



Intellectual Property Policy

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2.4	May 2022	Fiona Bell (Head of Research)	D	Added references to foreground and background IP, and IP generated via research funding. Removed references to defunct Innovation Champions Network.

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<p>YAS Research Governance Policy YAS Research Strategy YASRDSOP14 Yorkshire Ambulance Service Intellectual Property Management and Innovation Disclosure Standard Operating Procedure</p>				

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Staff Summary

Intellectual Property (IP) may be a novel treatment, a new diagnostic tool or device, new drug or new use of a drug or treatment, training material, system of management, or software application.
This policy contains guidance for staff throughout the development of ideas or concepts which have potential to be commercially exploited
Top tips for staff who think they have developed IP which could be sold (more detail at section 3.5): <ul style="list-style-type: none">• Keep it secret• Do not publish, present at conferences, or talk to commercial companies until your idea has been assessed and protected• Contact the Research team (yas.research@nhs.net or 01924 584028) for help and notify your manager• The Research team will advise on any contracts or agreements.
The Trust has responsibility to assess, develop and exploit IP, and employs the services of Medipex Ltd to support the identification and exploitation of IP
This Policy outlines the ownership of IP arising from an employees' work (including joint employees)
This Policy outlines the responsibility of the Research Department in the protection and use of Intellectual Property in relation to the development and contracting of research projects (background, research data, and foreground IP).

1.0 Introduction

- 1.1 It is the vision of Yorkshire Ambulance Service NHS Trust (YAS) to be trusted as the best urgent and emergency care provider, with the best people and partnerships, delivering the best outcomes for patients. As part of this vision, staff should be given the opportunity to pursue their ideas, and the Trust has a responsibility to ensure that advancements in working practices are disseminated across the Trust and, if appropriate, nationally.
- 1.2 Most innovations are best implemented by making them freely available through normal knowledge management processes when they have demonstrated a quantifiable health gain or improvement for delivering healthcare. However, some innovations are inventions which can be realised only through commercial development, and for these the professional management of associated intellectual property (IP) is crucial.
- 1.3 Many innovations will not be able to be commercially exploited but may have potential benefits if successfully implemented. The Trust will assess, develop and exploit Intellectual Property (IP) in conjunction with the Regional NHS IP Hub (Medipex Ltd.).
- 1.4 IP may be know-how, data sets, or clinical tools (e.g. questionnaires). IP may be a novel treatment, a new diagnostic tool or device, new drug or new use of a drug or treatment, training material, a product, a new system of management or software application which could require protection using copyright, trademarks or patents.

Background IP (e.g. know-how, data sets) is often required in order to develop any Foreground IP (e.g. screening tool). Any new idea has an owner and can be bought, sold or licensed and therefore must be adequately protected. The owner of IP can control its use and be rewarded for it. IP may be developed through many routes, including service-driven need or through funded research projects.

1.4.1 IP may fall into the following categories:

- Inventions
- Literary and artistic works
- Designs and design drawings
- Engineering components, architectural drawings
- Product brand names, logos
- Trade secrets

1.4.2 For an innovation to be developed commercially, IP needs to be professionally managed, and it is agreed that Medipex (www.medipex.co.uk) will provide this service for the Trust.

2.0 Purpose/Scope

2.1 This policy sets out the rules of ownership of IP arising from employees' work, and its protection and exploitation. 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.

2.2.1 This process may include publishing the IP in the public domain, or exploiting it through commercial channels in order to potentially acquire monetary gain.

2.2 In order to ensure the benefits of these innovations are maximised, this policy gives details regarding the ownership and required protection in relation to IP.

2.3 This policy has the following objectives:

- To ensure that all IP is identified and appropriately protected;
- To ensure all IP has ownership established;
- To confirm the arrangements regarding IP, including those involving Medipex;
- To ensure that, where appropriate, IP is fully exploited in terms of patient and staff benefit;
- To ensure that, where applicable, all monetary gains are divided appropriately between the Trust and the inventor;

- Encourage innovation by employees;
- Increase awareness and understanding of IP issues by Trust employees.

3.0 Process

3.1 Ownership of Intellectual Property

- 3.1.1 YAS is committed to ensuring a balance between the legitimate needs of the Trust to protect its interests and the provision of a creative working environment for staff members.
- 3.1.2 In order to maintain this balance, and in line with the NHS strategy for exploitation and commercialisation of IP, the Trust employs the services of Medipex Ltd (the local NHS Innovation Hub) to exploit IP in conjunction with, and on behalf of, the Trust.
- 3.1.3 Through this contract, if a Trust employee wishes Medipex to advise or undertake commercialisation of IP for which they are the inventor, it is done on the understanding that Medipex is acting on behalf of Trust and in line with the Trust policy.
- 3.1.4 As a general rule, IP created by an individual during the course of his/her employment, or training arising out of his/her employment belongs to their employer (the Trust) and any benefits accrued from such work will belong to the Trust. Where the IP created by a YAS employee is not specifically commissioned by YAS, and is not part of usual staff duties, YAS will share benefits with the inventor as outlined in Section 3.4 - Management of IP and Equity Division.
- 3.1.5 In certain circumstances, however, the Trust may decide not to take up its rights to the intellectual property, in which case the intellectual property rights of ownership may be assigned to the employee; in these cases Medipex may, with the explicit agreement of the Trust, continue to advise the inventor.

3.2 Protection of Intellectual Property

- 3.2.1 IP can be protected by legal rights such as Patents, Copyright etc. Acquiring such rights can be costly and is only the initial step. Little or no benefit will accrue from protecting IP unless it is then developed and commercialised.
- 3.2.2 The Department of Health established the IP Hubs to advise Trusts on whether or not the IP has commercial potential and how best to take it forward.

3.3 Exploitation of Intellectual Property

- 3.3.1 Exploitation of IP involves both costs and risks. Consequently, it will by no means always be appropriate or cost effective to seek to protect and exploit potential IP.

- 3.3.2 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.
- 3.3.3 In some instances the IP may be an example of “best practice” that could be shared with other Trusts and the network of IP Hubs may be used to disseminate these innovations, either through their own network, e.g the Academic Health Science Networks or via other appropriate NHS bodies.
- 3.3.4 Exploitation of the Trust IP will be the responsibility of the relevant Directorate and Corporate Functions, in conjunction with the Trust Research Department, who will retain management responsibility for IP generated by Trust staff.
- 3.3.5 All developments of IP should be channelled through Medipex Ltd who have a contract to manage the Trust IP rights. They will assess the potential of the IP and decide whether or not it is worth protecting and exploiting.

3.4 Management of Intellectual Property and Equity Division

- 3.4.1 If the Trust chooses to protect and exploit IP rights then, where the innovation is not part of the employee’s usual duties, it is appropriate that members of staff who have developed the IP should have a share in any benefits e.g. through a royalty income.
- 3.4.2 Where it is part of a staff member’s role to innovate or where the innovation has been specifically required by the Trust, any IP benefit will belong wholly to the Trust. This is most likely to apply in technical or training roles.
- 3.4.3 Where the IP income is shared between the Trust and the employee, the net benefits to the Trust (after deductions of the costs due to Medipex Ltd related to protection and commercialisation of the IP) will be split as follows:
- 40% for the inventor
 - 60% for the Trust; to be divided equally between the Trust Research Department and inventor’s Directorate(s)
- 3.4.5 The National Institute for Health and Social Research (NIHR) has a responsibility to ensure that IP created through NIHR funding has the best chance of realising benefits for the NIHR, NHS and the public. Within standard NIHR contracts, the IP rights for the project are vested in the contractor (host of the research NIHR research funding). The contractor should describe arrangements for the use of Background IP, and the ownership and licencing of any Foreground IP, in formal collaboration agreements with all research partners. It is expected that standard collaboration agreements will be used, where this is not the case, agreements will be developed with our IP partner.
- 3.4.6 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 on behalf of the Trust with the funding body.
- 3.4.7 If the Trust does not wish to own a certain piece of IP 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 may wish to retain a residual share of the financial benefits, for example 20%, with the agreed percentage to be negotiated on a case-by-case basis.

- 3.4.8 Under the terms on which the Trust has engaged Medipex Ltd to lead or assist with the exploitation of IP, an annual membership will be levied on the Trust, and a proportion of any income generated will be retained by Medipex Ltd.

3.5 Guidance for Staff

- 3.5.1 If an employee develops an idea or concept, that may have commercial potential, they must report this to their Director or Senior Manager, who should contact the Trust Research Department at the earliest opportunity. This must occur before any disclosure of the idea to any party outside the Trust, either orally or in writing.

Examples of ideas or concepts include the development of new techniques, devices, software, pharmaceutical products, formulae and writings.

- 3.5.2 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:-

3.5.2.1 Keep it secret and resist pressure to announce or publish details until the matter has been discussed with either Trust Research Department 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;

3.5.2.2 Notify your Manager and also the Trust Research Department in order to discuss how to take the IP forward;

3.5.2.3 Confidentiality Agreements must be used whenever information that is considered to have commercial potential and is not already in the public domain is shared with another party. A confidentiality agreement is a legal document, binding the signed parties to hold in confidence any information pertaining to the field described within the agreement. The rights of the Trust (and by extension the interest of the inventor) are thus protected. These can be obtained from Medipex Ltd. ;

3.5.2.4 Avoid giving away or selling samples;

3.5.2.5 Don't involve external organisations or companies in testing or prototyping without a written agreement together with confidentiality agreement being in place. These agreements must be reviewed by Trust Research Department and Medipex Ltd prior to signature;

3.5.2.6 Don't sign any contracts or agreements until they have been reviewed by Trust Research Department with the support of Medipex Ltd.

3.5.3 In the event of any dispute about the interpretation of this policy, Trust employees have recourse to the Trust Issue Resolution (Grievance) Policy to resolve the dispute.

3.6 Joint Employees

3.6.1 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.

3.6.2 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.

3.6.3 Partnership agreements will be appended to this policy as and when they are developed and will be deemed to form part of this policy.

4.0 Training expectations for staff

4.1 Training in IP is available to YAS staff via Medipex Ltd. Staff wishing to attend this training should contact the research department to find out about available courses.

5.0 Implementation Plan

5.1 The latest approved version of this Policy will be posted on the Trust Intranet site for all members of staff to view. New members of staff will be signposted to how to find and access this guidance during Trust Induction. Any further amendment to this policy that may effect change will be addressed in the same manner.

6.0 Monitoring compliance with this Policy

6.1 Monitoring of this policy will be the responsibility of the Clinical Governance Group, who will receive reports and audits from the YAS Research Department to inform and assure the trust.

6.2 Reports and audits will be produced at least annually.

6.2.1. Non-compliance with this Policy may result in lost revenue or reputational damage for the Trust.

6.3 The Trust Research Department with the assistance of Medipex Ltd will, from time to time, arrange for an audit of Trust activity to identify IP of potential commercial value. Staff are required to co-operate fully with this activity.

6.4 A Register of IP will be maintained by the Trust Research Department and this will be made available to the auditors, as required.

6.5 This policy is to be reviewed every two years by the Trust Clinical Governance Group or earlier as and if required, and approved by the Trust Management Group.

7.0 References

A Framework and Guidance on the Management of Intellectual Property in the NHS (Department of Health, 2002)

Intellectual Property and Commercialisation Guidance version 1.1 – March 2021 (NIHR, 23/03/2021)

Definitions

Key terms used within the document should be explained here in a table, to provide clarity and aid understanding of any terminology used.

Intellectual Property	IP may be know-how, data sets, a novel treatment, a new diagnostic tool or device, new drug or new use of a drug or treatment, training material, or a new system of management or software application.
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8.0 Roles & Responsibilities

The details for Medipex Ltd can be found at www.medipex.co.uk where there are a number of IP related fact sheets and a list of services provided to the NHS.

It is the responsibility of the Head of Research to ensure that this Policy, supporting Standard Operating Procedures and associated documentation are up to date.

YAS staff are responsible for compliance with this Policy and the processes within.

The research team are responsible for managing initial innovation disclosures as described In YASRDSOP14 'Yorkshire Ambulance Service Intellectual Property Management and Innovation Disclosure Standard Operating Procedure'.