

INTELLECTUAL PROPERTY POLICY	Type: Policy Register No: 09069 Status Public
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1.0 Purpose

- 1.1 To promote the use of research results and other knowledge generated within the Trust to benefit a wider community
- 1.2 It is the Trust's purpose to promote wide and effective use of such information and the ideas generated within the Trust. If there is a commercial return to the Trust this can be reinvested in its activities. The Trust can identify valuable information and rights to secure appropriate protection, and to promote use; and to educate those involved in the value and opportunities which may arise.
- 1.3 The full background to this policy and the reasons for its development are attached as Appendix 1.

2.0 Aims

- 2.1 The aims of the Trust's IP (Intellectual Property) Policy are:
- To clarify the IP ownership and management arrangements adopted by the Trust
 - To ensure the NHS/Trust benefits from IP arising from NHS funded activity
 - To encourage staff/researchers to consider the relevance of their work (whether R&D or not)
 - To enhance IP identification and management
 - To promote commercial exploitation, where appropriate

3.0 Scope

- 3.1 This policy applies to all staff employed by or contracted to work with the Trust and to all external agencies connected to the Trust, their staff, patients and their services including any local universities and academic institutions, specifically:
- All staff that are full or part-time employees of the Trust where the IP generated relates to their area of employment by the Trust whether it was created during the course of a working day or outside normal working hours and/or away from the place of work.
 - Staff with contracts of employment with the Trust whose payroll costs are partially or fully funded by another party (e.g. medical charity, Government Department) unless the contract between the Trust and that party gives ownership of the IP to that party.
 - Staff employed part-time by the Trust who are self-employed or otherwise employed part-time. Where IP is generated during the non-Trust employment but involves use of or access to Trust resources then 5.5 above will apply.
 - Trust staff seconded to another organisation or employees of another organisation hosted by the Trust under contract subject to the terms defined in the contract between the Trust and that organisation.

- Independent providers of services who generate IP from research funded by the NHS are required to inform the Trust and share the benefits of its commercialisation. Where IP is assigned to the Trust, the independent service provider will benefit under the revenue sharing scheme of the Trust.
- Collaborative projects - if work/research is conducted by a Trust employee in partnership with another organisation, a formal agreement setting out ownership (or sharing) of generated IP is required. The R&D Lead will have primary responsibility for agreeing IP sharing agreements with collaborating institutions.

3.2 It applies to **all research and development activity** including student projects, national studies and commercial trials, and includes all staff, both clinical and non-clinical.

4.0 Definitions

4.1 **Intellectual Property (IP):** is the novel or previously un-described tangible output of intellectual and creative activity. IP can arise in the form of ideas, inventions, discoveries, software, research material, know-how & expertise, designs and images. Like physical property, it can be bought, sold or licensed to others.

4.2 **Intellectual property rights (IPR)** are rights which are protected by law and which enable the owner to control the IP and be rewarded for its use, encouraging further innovation. The main intellectual property rights are:

4.2.1 **Patents** (for inventions, covering for example new diagnostic equipment or surgical tools, new drugs, and new processes and equipment). Patents must be registered to be effective. Publication of results before seeking patent protection may be fatal to the protection of the invention. An invention must not be obvious development, compared to what is already known to someone who is experienced in the relevant field. Where there is a possibility of patent protection being obtained this should be reported to the Trust's IP Lead as soon as possible.

4.2.2 **Copyright** (for written works, drawings, photographs, sound recordings, and works such as computer software and collections of data, written or computer based protocols, forms). Copyright arises automatically in most cases. However, it is desirable to ensure that documents or other works which may be covered by copyright contain appropriate notices, such as:

"© Mid-Essex NHS Trust 2013. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner."

4.2.3 **Designs** (covering the shape and configuration of articles, such as equipment and tools). Designs can be protected both without registration and by registration. If there is the possibility of design protection advice should be sought from the Trust's IP Lead.

4.2.4 **Trade names** such as the Trust name and brands used by the Trust.

4.3 **Confidentiality:** In this context confidentiality means confidential business information or "Know-how" (and is not related to the requirement to protect person identifiable information) It is information which may be commercially or technically valuable, and which is regarded as secret. It may, for example, include information on industrial processes or be a list of clients. Confidentiality is generally protected by

written agreements. 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). Such an agreement should only be signed by an appropriate, authorised representative of the Trust, so that the risk from disclosure can be assessed and suitable records kept.

- 4.4 **Invisible value:** The Trust generates valuable information and intellectual property in many of its activities.
- 4.5 **Application:** Intellectual property provides the basis for protecting information, ideas and developments. Be it from new drugs or methods of diagnosis, to papers, manuals and forms; from software and collections of data to new procedures. It arises from research, but also in day to day Trust activity. Examples are rights in inventions, copyright in papers, books, or collections of information and data and in software, rights in designs, and trade and brand names used by the Trust.
- 4.6 **Ownership:** In general, intellectual property rights generated by those working in the Trust in the course of their work, belong to the Trust. In relation to some types of work, such as academic books, the Trust may transfer its rights to the person involved.
- 4.7 **Third party contracts:** In some cases there will be contractual arrangements under which the arising intellectual property belongs to a third party. Normally, unless a third party in the private sector meets the full cost of any research or development, the Trust will expect to retain an interest in the intellectual property. Staff should ensure they are familiar with any relevant third party contract, so as to meet any requirements in relation to reporting and protection of intellectual property.
- 4.8 **Protection:** If such material is potentially valuable, those in the Trust should ensure that they report this, with appropriate details, to their line manager or the Trust's IP Lead. This will ensure appropriate steps can be taken to protect any relevant intellectual property. Until appropriate protection is obtained, those who know of the material should avoid doing anything which might damage its value (and in particular disclosing information without protection), as long as this can be achieved whilst doing their job.
- 4.9 **Evaluation:** The Trust's IP Lead will consider, in conjunction with the originator, the value of the material. They will also review what steps can be taken to promote the wider beneficial use of any material, and whether commercial exploitation is appropriate; and what steps are appropriate to take to protect the material. The Trust's IP Lead may review this with a panel of advisors.
- 4.10 **Exploitation:** If appropriate the Trust's IP Lead will advise on what steps should be taken to promote wider dissemination, and/or prepare a plan to implement suitable exploitation. Any conclusions will be reported to the originator. The Trust will not normally be willing to undertake significant risks in the course of exploitation and where commercial exploitation is possible, the Trust will look to a third party to assume such risks.
- 4.11 **Sharing the benefits:** If revenue arises for the Trust from exploitation of any material, after accounting for any costs it has incurred the Trust will share a part of the benefit with the originator in accordance with the current revenue sharing policy.

- 4.12 **Additional assistance:** Those involved should provide such assistance as the Trust's IP Lead requests to help protect and permit exploitation of relevant material. In some cases they may be required to sign documents relating to rights in the material.
- 4.13 **Own development:** If the Trust concludes that it is not appropriate for it to be involved in exploitation, unless there are reasonable grounds for it not doing so, it will allow the originator to take steps to exploit the results. The Trust may need to maintain some control, in order to protect its interests or the interests of patients.
- 4.14 **The Trust's name:** The Trust's name and brands are valuable assets of the Trust. It is important that they are not damaged by inappropriate use, and at the same time that the Trust can be promoted by use of its name in the right circumstances. Any use of the Trust's name in relation to any publication or other publicity should be cleared with the Trust's IP Lead in advance, and advice obtained on how the name may be used.
- 4.14 **Records and Administration:** The Trust will maintain an administrative procedure for handling the matters set out above, and will maintain records of developments, ideas, and other information reported under this policy. In addition, so far as relevant, the Trust will implement the terms of this policy in contracts of employment for staff and in relation to research and other contracts with third parties.

5.0 Roles & Responsibilities

5.1 Managing Director

The Managing Director is accountable for ensuring that appropriate policies and procedures are in place but day to day responsibility is that of "the responsible Executive Director"

5.2 Responsible Executive Director

- 5.2.1 The Finance Director shall be the Executive Director. In the event of a dispute, a committee comprising of the Chief Executive, Director of Finance, Chief Research Officer and Chairman of the R&D Internal Steering Group shall arbitrate.

5.3 R&D Steering Group

- 5.3.1 The R& D Steering Group are responsible for the strategic management of Intellectual Property

5.4 R&D Internal Steering Group

- 5.4.1 Overseen by the R&D Internal Steering Group

5.5 R&D Co-Directors

5.6 IP Scouts

- 5.6.1 The Trust will have trained innovation scouts to guide, support and inform staff on processing their idea further.

5.7 **IP Lead**

5.7.1 The Trust's IP Lead will maintain records of developments, ideas, and other information reported under this policy.

5.8 **Dispute Group**

5.8.1 In the event of a dispute, a committee comprising of the Chief Executive, Director of Finance, Chief Research Officer and Chairman of the R&D Internal Steering Group shall arbitrate.

5.9 **All Staff**

5.9.1 Staff are required to notify the Director of Finance of any idea or other form of Intellectual Property that they have developed prior to it being disclosed.

5.9.2 All staff Trust must consider whether any developments, ideas or results they or their colleagues generate or information or data they collect could be used to benefit others, especially outside the Trust. If so they should review this with the person to whom they report, or with the Trust's IP Lead.

5.9.3 Publication and dissemination of relevant ideas and information is important. However, unless the appropriate steps are taken in advance, disclosure to others outside the Trust may invalidate any protection. Staff involved should therefore not disclose information to anyone outside the Trust without considering whether it is valuable or disclosure could be damaging to the Trust, and if so, permitting the Trust to put in place appropriate protection. This may be in the form of confidentiality agreements, or copyright notices, or in suitable cases, patent protection. If in doubt staff should consult their line manager or the Trust's IP Lead.

5.9.4 From time to time an employee may generate IP which may have value in the delivery of better patient care. All employees who may have created any form of intellectual property are required to bring it to the immediate attention of the Trust IP Lead who will provide first level advice and engage the services of outside advisors as appropriate.

5.9.5 Disclosure to persons outside of the Trust (other than under explicit terms of confidentiality) may invalidate any subsequent attempt to gain IP rights and significantly diminish both potential commercial value and benefits accruing to both the Trust and the inventor. It is essential therefore that all ideas and developments are not generally discussed and are reported instead through the correct channels.

5.9.6 All employees should treat as confidential and not disclose to any third party any research results or other confidential information relating to IP developments without prior written approval of the Trust's IP Lead. If there is any uncertainty as to the sensitivity or confidentiality of the information, the employee should consult with the Trust IP Lead prior to any disclosure.

5.9.7 Employees must not, under any circumstances, disclose before protection, sell, assign, licence, give or otherwise trade in IP without the Trust's written agreement.

5.9.8 Before negotiating or entering into any contract or other arrangement which addresses intellectual property or the rights in results or developments, it should be

reviewed with the Trust's IP Lead. The Trust's IP Lead must give written approval to any such contract before it is signed, and should be consulted as early as possible when such an arrangement is being considered.

- 5.9.9 Any employee wishing to discuss the protection of any idea or other form of intellectual property should inform the IP Lead at the earliest opportunity and, in any event, before disclosure of the idea (whether orally or in writing) to any party outside the Trust.

6.0 Exploitation and Ownership of Intellectual Property

- 6.1 Generally, if a member of the staff (an employee) of the Trust creates or generates any intellectual property, including inventions and information and results in the course of performing their duties, the rights in that intellectual property belong to the Trust (subject to some statutory exceptions).
- 6.2 In addition, if any other person working for or within the Trust creates or generates intellectual property while working for the Trust, the normal rule which the Trust will apply is that rights belong to the Trust. This is intended to apply to consultants, visiting research students and other categories of non-employed staff. In practice, in each case the position is also likely to be affected by the contract under which the work is being carried out, or relevant research contracts.
- 6.3 In each case this includes activities carried out wholly or partly under Trust auspices. It also includes activities using Trust facilities, and work carried out during time for which the member of staff receives financial reward or remission of duties or responsibilities from or through the Trust, for example where they are given times off to write a book.
- 6.4 In any case it may also be important that the Trust own the rights as the Trust may have entered obligations with third parties in relation to the intellectual property rights. It is important that the rights initially belong to the Trust so that it can comply with those obligations.
- 6.5 In cases where the intellectual property does not belong to the Trust, but has been generated by use of or access to Trust resources, this must not be exploited without prior written consent from the Trust. The Trust will not unreasonably withhold consent but may, in its discretion require a reasonable reward reflecting the contribution made from its resources.
- 6.6 In each case reported to the Trust's IP Lead, the Trust's IP Lead will consider what form of protection is suitable and appropriate for the results or developments.
- 6.7 The Trust has specific arrangements in place for the exploitation of intellectual property therefore you should not take any steps to exploit Trust intellectual property without the specific approval of the Trust Board.
- 6.8 The Trust may at its absolute discretion decide that the IP is best exploited through a spin-out company. In this case the Trust may take shares in that company and there may also be opportunity for the employee who created the relevant IP to take shares and/or otherwise participate in the spin out company. Setting up a spin out company is a complex procedure which may require consent of the DoH. Details of the procedures to be followed are set out in the Framework and Guidance document at www.innovations.nhs.uk.

7.0 Intellectual Property Revenue

- 7.1 To encourage staff to contribute to the generation of IP, the Trust operates a reward scheme for staff creating or generating IP which subsequently becomes commercialised. Revenue generated will be shared with the Trust and the inventor according to the Trust's revenue sharing policy, the current version of which is set out below:
- 7.2 The shared revenue will be net of any protection and exploitation costs incurred by or on behalf of the Trust.

Cumulative Net Income	Inventor	Department	R&D Dept.	Trust
First £50,000	50%	20%	10%	20%
Next £100,000	40%	25%	10%	25%
Next £100,000	30%	30%	10%	30%
Over £250,000	25%	32.5%	10%	32.5%

- 7.3 In cases where there are a number of inventors the income allocated will be divided between them. In all cases the shared revenue will be net of any protection and exploitation costs incurred by or on behalf of the Trust.

8.0 Copyright

- 8.1 Although copyright of any work produced by an employee in the course of normal employment belongs to the Trust, the Trust will normally grant to the author a royalty free licence to the copyright of any work published in a recognised scientific, technical, professional or management journal or book and will not claim a share of any income derived from such works.
- 8.2 The Trust will not grant such a licence for materials created by a member of staff during the course of and related to their employment, which are on the following non-exhaustive list:
- Course or training materials
 - Patient information
 - Software programmes
 - Designs, specification or other works which may be necessary to protect rights in commercially exploitable Intellectual Property.
- 8.3 The Trust will respect the moral rights of its employees as authors in copyright materials if asserted by notification to the R&D lead, with the exception to any materials related to computer programs, the design of a typeface or any computer generated work – in standing with the Copyright, Designs and Patents Act 1988.

9.0 Students and other non-employees at the Trust

- 9.1 Students and other non-employees of the Trust are required to sign a confidentiality agreement which provides that the student disclose details of any inventions to the Trust and assign the rights to the Trust on request. Similar provisions will apply to

other researchers at the Trust who are neither staff nor students e.g. Senior Research Fellows and other emeritus staff.

10.0 Rejected Development Decisions

10.1 When IP is generated, and the Trust chooses not to further the development or commercial exploitation of such IP for whatever reason, the IP will be assigned to the inventor on request, who may wish to pursue its further development independently.

11.0 Ownership Disputes

11.1 If the ownership of IP is disputed, dated written records relating to the IP in question will be assessed by the R&D committee with professional help to establish the ownership of the IP, the inventor(s) and their proportionate contribution as appropriate.

12.0 Record Keeping

12.1 Staff are reminded of the importance of keeping accurate and dated laboratory notebooks so that, in the event of similar intellectual property being generated elsewhere, ownership of the invention can be proved. Such notebooks can be important when applying for patents in the USA and also for identifying know-how.

12.2 In addition, a record will be kept of the date and time on which an employee reports to the IP Lead that they are the inventor of a creative product.

13.0 Audit and Monitoring

13.1 There is no formal obligation to capture IP through a process of technology audit. The Trust may however employ an auditing process to identify and evaluate IP and otherwise assist in its commercialisation.

13.2 Those involved in creating or generating intellectual property, or results or developments, may be asked to assist by providing further information which helps the Trust to protect or to arrange exploitation of it. For example you may be asked to sign formal transfer documents.

14.0 Training

14.1 The Trust will take steps to promote understanding by those working in the Trust of the issues arising under this policy, in particular the value and protection for intellectual property, and how to identify this.

15.0 Trust Intellectual Property Contacts

R&D Manager & IP Lead: Lauren Perkins

Board Contact: Stephen Beeson

IP Scouts: Paul Roberts and Fiona McNeela

16.0 References

The NHS as an Innovative Organisation: A Framework and Guidance on the Management of Intellectual Property in the NHS, published by DoH in 2002.

Health Service Circular 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 NHS Researchers. NHS Executive 1998.

(The full text of these documents is available from the NHS Innovations East website - <http://www.hee.org.uk>)

Background to the Development of the Intellectual Property Policy

Recent NHS policy frameworks and guidelines supported by the Health and Social Care Act 2001 place a duty on the Trust to protect and exploit intellectual property generated by its employees in the course of their normal duties for the benefit of patient care, staff and the wider health care community.

The NHS recognises the need to develop as an organisation, with innovation at the core of its business, developing new products and service innovations for better health care delivery. Innovation occurs naturally in the normal course of employment at all levels throughout the NHS. The innovation may be a novel treatment, device, new drug, data, software, training material or a new management system.

Most innovations are best implemented by making them freely available through normal knowledge management processes once they have demonstrated a quantifiable health service gain. However, some innovations can only be realised through commercial development. For these innovations, professional management of the associated Intellectual Property (IP) is crucial. The NHS recognises that the protection of IP facilitates rather than impedes the uptake of innovations with commercial potential.

All of these considerations made it desirable for the Trust to develop this policy, which outlines how the Trust, with the aid of specialist organisations within the NHS will protect and manage the IP created by its employees for the improvement of healthcare. This will also ensure that any revenue generated is shared equitably with the employees creating the IP. In 2002 the Department of Health published a Framework and Guidance on the Management of Intellectual Property in the NHS. The Framework and Guidance builds on the previous 1998 policy published in the Health Service Circular HSC 1998/106, which dealt with the management of IP arising from Research and Development (R&D) funded in whole or in part from the NHS R&D Budget.

The Framework and Guidance extended the 1998 policy to include IP generated by all NHS employees involved in healthcare delivery. As a result of this, IP generated from any source is now recognized by the NHS as an asset of value which should be managed in the best interests of NHS patients, employees and society as a whole. All NHS Trusts and Primary Care Trusts are required to ensure that IP arising within their trusts is managed within the given Framework and according to the provisions of Section 5 of the Health and Social Care Act 2001.

Under the 1998 policy, Trusts already have the power to generate income through commercial exploitation of IP. The Health and Social Care Act is aimed at supporting the delivery of the NHS Plan, and is intended to enable Trusts, subject to the approval of a business case, to take a shareholding in spin-out companies set up as a vehicle to exploit IP provided that it does not interfere with its functions or obligations under NHS contracts. Income generated by successful commercial exploitation of IP arising from the Trust will be retained by the Trust and shared with inventors.

Intellectual Property Flowchart



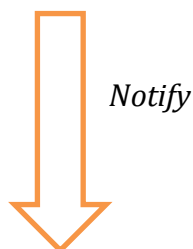
IDEA

*Any research and development activity including student projects, national studies or commercial trials.
 *From all staff, both clinical and non-clinical.



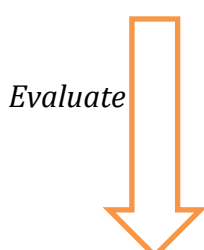
Research and Development Dept.

*Promote the use of research results and other knowledge generated within the Trust to benefit a wider community.



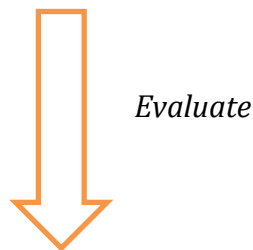
Trust IP Lead

*Evaluates whether any developments, ideas or results staff generate or information (data) they collect can be used to benefit others, especially those outside the Trust.
 *Evaluates the value of the material and the appropriate steps to take in order to protect it.
 *Advises on steps to take in order to promote the material and its wider distribution.



Rejected

*Inventor is allowed to take steps to exploit the material, as long as Trust can maintain control in order to protect its interest or the interest of the patients.
 *IP will be assigned to inventor upon request for its further development independently.



Accepted

*Trust will share revenue generated by IP with inventor in accordance with the Trust's current revenue sharing policy.

Revenue Sharing Agreement

Cumulative Net Income	Inventor	Department	R&D Dept.	Trust
First £50,000	50%	20%	10%	20%
Next £100,000	40%	25%	10%	25%
Next £100,000	30%	30%	10%	30%
Over £250,000	25%	32.5%	10%	32.5%