to be rewarded at the departmental level, not the individual level.

## 5.1 Revenue Sharing

Where the Trust Investment Committee, or Joint Business Executive (JBE) for joint projects, decide that the best route to commercialising IP generated within (or in partnership with) the Trust is through licensing, then the below revenue sharing formula shall be applied.

### *Revenue Sharing with External Partners*

The Trust recognises that it does not, and should not, hold all of the resources or capabilities necessary to take an initial idea all the way from initial concept to market. In order to achieve this it is likely that external organisations will play a part in the development and commercialisation of intellectual property and that these organisations may be eligible for a share of revenues generated from product sales.

The main external partners who might be entitled to a share of revenues generated from the exploitation of IP would be:

- Commercial Partner i.e. the organisation that the IP is sold, licensed or assigned to for commercial exploitation
- Co-Developer i.e. organisations that aid in the development of intellectual property
- Funding Body i.e. government grants, charitable bodies, financial institutions or private finance
- Technology Transfer Body – a function or organisation that aids the commercialisation process and transfers intellectual property from the Trust to the commercial partner for further development and exploitation.

Please note that not all IP might require funding from external sources, engagement with a co-developer and/or utilisation of an external technology transfer organisation to aid in the commercialisation of IP. It is asked that employees give due consideration to the income dilution effects of engaging with external organisations for the development and commercial exploitation of intellectual property. Any approaches to external funders should be done so either through the Joint Research Office for research-based funding or the Assistant Director for Enterprise & Development for non-research based funding.

Approaches to commercial partners and external technology transfer bodies will be made by the Chief Operating Officer or his nominated person(s). Employees should not negotiate with commercial partners without express permission from the Trust's Chief Operating Officer (see section 4.3).

## Trust Internal Revenue Sharing

Due to close working arrangements often found between Hospital Trusts and University medical schools, previous guidance<sup>2</sup> has suggested the adoption of a similar or identical revenue sharing schemes to that of University partners. This avoids co-inventors in separate institutions being rewarded differently. The Trust has therefore decided to broadly align its internal revenue sharing agreement to that of the University's for the avoidance of confusion and/or doubt.

After revenue shares have been apportioned to the external partners involved in the development and commercialisation of the intellectual property, the share of revenues eligible to the Trust from Tier 1 will then be distributed between:

- the lead inventor(s)<sup>iii</sup>
- the directorate(s) involved in the concept and development of the intellectual property<sup>iv</sup>
- the Trust's corporate services

The share of revenues will be allocated as per the following formula, net of any protection and exploitation costs (e.g. patent protection costs).

<b>Cumulative Net Income</b>	<b>% Revenue Share</b>		
	<b>Trust</b>	<b>Directorate</b>	<b>Lead Inventor(s)</b>
<b>First £5,000</b>	n/a	n/a	100%
<b>Next £200,000</b>	35%	25%	40%
<b>Next £795,000</b>	40%	20%	40%

The division of net royalties above £1 million are for negotiation between the lead inventor(s) and the Trust.

The Trust will always be willing to consider arrangements to reinvest lead inventor(s) shares in further departmental research should the lead inventor(s) wish to do so.

## 5.2 Equity Sharing

As an alternative to licensing IP, it may be decided by the Trust Investment Committee, or Joint Business Executive (JBE) for joint projects, that the best way to

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<sup>iii</sup> If there is more than one lead inventor, the lead inventors share will be divided in a ratio which is agreed between them.

<sup>iv</sup> If more than one department is involved, the departmental share will be divided in a ratio which is agreed between the departments depending on the relative contribution by those departments to the project. In the event of non-agreement, the CEO, or his nominated person(s), will act as the arbitrator.

exploit IP might be to form a spin out organisation. This would involve sharing equity between the lead inventor(s), institution(s) and any external partners involved in the company formation.

The Trust Investment Committee (or JBE) will review projects on a case by case basis to agree the appropriate equity sharing arrangements between inventors and the other organisations involved, taking into account the relative contributions made by each party.

All enquiries should be directed towards the Assistant Director of Enterprise and Development in the first instance.

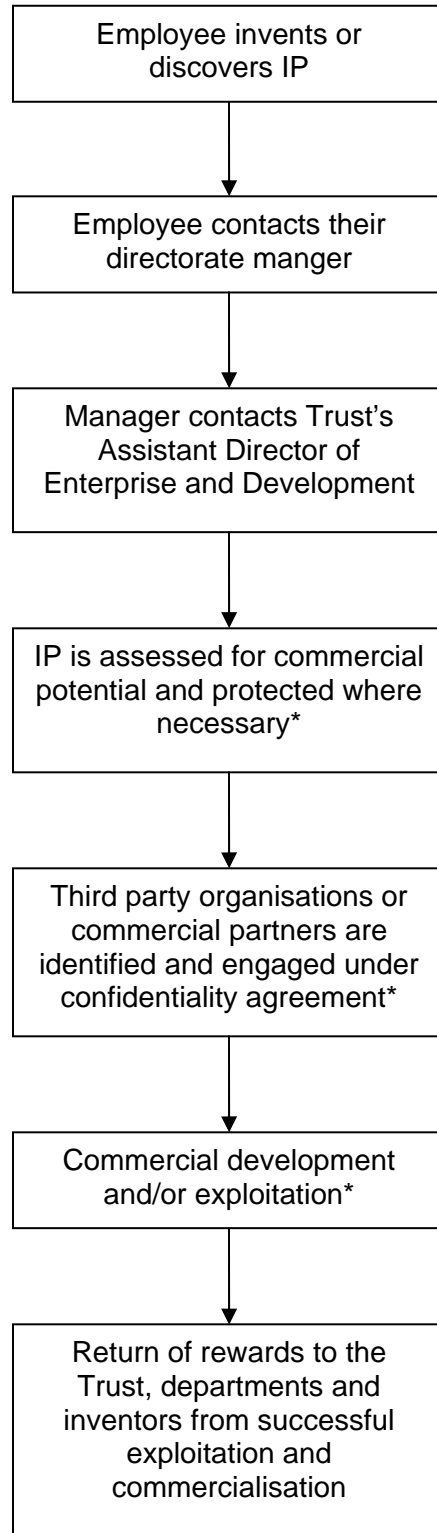
## Appendix 1: Forms of Intellectual Property

This appendix describes certain areas of intellectual property and how it can be protected. Intellectual property law is very complex and members of staff are advised to contact the Assistant Director of Enterprise and Development to discuss intellectual property protection at their earliest convenience.

Employees are strongly advised not to disclose their inventions or ideas in any way (i.e. publication, presentation, word of mouth) to third parties before seeking advice. This can seriously diminish the potential value of the invention or idea.

Category	Protection	Examples	How to protect
Inventions	Patents	Medical devices, novel processes, methods of operation	Filing of a patent application. The invention should not be made public anywhere in the world (e.g. journals, presentations, posters)
Literary works	Copyright	Leaflets, articles, assessment tools, training packs, databases, computer software	Automatic. Should include a statement e.g. " <i>Company name, year. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner.</i> "
Designs	Registered and Unregistered Design Rights	Engineering components, architectural drawings, medical illustrations, unique appearance of commercial objects	Automatic or registration
Branding	Trademarks	Trust logo, slogans, labeling	Registration
Trade Secrets	Know-how	Surgical techniques, chemical processes, client lists	Non Disclosure Agreement

## Appendix 2: Trust IP Commercialisation Pathway



\*May involve using external expertise

## **Appendix 3: Staff Procedures and Expectations**

### **Publications**

Whilst the Trust realises that employees may, from time to time, publish their work and be named as the author of the copyright material which may be shared with colleagues, it urges employees to consider that the best and most efficient way to develop and distribute concepts and idea might not always be through publication but to protect that intellectual property and exploit it. If this route is to be taken then employees should be aware that all work needs to be kept confidential until it is correctly protected before publication.

The employee should seek advice from their directorate manager or the Assistant Director of Enterprise and Development before publicly disclosing work which they believe may have potential for commercial exploitation.

### **Confidentiality**

All work must be kept strictly confidential prior to seeking the correct intellectual property protection. If it is necessary to disclose commercially sensitive information advice should be sought from the Assistant Director of Enterprise and Development.

### **Record Keeping**

It is important for staff working on projects which generate IP, to keep written, dated records of their activities and results. This is especially important for patenting in the US who have a policy of 'first to invent' rather than the 'first to file' rule in the UK. It is important that all correspondence, including e-mails, telephone conversations and meeting are logged and documented to provide a detailed account of any discussions relating to the IP. This is in accordance with clinical and research governance and good clinical practice guidelines for R&D.

### **Supporting Technology Transfer**

From time to time it may be necessary for the lead inventor(s) to support the technology transfer of the intellectual property rights from the Trust to the commercial partner and aid in the commercialisation of that intellectual property.

This may involve:

- The translation of the intellectual property rights and know-how relating to the intellectual property either through written instruction or otherwise; and/or,
- Reasonable support in commercialisation of the intellectual property through sharing of industry knowledge, hosting reference site visits, conducting further commercial research and development and presenting research at conferences, seminars and workshops.

## References

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<sup>1</sup> Department of Health (2002) *The NHS as an Innovative Organisation: A Framework and Guidance on the Management of Intellectual Property in the NHS* (available from: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4002660](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4002660))

<sup>2</sup> Health and Social Care Act 2001 (available from: <http://www.legislation.gov.uk/ukpga/2001/15/contents>)

<sup>3</sup> Department of Health (2005) *Research Governance Framework for Health and Social Care* (available from: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4108962](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962))

<sup>4</sup> HSC 1998/106 (1998) *Policy Framework for the Management of Intellectual Property within the NHS Arising from Research and Development*, (available from: [http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculardh/DH\\_4004971](http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculardh/DH_4004971))

<sup>5</sup> Department of Health (2009) *The NHS Plan 2010-2015: From Good to Great*, available from: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_109876](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_109876)

<sup>6</sup> Patents Act 1997 (available from: <http://www.ipo.gov.uk/patentsact1977.pdf>)

<sup>7</sup> Copyright, Designs and Patents Act 1988 (<http://www.legislation.gov.uk/ukpga/1988/48/contents>)

**THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST**  
**IMPACT ASSESSMENT – SCREENING FORM A**

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy Title:	<b>Intellectual Property (IP), Revenue Sharing &amp; Equity Policy</b>	Policy Author:	<b>Steven Reed, Trust Secretary</b>
		Yes/No?	You must provide evidence to support your response:
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of the following: (* denotes protected characteristics under the Equality Act 2010)		
	• Race *	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender *	No	
	• Culture	No	
	• Religion or belief *	No	
	• Sexual orientation including lesbian, gay and bisexual people *	No	
	• Age *	No	
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems *	No	
	• Gender reassignment *	No	
	• Marriage and civil partnership *	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination which can include associative discrimination i.e. direct discrimination against someone because they associate with another person who possesses a protected characteristic, are any exceptions valid, legal and/or justifiable?	N/A	
4(a).	Is the impact of the policy/guidance likely to be negative? (If “yes”, please answer sections 4(b) to 4(d)).	No	
4(b).	If so can the impact be avoided?	N/A	
4(c).	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
4(d).	Can we reduce the impact by taking different action?	N/A	

<b>Comments:</b>	<b>Action Plan due (or Not Applicable):</b>
	N/A

Name and Designation of Person responsible for completion of this form: Steven Reed, Trust Secretary..... Date: ....28/4/2011

Names & Designations of those involved in the impact assessment screening process:.....Joint Business Executive and Investment Committee.....

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)

*For advice on answering the above questions please contact Frances Blackburn, Head of Nursing, Freeman/Walkergate, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) [steven.stoker@nuth.nhs.uk](mailto:steven.stoker@nuth.nhs.uk) together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation, with relevant stakeholders, to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker within six weeks of the completion of this form.*