

**Intellectual Property Management and Exploitation Policy (IP Policy)
Version 1.0**

DOCUMENT CONTROL

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Review and amendment log

Version No	Type of Change	Date	Description of change

1 Introduction

Trust employees may develop innovations that have practical application and/or commercial potential. These concepts are known as Intellectual Property (IP) and, as with other forms of property, they may be owned and should be protected. In line with the NHS strategy for exploitation and commercialisation of IP, the Research Governance Framework¹ and more recently the focus on innovation^{2,3} The Mid Yorkshire NHS Trust encourages its staff to develop and exploit intellectual property in conjunction with the Trust and Medipex Ltd (the Regional Innovation Hub).

2 Aims, objectives and scope

This policy sets out the rules of ownership, protection and exploitation of intellectual property arising from employees' work. It aims to maintain a balance between the legitimate needs of the Trust to protect its interests and the provision of a creative working environment for staff.

The policy applies to exploitation of ideas and innovations, via licensing and spin-out companies (See Appendix I). Should commercial exploitation be contemplated via the formation of a commercial company or 'spin out' company, advice should be sought from the Trust Chief Executive Officer and Trust Finance Director.

3 Roles, Responsibilities and accountability

Trust Chief Executive is responsible for

- Intellectual property arising from research activity

Trust Research Director, is responsible for

- Research governance and innovation activity across the Trust

Trust Research Manager is responsible for:

- Compliance with Research Governance Framework and other regulations that govern research activity

Trust Research and Quality Managers are responsible for:

- Implementation and maintenance of this policy
- Co-ordination of the exploitation of individual cases of identified IP working with the staff member, the relevant General Manager and Medipex Ltd.
- Ensuring there is a process of tracking, collating and reporting information on IP exploitation.

General Managers/ Clinical Directors are responsible for:

- Implementation of this policy within their Division
- Working with staff members who have identified potential IP to see whether exploitable and to signpost them to the appropriate advice

Drs and Heads of Clinical Service in the area where the IP is identified are responsible for:

- Liaising with the appropriate Divisional staff and the Trust Research Manager at the earliest opportunity to ensure the correct accounting treatment and presentation (See Section 11).

All staff are responsible for:

- Protecting intellectual property and ensuring they take the appropriate action if they believe they have potentially exploitable IP (see Section 8)
- Co-operate with any audits to identify any areas of exploitable IP (see Section 8)

4 Protection of Intellectual Property

Intellectual property can be protected by legal rights such as Patents, Copyright etc (fact sheets are available at www.medipex.co.uk). Acquiring such rights can be costly and is only the initial step with patents, trademarks and design rights. Copyright, however, is free, and any Trust documents should bear copyright, e.g. Copyright © Mid Yorkshire NHS Trust 20.. (year). Little or no benefit will accrue from protecting the intellectual property unless they are then developed and commercialised. Medipex Ltd can advise Trusts on whether or not the intellectual property has commercial potential and how best to take it forward.

5 Ownership of Intellectual Property

As a general rule, intellectual property created by an individual during the course of his/her employment, or training arising out of his/her employment, belongs to their employer. In certain circumstances, however, The Mid Yorkshire NHS Trust may decide not to take up its rights to the intellectual property, in which case the intellectual property rights of ownership would be assigned to the employee.

Over recent years most funding bodies, in particular NIHR and Research Councils are more interested in the Intellectual Property arising from research they fund and its exploitation.

Research Councils UK stipulate that:

“Where the grant is associated with more than one research organisation, and/or other project partners, the basis of the collaboration between organisations including ownership of IP and rights to exploitation is expected to be set out in a formal collaboration agreement. It is the responsibility of the Research Organisation to put this in place before the research begins. The

terms of the collaboration must not conflict with the Research Council's Terms and Conditions".

This means that there needs to be a collaboration agreement in place between all the organisations involved in delivering a programme of research through such a grant. Additionally in the case of NIHR they will require an Intellectual Property protection and exploitation plan to be in place and Medipex Ltd can help with both of these.

5.1 Joint Employees

Where employees have joint contracts with other organisations, for example universities, a partnership agreement on intellectual property issues will need to be developed with each such organisation. Similarly these partnership agreements will need to cover situations in which the NHS would be considered a secondary employer, or where more than one member of staff is involved.

In general, the organisation with the main contract will be responsible for protecting the property rights and for any commercialisation. Agreement will need to be reached as to the way the costs and benefits will be apportioned between the two organisations. These working arrangements may differ with each particular organisation.

6 Exploitation of Intellectual Property

Exploitation of intellectual property involves both costs and risks. Consequently, it will by no means always be appropriate or cost effective to seek to protect and exploit potential intellectual property. In cases where patenting or licensing may be the most appropriate option, Medipex Ltd will undertake the negotiations on behalf of the Inventor and the Trust. In some instances the intellectual property may be a case of "best practice" which could be shared with other Trusts and the network of IP Hubs may be used to disseminate these innovations, either through their own network or via other NHS organisations.

Exploitation of the Trust's IP will be the responsibility of the Research Management Team or their Designee. Management responsibility for IP generated by the Trust's staff will reside with the General Manager of the Division concerned. All developments of IP should be channelled through Medipex Ltd who manage the Trust's intellectual property rights. They will assess the potential of the intellectual property and decide whether or not it is worth protecting and exploiting.

7 Sharing the Benefits

If the Trust chooses to protect intellectual property rights then it is considered appropriate that members of staff who have developed the intellectual property should have a share in any benefits e.g. through a royalty income.

Research

It is suggested that typically the **net benefits** (direct sale or licensing of IP) to the Trust should be split 40% for the inventor and 60% for Trust (after the recovery of costs). The benefit to the inventor of the Trust commercialising their innovation is that the Trust will normally cover the development costs including the costs of protecting the IP e.g. patent filing. Of the Trust's share (60%), 30% will go to the inventor's Clinical Division (where the IP was first devised, made or created) in recognition of the time taken to develop the innovation and 30% will go into a central Innovation Fund for use on the development of future innovations. If a spin-out company is formed then both the Trust and inventor will have an equity stake in the company.

If IP arose from research which was funded by an external, non-NHS or University agency, whose policy on the commercialisation of IP was different from the Trust and which formed part of the research contract, then the distribution of financial benefit would be negotiated by Medipex Ltd on behalf of the Trust with the funding body.

If the Trust does not wish to own a certain piece of Intellectual Property then it may be assigned to the member of staff who would then assume ownership. The member of staff would then take up responsibility for protection and commercialisation. In this case the Trust would retain a residual share of the financial benefits, for example, not more than 20%.

Medipex Ltd will only undertake work on behalf of the Trust. If a Trust employee wishes Medipex Ltd to advise or undertake commercialisation of IP for which they are the inventor, it is done on the understanding that Medipex Ltd is acting on behalf of the Trust, in line with the Trust's policy and any benefits accrued from such work will belong to the Trust who will split them with the inventor as outlined above.

8 Guidelines for Staff

If an employee develops an idea or concept, which may have commercial potential, they must report this to their General Manager, who should contact the Trust Innovation Lead, the Research Director, or Medipex Ltd at the earliest opportunity and, in any event, before disclosure of the idea to any party outside the Trust, either orally or in writing.

Examples include the development of new techniques, ways of working or diagnostics; devices; software; pharmaceutical products; formulae and writings.

It is often difficult to protect IP and advice is needed at the earliest stages. If an employee thinks they have an item of intellectual property there are a few simple guidelines which will help maximise the chances of being able to protect it:-

- Keep it secret and resist pressure to announce or publish details until the matter has been discussed with either, the Trust Innovation Lead, or Medipex Ltd. Public disclosure (other than under explicit terms of confidentiality) will invalidate any subsequent patent application and severely diminish both potential commercial value and benefits accruing to the Trust and the originator. Disclosure without entering into an undertaking of confidentiality may prejudice negotiations of commercial arrangements with a company.
- Confidentiality Agreements must be used when discussing intellectual property with external parties. These can be obtained from Medipex Ltd.
- Avoid giving away or selling samples.
- Don't involve external organisations or companies in testing or prototyping without a written agreement together with confidentiality agreement being in place. Agreements related to innovations derived through research will be reviewed by the Trust Research Manager prior to signature; agreements related to all other innovations will be reviewed by both Medipex/the Trust Legal team and the Research Manager prior to signature.
- Don't sign any contracts or agreements until they have been reviewed by the Trust Research Manager and Medipex

9 Process for monitoring compliance and effectiveness

A Register of intellectual property will be maintained centrally to identify intellectual property of potential commercial value, supported by Medipex Ltd, and this will be made available to the auditors, as required (Table 1).

Minimum requirement to be monitored	Process to be used for monitoring eg. audit	Responsible individual/ committee for carrying out monitoring	Frequency of monitoring	Responsible individual/ committee for reviewing the results	Responsible individual/ committee for developing an action plan	Responsible individual / committee for monitoring the action plan
IP Register	Written report	Research Committee via Research Quality Manager	Annually	Research Committee/ Medipex Ltd	Research Committee / Medipex Ltd	Research Committee via Research Quality Manager

Table 1: Process for monitoring compliance with intellectual property management and exploitation policy

All registered intellectual property will be reviewed, and the following criteria will be applied:

	Criteria	Y/N/NA	Comments
1	Has all intellectual property been registered on the central database?		
2	Has all intellectual property been channelled through Medipex Ltd?		
3	Is a confidentiality agreement in place if the intellectual property has been discussed with an external party?		
4	If a confidentiality agreement is in place, has this been reviewed by Medipex Ltd?		
5	Is there a statement on intellectual property ownership in the employee's contract of employment?		
6	Is there evidence that staff have been made aware of their responsibilities?		
7	Can General Managers provide evidence of implementation of this policy within their Divisions?		

Audit Criteria for identification of intellectual property and process management, and contracts of employment

10 Equality Implication

Statement: This policy aims to ensure that fair systems are in place for staff who wish to exploit intellectual property. It aims to ensure that all our staff have the same rights and responsibilities under the policy and that they are treated equitably with regard to age, disability, gender, race, religion and belief or sexual orientation.

Initial Equality Impact Assessment: An initial Equality Impact Assessment (EqIA) was carried out on this policy which highlights that there is no impact on any equality groups with regard to the operation of this policy with the exception of staff with a visual impairment.

However, it is the responsibility of the employing Division/Department to ensure that reasonable adjustments are made to ensure that a visually impaired staff member who develops or proposes an activity that would be covered, is made aware of the content of this policy.

As there is no other impact, the Policy will not be subjected to a full Equality Impact Assessment. However, it will be reviewed for equality impact when it is reviewed in 2018. A copy of the initial EqIA can be found at Appendix ?.

11 Financial Implications: Accounting for intellectual property comes under International Accounting Standard (IAS) 38 – Intangible Assets. IAS 38 is complex and details the criteria that have to be satisfied before intellectual property is recognised as an asset.

This policy has the potential to have ongoing financial consequences for the Trust with regards to investment into exploiting IP. The process by which the decision to make such an investment will be made on a case by case basis. Such a decision will take into consideration the levels of investment required and the likelihood of a return on investment.

12 Training requirements, implementation and dissemination

There are no implications for training requirements. Staff, as part of their contracts of employment, are required to comply with the Research Governance Framework and this policy forms part of the Trust's work to meet the standards set out by the Research Governance Framework. However work will be undertaken to include a statement on Intellectual Property Ownership within all contracts of employment to ensure that all staff adhere to this policy.

The implications for staff of this new policy will be incorporated in all new staff induction documentation and will be circulated to all present staff.

13 Related policies and associated documents

- Trust Code of Conduct for Research involving Human Participants
- Research Governance Framework for Health and Social Care, 2nd Edition 2005, Department of Health
- High Quality Care for All; Next Stage Review Final Report 2008, Lord Darzi, Department of Health
- Innovation Health and Wealth – Accelerating Adoption and Diffusion in the NHS 2011, Department of Health.
- Mid Yorkshire NHS Trust Research And Innovation Strategy 2015

14 References

- ¹ “Research Governance Framework for Health and Social Care 2nd Edition” 2005, Department of Health
- ¹ “High Quality Care for All; Next Stage Review Final Report” 2008, Lord Darzi, Department of Health
- ³ “Innovation Health and Wealth – Accelerating Adoption and Diffusion in the NHS” 2011, Department of Health.

Appendix I – Guidance on Spin Out Companies

An alternate commercial exploitation route for NHS IP other than through licensing is via formation of a commercial company often referred to as a spin out company. The consideration of a spin out company, rather than the normal route of licensing, is where there are good long term prospects of a commercial return but the short term development costs and risks are high and therefore unlikely to attract an industry partner. The IP is transferred in to the company and used as the asset to raise external finance in return for a share of the equity. Medipex Ltd would advise the Trust on the appropriateness of this, provide template documentation and lead on initial fund raising.

The Secretary of State for Health enabled NHS Trusts and other NHS bodies to generate income, when the activity is subsidiary to, and does not significantly interfere with the provision of their core services. Further info can be found in Section 5 of the Health & Social Care Act 2012. Prior to an NHS Trust, other than Trusts, participating in establishment of a company a business case needs to be submitted and where NHS IP is involved the business case should come via Medipex Ltd. Note: this can take several months.

The Trust internal management and approval process can often be cause of delay which, in the past has caused concern amongst external funders and backers. Therefore it is recommended that where it is likely that at some point an NHS company might be formed that the Trust develop a policy and give consideration to how they would gain board approval in a timely manner. It is appropriate, though not essential, for the Trust to appoint someone senior to become a non-executive director on the board of the commercial company.

From experience an area that has worked out well is where Medipex Ltd take responsibility for seeking appropriate legal advice on the agreements, deal structure and the Trust liability. This minimises the need for the Trust to consult their own lawyers each time hence keeps costs down and speeds up the process.

The key documentation that will require sign off includes:-

Articles of Association - The Articles of Association contain the internal regulations and bye-laws covering procedure, shares, meetings, directors and other administrative issues and is commonly based on Table A taken from Companies Act. However in the first instance it is usual to adopt the Standard Articles of Association and refine them at a later date when the first group of shareholders/members has been clearly defined.

Memorandum of Association - The Memorandum of Association is the first constitutional document of a company. Since the Companies Act of 2006 is a very simple document that just lists the founding member(s) or shareholder(s) who sign it off against their organisation's name. This document is only filed

once at the company's inception and is never changed or added to. All changes to shareholders or members are reflected in the shareholder/membership agreement.

Shareholders Agreement - This is a legal documentation signed as a deed of trust by all parties that is used where two or more parties wish to carry on business together as a limited company (i.e.: limited by shares) and wish to regulate the relationship between shareholders, and determine actions in the event of deadlock. It sets out what restrictions there may be on share dealing (buying & selling), warranties and liabilities and who the directors are.

Assignment of IP - It is normal practise to either transfer the ownership or licence of the rights to the IP (patents, know how and access to data) in to the company. Generally, this is the major asset around which external investors would be prepared to invest. Usually the patents are assigned i.e. ownership passes to the company and its shareholders but occasionally a licence is used. Medipex Ltd would advise on the appropriateness of which route to suit the particular circumstances.

Other issues that will crop up include:

Inventor/Trust share - Generally, we would encourage the principal inventors to commit to the project and in return to be awarded a % of the equity. This is not the same as becoming a director of the company and in most cases we wouldn't advise NHS staff to become involved in management of the company as this is a complex area and requires specific skills and commercial experience. Where a team of staff is involved it becomes impractical to distribute equity options to everyone. However, it is recommended that staff involved should either benefit in a direct reward scheme or that the proceeds are used in an agreed way for the common good.

Alternates to Equity in a Spin out Company - A share of ownership in IP does not automatically equate to an equity stake in a spin out company there are several alternates.

Equity Option - This option confers rights on the holder to acquire a predetermined amount of shares in the company subject to certain milestones usually when the company is sold or floats. This option does not confer any voting rights or other shareholder duties but equally it has much less involvement and would not require DH approval.

Royalty - The equity option could be converted into a royalty which would be payable via a standard licence agreement when and if the company generated any sales. It is much more difficult to determine an acceptable royalty rate that would financially equate to the equity position but if the company were sold as a viable concern then the royalty would be expected to transfer to the new owners who would continue to pay

iAppendix D - Checklist for the Review and Approval of Procedural Documents
To be completed and attached to any document which guides practice when submitted for ratification

	Title of document being reviewed	Yes/No/ Unsure	Comments
1.	Title		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard? (Appendix A)	Yes	
2.	Rationale		
	Are reasons for development of the document stated?	Yes	
3.	Development process		
	Is the method described in brief?	Yes	
	Are individuals involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with relevant stakeholders and users?	Yes	
4.	Content		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	Evidence Base		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?	Yes	
	Are local/organisational supporting documents referenced?	Yes	
6.	Approval		
	Does the document identify the approving Director?	Yes	
	If appropriate, have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	Dissemination and Implementation		
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary	Yes	

	training/support to ensure compliance?		
8.	Document Control		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	
9.	Review Date		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so, is it acceptable?	Yes	
10.	Overall Responsibility for the Document		
	Is it clear who will be responsible for the coordinating the dissemination, implementation and review of the documentation?	Yes	

Sponsoring Director			
If you are happy to approve this document, please sign and date it and submit to CEG for approval			
Name		Date	
Signature			
Submission to Clinical Executive Group			
Date of meeting			
Decision			