

Intellectual Property Policy

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A = Approved D = Draft

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Associated Documentation: Insert names of associated Policies or Procedures here

YAS Research Governance Policy

YAS Research Strategy

YASRDSOP14 Yorkshire Ambulance Service Intellectual Property Management and Innovation Disclosure Standard Operating Procedure

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Staff Summary

Intellectual Property (IP) may be created through the development of novel interventions and methods that improve patient care and/or service delivery. This may include: a novel treatment, a new diagnostic tool or device, new drug or new use of a drug or treatment, training material, toolkits, guidelines, patient resources, system of management, or software application etc.

This policy contains guidance for staff throughout the development and sharing of ideas or concepts which have potential to deliver patient and/or system benefits both within and outside of YAS.

Top tips for staff who think they have developed IP that could be useful to other organisations outside of YAS if shared appropriately (more detail at section 3.5):

- Keep it secret (only share with other YAS staff on a 'need to know' basis) until you have obtained advice on protection
- Do not publish, present at conferences, or talk to anyone outside of YAS until your idea has been assessed and protected
- Contact the Research department (<u>yas.research@nhs.net</u>) for help and notify your manager
- The Research department will advise on any contracts or agreements that you may need.

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 and management of IP arising from an employees' work (including joint employees) and benefits sharing arrangements

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 purpose of Yorkshire Ambulance Service NHS Trust (YAS) to provide and coordinate safe, effective, responsive and patient-centred out-of-hospital emergency, urgent and non-emergency care, so all our patients can have the best possible experience and outcomes. 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, the benefits of some innovations (e.g. inventions) can only be realised through commercial development, and for these the professional management of associated intellectual property (IP) is especially crucial.
- 1.3 For those innovations that are not suitable for commercialisation, but that may have potential benefits if successfully implemented, IP protection is still important (i) to reduce misuse of the innovation and inadvertent reputational risk and (ii) to ensure the Trust is recognised for its innovation activities. The Trust will assess, develop, protect and disseminate/exploit Intellectual Property (IP) in conjunction with a healthcare innovation hub (Medipex Ltd.) that was set up to help manage NHS IP.
- 1.4 IP may be know-how, data sets, or clinical tools (e.g. questionnaires). IP may be a new (or improvement to), treatment, diagnostic tool or device, drug (or new use of a drug or

treatment), training material, information resource, a product, system of management or software application, which could require protection using copyright, trademarks or patents. 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 be protected by the following rights:
 - Patent (applies to inventions e.g. new devices)
 - Copyright (applies to literary and artistic works e.g. written documents, videos and websites)
 - Design rights (applies to designs and design drawings)
 - Trade marks (applies to the distinctive 'brand' of a product or service e.g. name or logo)
 - Know-how (applies to trade secrets e.g. novel recipes or methods).
- 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 This process may include publishing the IP in the public domain, or exploiting it through commercial channels in order to potentially acquire monetary gain.
- 2.3 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.
- 2.4 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 to achieve maximum 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 (the Trust) 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 healthcare 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 Under UK law (The Patents Act 1977 and The Copyright, Designs and Patent Act 1988), IP created by an individual during the course of his/her normal employment duties, 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 inventing employee(s) who would then take up responsibility for protection and commercialisation; in these cases Medipex may, with the explicit agreement of the Trust, continue to advise the inventor(s) however the Trust will likely require some share of any financial benefits in return for such agreement, the percentage to be agreed on a case by case basis.
- 3.1.6 Should an employee leave the Trust and move to another organisation, the Trust may agree (but shall not be obligated) to grant a license or assign ownership of any IP created by that employee to their new employing organisation if the interests of IP development are best served by any such agreement.

3.2 Protection of Intellectual Property

3.2.1 IP can be protected by legal rights as outlined in 1.4.1. 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.

3.3 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 partnering with or licensing to third parties 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 Medipex can help to determine the most efficient route and put in place any necessary agreements if appropriate.
- 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 advise 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 development of innovations is not part of the employee's usual duties or job description, 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 is it part of a staff member's role to innovate or where the innovation has been specifically requested by the Trust, the Trust shall not be under any obligation to share any benefits with any members of staff that created the IP. This is most likely to apply in technical (e.g. software development) 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 any costs due to the Trust or any other party (e.g. Medipex in accordance with section 3.4.7) related to protection and commercialisation of the IP) will be split as follows:
 - 40% for the inventor (or to share between inventors)
 - 60% for the Trust; to be divided equally between the Trust Research Department and inventor's Directorate(s)
- 3.4.4 Inventors will continue to receive their share of any agreed benefit when they retire or are otherwise no longer employees of the Trust until their death or cessation/expiry/termination of the benefits from the IP, whichever is sooner.
- 3.4.5 The National Institute for Health and Care 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 should be vested in the contractor (host of the NIHR research funding) but certain rights to the newly created IP may be granted to collaborators. The contractor should describe arrangements for the use of Background IP (that is IP created outside of the funded project), and the ownership and licencing of any rights to the newly created (Foreground) IP, in formal collaboration agreements with all research partners. Trust employees must seek support from the Trust Research Department if they are involved in, or leading on, any such project and the Trust may enlist the help of Medipex to draft and review/negotiate any necessary collaboration agreements.
- 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 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 may be retained by Medipex Ltd in accordance with the service level agreement between the Trust and Medipex.

3.5 Guidance for Staff

- 3.5.1 If an employee develops an idea or concept, that may have commercial potential or that may be useful to other organisations, 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.
- 3.5.2 Examples of ideas or concepts include the development of new techniques, devices, diagnostic methods, software, toolkits, guidelines, information resources, pharmaceutical products, formulae and writings.
- 3.5.3 IP protection requires expert knowledge 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:-
- 3.5.3.1 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.
- 3.5.3.2 Notify your Manager and also the Trust Research Department in order to discuss how to take the IP forward.
- 3.5.3.3 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.
- 3.5.3.4 Avoid demonstration of prototypes outside of the trust or giving away or selling samples.
- 3.5.3.5 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.
- 3.5.3.6 Don't sign any contracts or agreements until they have been reviewed by Trust Research Department with the support of Medipex Ltd.
- 3.5.4 If any employee of the Trust makes (or intends to make) a significant contribution to the development of a third party's IP (e.g. through working on a collaborative research project or following an approach by a company representative) then the Trust Research Department should be informed so that they can ensure the Trust's rights to recognition and reward are secured. Such input may include intellectual input (e.g. design/functionality/mechanism suggestions) or valuable resources (such as time/knowledge/equipment).
- 3.5.5 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 employment contract will be responsible for protecting the property rights and for any dissemination/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 Trust 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.
- 6.3 Non-compliance with this Policy may result in lost revenue or reputational damage for the Trust.
- 6.4 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.
- 6.5 A Register of IP will be maintained by the Trust Research Department and this will be made available to the auditors, as required.
- 6.6 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)

8.0 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	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
Property	
	material, or a new system of management or software application.
	The NIHR defines IP as all patents, rights to inventions, copyright and
	related rights, trademarks and trade names, rights to goodwill or to
	sue for passing off, rights in designs, database rights, rights in
	confidential information and any other intellectual property rights, in
	each case whether registered or unregistered and including all
	applications (or rights to apply) for, and renewals or extensions of,
	such rights and all similar or equivalent rights or forms of protection
	which subsist or will subsist now or in the future in any part of the
	world.

9.0 Roles and 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'.