

# STANDARD OPERATING PROCEDURE

Research Department

Intellectual Property

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<i>Approved by</i>	<i>Research Coordinator (MC)</i>

## **Standard Operating Procedure: Research Department**

### **Intellectual Property**

This SOP has been produced in accordance with 'A Framework & Guidance on the Management of Intellectual Property in the NHS (2002)' and the STH policy entitled 'Policy for the Management of Intellectual Property'. This SOP will outline the procedure for the protection and exploitation of Intellectual Property (IP) arising from research projects undertaken by, Sheffield Teaching Hospitals NHS Foundation Trust (STH) employees or, those employed by external organisations (e.g University of Sheffield or Sheffield Hallam University) using STH resources.

#### **Background**

Under the Patent Act 1977 and, the Copyright, Designs and Patent Act 1988, employers own all IP generated by their employees in the course of their duties. As an employer, the NHS will own any IP generated as part of or relating to its employees role and/or duties in the NHS. The Framework & Guidance on the Management of Intellectual Property in the NHS (2002) sets out the arrangements for NHS staff, which will help to ensure that intellectual property derived from NHS R&D is owned and exploited in the best interests of the NHS.

The policy of the Sheffield Teaching Hospitals NHS Foundation Trust is to encourage the generation of IP that has a potential value in both service and financial terms. The Trust has a responsibility to ensure that innovations, including advances in equipment, materials and working practices, are disseminated as widely as possible for the benefit of patients. Depending on circumstances, this may be achieved either by putting the IP in the public domain or by encouraging commercial exploitation.

STH arrangements for IP are set out in the 'Policy for the Management of Intellectual Property'.

In order to retain novelty, and to maintain the possibility of IPR, invention details must not be published or disclosed to any third party without a Confidentiality Disclosure Agreement being agreed and signed by all parties.

#### **Definition**

Intellectual Property (IP) can be defined as any ideas, inventions, technology, software, creative expression (and derivatives thereof), in which a proprietary interest may be claimed and includes those novel ideas or inventions arising from NHS employees work.

Intellectual Property Rights (IPR) can be defined as the legal rights that enable the owner of the IP to control or prevent unauthorised use of this IP, and include copyright, design rights, trade marks and patents.

#### **1. Where Chief Investigator is an STH employee**

##### **Procedure<sup>a</sup>**

1. The researcher submits to their assigned R&D Coordinator a project protocol and research agreement (if any) for review or as part of submission for Research Department project authorisation.
2. STH employees who have an idea or invention which may be considered commercially viable, should contact their relevant director or senior manager at the earliest possible stage.
  - a. The researcher together with relevant director or senior manager, where appropriate, contacts their assigned R&D Coordinator, providing STH project reference number, project title, researcher details and details of idea.

3. The R&D Co-ordinator reviews the protocol and assesses whether there is any potential for IP arising from this project, where IP resides, is it exploitable and are arrangements in place for protection of IP during the project authorisation process.
  - a. For commercially-sponsored trials, IP will tend to reside with the commercial sponsor.
4. If the R&D Co-ordinator is unsure of any potential IP, the R&D Co-ordinator confirms this with the researcher.
5. If there is any potential of IP, the R&D Co-ordinator refers the researcher to the Research Department lead for IP.
6. The Research Department IP lead or delegate refers the researcher to Medipex (NHS Innovation Centre for the Yorkshire and Humber region).
7. Medipex liaises with the researcher<sup>b</sup> and sends an Invention Disclosure Form to the researcher for completion. This form requires details of the invention, potential applications for the invention, and the current status of the invention to be provided.
8. On receipt of the form, Medipex determines if the invention has commercial potential and considers what if any form of protection is required. The appropriate form of protection will depend upon the type of IP to be protected.
9. Medipex will negotiate and manage IP on behalf of the Trust. IP ownership is retained by the Trust.
10. Where it is identified that IP is jointly owned, eg. with a University or company, Medipex will act on behalf of the Trust in negotiating the transfer of IP rights to/or from the Trust and the proportion of any income to be received.
11. If Medipex determines that an invention cannot be commercially exploited, Medipex will ensure that these non-commercial but valuable ideas are brought to the attention of the appropriate NHS agency (eg other primary or secondary Trusts, other NHS Innovation Hubs) for dissemination.

## **2. Where Chief Investigator is a non-STH employee**

### **Procedure<sup>a</sup>**

1. The researcher submits to their assigned R&D Coordinator a project protocol and research agreement (if any) for review or as part of submission for Research Department project authorisation.
2. Non-STH employees who have an idea or invention which may be considered commercially viable, should contact their relevant director or senior manager at the earliest possible stage.
  - a. The researcher together with their relevant director or senior manager, where appropriate, is recommended to contact the IP lead at their respective employing organisation.
3. The R&D Co-ordinator reviews the protocol and agreement, and assesses whether there is any potential for IP arising from this project, where IP resides, is it exploitable and are arrangements in place for protection of IP during the project authorisation process.
  - a. For commercially-sponsored trials, IP will tend to reside with the commercial sponsor.
4. If the R&D Co-ordinator is unsure of any potential IP, the R&D Co-ordinator confirms this with the researcher.
5. Where there is potential IP, the R&D Co-ordinator recommends the researcher, together with their relevant director or senior manager where appropriate, to contact the IP lead at their respective employing organisation.
6. Where there is scope<sup>c</sup> for STH to share any potential IP, the R&D Co-ordinator refers the researcher to the Research Department lead for IP.
7. The Research Department IP lead or delegate refers the researcher to Medipex (NHS Innovation Centre for the Yorkshire and Humber region).
8. Medipex liaises with the researcher<sup>b</sup>, employing organisation and Research Department to negotiate any IP on behalf of the Trust where appropriate.

**Footnote**

<sup>a</sup>In order to retain novelty, and to maintain the possibility of IPR, invention details must not be published or disclosed to any third party without a Confidentiality Disclosure Agreement being agreed and signed by all parties.

<sup>b</sup>Medipex and researcher keep STH Research Department informed at all times.

<sup>c</sup>For example, the study uses predominantly STH patients, resources and facilities.

**Note**

Contact details for Medipex:

[enquiries@medipex.co.uk](mailto:enquiries@medipex.co.uk)

[www.medipex.co.uk](http://www.medipex.co.uk)

**Appendix 1**

The following table illustrates the type of cover for the different types of IP.

<b>Intellectual Property</b>	<b>Intellectual Property Rights</b>
Text, graphics, computer software, data compilations, art, music	Copyright
Databases	Copyright / Database Right
Form and appearance, decoration	Design Rights
Brands, image and reputation	Trade marks
New technical concepts, inventions including computer software	Patents
Confidential information / know how	Law of contract

**Appendix 2**

**Associated Documents**

	<b>Document</b>	<b>Research Department Network Location</b>	<b>Website</b>	<b>Database</b>	<b>Created by</b>
1	A Framework & Guidance on the Management of Intellectual Property in the NHS (2002)	n/a	No	No	DoH
2	STH Policy for the Management of Intellectual Property	n/a	No	No	Chris Linacre/ Sue White

Appendix 3

