



THE STATE HOSPITALS BOARD FOR SCOTLAND

MANAGEMENT OF INTELLECTUAL PROPERTY POLICY

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REVIEW SUMMARY SHEET

No changes required to policy (evidence base checked)

Changes required to policy (evidence base checked)

Summary of changes within policy:

December 2022 review

All references to Scottish Health Innovations Ltd (SHIL) have been replaced with InnoHealth after SHIL was rebranded as InnoHealth.

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1. Introduction

- 1.1 The State Hospitals Board for Scotland (TSH) recognises the importance of protecting and exploiting Intellectual Property (IP) and to utilise this IP to support the long term improvement of patient care within a Forensic Mental Health setting.
- 1.2 TSH wishes to be at the forefront of NHS IP initiatives for Forensic Mental Health by encouraging the development of IP with a view to, where appropriate, the commercial exploitation of the IP for the mutual benefit of TSH patients and all staff involved.
- 1.3 This policy embodies the principles of the Registered Designs Act 1949, the Patents Act 1977 and the Copyright, Designs and Patents Acts 1988 governing the ownership, protection and exploitation of IP and is intended to provide guidance to aid in the identification of IP that is capable of commercial exploitation.
- 1.4 The IP policy is also framed within the context of the Services Agreement in place between The State Hospital's Board for Scotland, and InnoHealth (Formerly SCOTTISH HEALTH INNOVATIONS LIMITED (SHIL)). See section 5.

2. Key Objectives of this Policy

- Identify training needs in the management and exploitation of IP.
- Put in place effective procedures for audit and protection of TSH IP.
- To outline the Services Agreement in place between TSH and InnoHealth.
- To protect and respect the moral rights of originators of IP.
- Facilitate the appropriate exploitation of TSH IP to improve patient care and ultimately generate income.

3. What is Intellectual Property?

IP refers to the novel or previously undescribed tangible output of any intellectual activity. It can include inventions, industrial processes, software, data, written work, designs and images, i.e. results of Research and Development (R&D) which lead to ideas for a new product or process, be it a potential new treatment or a diagnostic technique, new piece of equipment or new drug or software material.

IP arising from research activities may have commercial potential. This can be through patenting, copyright or know-how and later licensing or through co-operation with commercial companies to develop products with a market value.

There are strict rules about safeguarding such Intellectual Property. If details are published prior to IP protection, exclusive rights over exploitation are lost. Researchers who feel they have a commercially viable idea or project should check with an appropriate officer before publishing the results of their activities.

There are five main categories of IP:

- 1) Patents
- 2) Copyright
- 3) Design Rights – both registered and unregistered
- 4) Trade Marks – both registered and unregistered
- 5) Confidential know-how or information

IP can generate revenue for the NHS and the originator/researcher, if protected and harnessed properly.

4. Intellectual Property Management Structure

- 4.1 The Medical Director will assume overall responsibility for the management of IP and commercial exploitation of TSH R&D activity and will report to the TSH Research and Research Funding Committees; and the NHS Board on IP issues.
- 4.2 The R&D Manager will be a first point of contact for members of staff seeking guidance/information on IP issues. The R&D Department is able to obtain, when deemed necessary, external expert advice from a variety of sources including Central Legal Office (CLO) and InnoHealth.
- 4.3 The successful NHSScotland Consortium bid for Public Sector Research Exploitation capacity building funding from the Department of Trade and Industry (announced October 2001) which was further supported by the Scottish Executive, Scottish Enterprise and several commercial partners is being used to provide essential core funding (totalling £1.3M) to the establishment of a Scotland-wide Commercialisation and Exploitation Initiative including the establishment of InnoHealth. InnoHealth will provide a focal point for novel ideas and innovations, to assess whether these have commercial potential, to support the exploitation of such commercial potential and to capture any wider benefits to the NHS by sharing good ideas. InnoHealth will seek to support R&D managers in NHS Board Areas providing a national focal point with the necessary expertise to efficiently manage the IP exploitation process.
- 4.4 The IP Policy will be posted on the Board wide intranet R&D section. At the request of a Director or a Project Leader, the R&D Manager will explain or clarify any aspect of the IP Policy.

5. Scottish Health Innovations Limited

- 5.1 InnoHealth works in partnership with NHS Scotland to identify, protect, develop and commercialise new innovations from healthcare professionals. Such work includes contributing to the development, testing and exploration of technology, innovations and intellectual property owned or licensed to NHS Boards in Scotland.
- 5.2 In October 2018, TSH and InnoHealth entered a Services Agreement to manage the identification, protection, development and commercialisation of IP, in line with the definitions and schedules as set out within the Services Agreement. The services agreement in place requires TSH to provide InnoHealth with the 'right of first refusal to protect, develop and/or commercialise any idea, innovation or Intellectual Property Rights which TSH receives from healthcare professionals in its employment or under contract to it'. In return InnoHealth will provide a wide range of expertise and direct support to the identification, protection and commercialisation of all IP within TSH, regardless of whether InnoHealth take up their option on the management and commercial exploitation of that IP. In the instance that InnoHealth take up their option on any identified IP, this will be defined as 'Selected IPRs'. The Services Agreement can be viewed and discussed through contact with the Research and Development Manager.

6. Employment Contracts

TSH employment contracts require adherence with all of TSH Policies and the appropriate statutory legislation.

7. Ownership of Intellectual Property

- 7.1 Members of staff are obliged to inform TSH (via the R&D Department) about identified or potential IP resulting from their activities in the course of their employment and must not under any circumstances, sell, assign or otherwise trade IP without TSH agreement.

- 7.2 An invention (or any other type of IP) made by a member(s) of staff shall be taken to belong to the employer if:
- it was made in the course of the duties of the member(s) of staff and the circumstances were such that an invention might reasonably be expected to result from the carrying out of his duties, or
 - the invention was made in the course of the duties of the member(s) of staff and because of the nature of the duties had a special obligation to further the interests of the employer's undertaking
 - any member of staff creates IP which is thought to be capable of protection and/or commercial exploitation, while acting in the course of his/her employment, whether during a research project, using knowledge gained as a consequence of employment or at any other time using NHS resources, that member of staff is obliged to inform his/her Group Director and the Medical Director.
 - Resulting discussion will review the ownership of the IP and the prospects for commercialisation.
- 7.3 TSH will have the right to determine the route of exploitation of any IP owned by TSH, within the terms of the Services Agreement with InnoHealth. Where TSH deems it appropriate or where so required under the terms of a contract with a third party TSH may assign or license IP to a third party on such terms as it deems fit. A Member of staff may be required to sign a formal assignation in favour of TSH of all IP made or created by that member of staff (whether alone or in conjunction with others) that belongs to TSH under the Policy.
- 7.4 Where an employee's contract involves a commitment to more than one employer, the employer holding the contract of employment will own the IP. This employer will take account of the contribution of other parties involved in the employment contract when distributing income resulting from exploitation.
- 7.5 IP generated by Independent Contractors will be managed according to Section 2.11 of the NHS HDL (2004) 09 Management of Intellectual Property in the NHS.
- 7.6 Students - with certain exceptions, are not classed as employees and as such are not covered by the statutory provisions applicable to employees. An agreement can be signed by the student assigning to the Board the rights for any IP arising from research. The student will subsequently be regarded as an employee in respect of sharing income earned from exploitation of the IP generated.
- 7.7 Copyright protects original artistic, literary and musical works, computer programs, written materials, drawings, sound recordings, videos, CD-ROMs and broadcasts. Copyright prevents any third party from reproducing work without the copyright owner's consent. Unlike patent protection it is not necessary to register copyright within the UK. Nevertheless, it is vital that you have **documentary evidence to prove the date of first production** and the R&D Department can assist here. It is then advisable to declare copyright protection by using the following convention:
- © Owner's name – Year – Version
- e.g. © TSH 2003 Version 1.0
- This is especially useful when sending computer programs to others or exhibiting work at conferences. Copyright in most works lasts for the lifetime of the author plus a period up to 70 years depending on the nature of the copyright work.
- 7.8 Authors have the right to be identified even when they are not the owner of the copyright.

8. Contracts with External Organisations

8.1 Contracts with external organisations that include the likely development and subsequent management of any IP cannot be entered into without all IP aspects being fully disclosed to and negotiated with InnoHealth. The Research and Development Department must be contacted before any contract with an external organisation is negotiated where IP will be generated or is likely to be generated from the contract or there is likely to be any IP implications arising or likely to arise from the contract. In particular all contracts must be signed by an authorised signatory of the Medical Director to ensure that they have legal validity. It is in the interests of TSH and members of staff to ensure that contracts with external organisations are on appropriate terms and that TSH has obtained necessary expert advice, where necessary.

8.2 In some cases research and clinical work will be undertaken either with the support of or in conjunction with organisations that are external to TSH (whether such organisations are commercial, government agencies or charities). In these cases it is essential that a research agreement is reached with the external organisation prior to any work commencing. It is the policy of TSH that such agreements will be negotiated by the Research and Development Department with full initial consultation with InnoHealth (or such other party on behalf of TSH that TSH deems appropriate). Such agreements should provide for *inter alia* the following:

- The input by TSH and the parties involved in the Project.
- A mechanism for sharing profits which may arise from the Project, including the exploitation of any result which may have commercial value – TSH will be entitled to an appropriate share of any subsequent profits. The size of this share will vary from case to case according to the relative contribution of each party involved.
- The ownership of the IP that may arise from the Project.
- The respective obligations of the parties to the agreement including the obligations of liability, confidentiality and publication procedures.

9. Confidentiality – Safeguarding Intellectual Property

9.1 Public disclosure of research results, including publishing, will jeopardise the potential for protection of IP. As one of the criteria of patentability is novelty, an invention must remain secret prior to any UK patent application. Know-how must remain confidential if it is to be exploited. Therefore, the R&D Department should be contacted.

9.2 Prior disclosure is one of the commonest reasons why inventions, otherwise patentable, arising from academic research are not patented. Disclosure means any dissemination of the invention or part of it, whether it is in the form of a publication in a journal, a paper or poster given at a conference, a talk at a seminar, a description of a research programme (even the title if it is descriptive enough) in a public document available, for example, on the Internet, or a discussion with a potential industrial collaborator.

9.3 If you think you have made an innovation, whether potentially patentable or any other type of IP, do not tell anyone until you have taken advice from the R&D manager (Contact Details on Page 11)

9.4 There will rarely be a conflict between the exploitation of IP and the appropriate dissemination and take-up of new knowledge to help improve the service which the NHS provides. Should a conflict arise, the best interests of the NHS and the country as a whole will prevail.

9.5 In negotiation with others on commercial exploitation of IP and to protect the interests of TSH, a Confidentiality Agreement should be brought into use (after discussion with the Medical Director).

- 9.6 In order to establish the date an invention has been made, and who made it (two factors which are crucial to obtaining patent protection in some countries) it is good practice to keep proper records of research (e.g. laboratory notebooks).
- 9.7 It is recommended that each page of laboratory notebooks is dated and signed by the research worker and countersigned, perhaps once a week.
- 9.8 The Medical Director will assess the IP and may call upon the resources of the technology transfer staff of INNOHEALTH to assist with protection and subsequent commercialisation.

10. Dissemination of Results

- 10.1 The IP which arises from R&D funded by the NHS is a potentially valuable resource both for the NHS and for the country as a whole. The NHS has a responsibility to help ensure that this IP can be appropriately exploited either within the NHS or by others, although this remains a subsidiary objective to securing proper dissemination and take up of new knowledge.
- 10.2 Researchers in receipt of NHS funding or other non-commercial external funding have an obligation to seek to publish their research results in national peer reviewed professional journals. This should be undertaken **after** consideration of the potential for protecting and/or exploiting IP.

11. Exploitation of Intellectual Property

- 11.1 TSH is responsible for cost effective exploitation of IP which it owns.
- 11.2 TSH must minimise speculative financial investment from public funds, therefore as much as possible, the financial risk of exploitation should be assumed by a private partner. To actively exploit IP *and* minimise the risks involved, the R&D Department should seek to assign or license IP to commercial or other organisations able and willing to meet all or most of the exploitation costs in return for a share of any subsequent income.

12. Commercialisation of Intellectual Property

- 12.1 The decision to protect IP and to commercialise it will be the responsibility of the R&D Committee, who will seek advice from InnoHealth and subsequently CLO as required.
- 12.2 IP may be commercialised by:

Licensing it, either exclusively, non-exclusively or under a sole-licence, in return for royalties and other payments such as an up-front fee and milestone payments; or
Assigning it for a lump sum, or
A combination of a lump sum and royalties; or
Establishing a spin-out company in which the individual inventors may have equity and equity may be held on behalf of the Trust, and assigning or licensing the IP to the spin-out.

The choice of commercialisation route will depend on the nature of the IP and the perceived market for it.

13. Patent Protection

- 13.1 Ideas for patenting should be recorded and submitted to the R&D Department for assessment as soon as possible. After assessment it may be possible to make public the nature of the idea by publishing an article, giving a talk or poster presentation or disclosing to any outside organisation.

- 13.2 To be patentable an invention must be new and involve an inventive step (i.e. a step not obvious to someone skilled in the subject) and it must be capable of industrial application. The main purpose of granting a patent is to encourage industrial activity, and the only substantial reason for TSH to process a patent application is to ensure that TSH and the individual(s) are in the best position to get full benefit of the invention through proper exploitation by means of licence agreements or other arrangements.
- 13.3 If patent protection is deemed to be desirable, TSH may:
- Apply for a patent in the name of TSH using a patent agent and thereafter:
 - Licence out the invention or,
 - Assign the invention.
 - Invite an outside commercialisation organisation to undertake the protection and commercialisation on behalf of TSH or,
 - Take other such action regarding the IP that TSH at its sole discretion deems appropriate.
- 13.4 At TSH's discretion, TSH may pay the costs of processing an initial patent application up to the filing and examination stages, provided that there is reasonable likelihood that the invention can be exploited. This will generally take the form of the patent application fee. If a patent application is to be filed, the inventor must continue to maintain secrecy concerning the invention. This precludes any publication, contributions to conferences, exhibitions and the publication of any scientific papers relating to the invention prior to filing a patent application.
- 13.5 TSH may provide help in manufacturing pilot devices for patenting purposes at the expense of TSH. TSH may also consider providing help through sessional substitution to bring the idea to exploitable form.

14. Assignment of Ownership

If TSH decides not to seek to protect an innovation or to exploit the know-how, on the basis of the information imparted by the innovator, the innovator will be informed of this in writing by the Medical Director. The innovator will be advised at that point if permission is granted for the innovator to proceed with protection / exploitation on his / her own account. TSH will be entitled to invoke its statutory rights in an innovation if it becomes evident that important material facts were not disclosed as required in this policy by the innovator when the decision was taken to assign the innovation.

15. Income Arising from Exploitation and Commercialisation

- 15.1 Prior to initiating actions to exploit IP, TSH (in consultation with InnoHealth) and appropriate staff should seek written agreement on the terms for subsequent revenue sharing. This income is quite separate from any grants or other monies received for the actual carrying out the project work which can be dealt with in the relevant contract.
- 15.2 If TSH deems an idea worthy of protecting an agreement is made (between TSH, the innovator and the department in which the innovator works) that any resulting income arising from royalties or other income payable, after deduction of expenses incurred in exploiting the innovation, will be fairly and equitably distributed on the following basis:
- one third to the Innovator*.
 - one third to the Innovator's research funds.
 - one third to TSH.

* This proportion is liable for taxation but the innovator can assign their personal income to a research fund if they wish.

- 15.3 In the event of TSH commissioning R&D, or undertaking joint R&D with another provider (including other NHS bodies, Universities, other academic institutions, and commercial organisations), TSH has a responsibility to ensure that the contract for the work contains, wherever appropriate, explicit agreement concerning revenue sharing of any resulting income generation through commercialisation.
- 15.4 The income sharing arrangements do not affect the statutory rights of any member of staff in terms of the Patents Act 1977.
- 15.5 Should TSH decide not to support the idea then the ownership of the idea will revert to the inventor if TSH is satisfied that all important material facts were disclosed. The innovator may wish to pursue exploitation of the innovation at their own expense in which case any income generated from the innovation reverts to the individual.

16. Disagreements

Any disagreement arising from the interpretation of this document, which cannot be mutually resolved, will be referred to the Chief Executive.

17. Equality and Diversity

The State Hospitals Board (the Board) is committed to valuing and supporting equality and diversity, ensuring patients, carers, volunteers and staff are treated with dignity and respect. Policy development incorporates consideration of the needs of all Protected Characteristic groups in relation to inclusivity, accessibility, equity of impact and attention to practice which may unintentionally cause prejudice and / or discrimination. The Board recognises the need to ensure all stakeholders are supported to understand information about how services are delivered. Based on what is proportionate and reasonable, we can provide information/documents in alternative formats and are happy to discuss individual needs in this respect. If information is required in an alternative format, please contact the Person-Centred Improvement Lead on 01555 842072.

Line Managers are responsible for ensuring that staff can undertake their role, adhering to policies and procedures. Specialist advice is available to managers to ensure that reasonable adjustments are in place to enable staff to understand and comply with policies and procedures. The EQIA considers the Protected Characteristic groups and highlights any potential inequalities in relation to the content of this policy.

Patient pre-admission assessment processes and ongoing review of individual care and treatment plans support a tailored approach to meeting the needs of patients who experience barriers to communication (e.g. Dementia, Autism, Intellectual Disability, sensory impairment). Rapid access to interpretation / translation services enables an inclusive approach to engage patients for whom English is not their first language. Admission processes include assessment of physical disability with access to local services to support implementation of reasonable adjustments. Patients are encouraged to disclose their faith / religion / beliefs, highlighting any adapted practice required to support individual need in this respect. The EQIA considers the Protected Characteristic groups and highlights any potential inequalities in relation to the content of this policy.

18. Stakeholders Engagement

Key Stakeholders	Consulted (Y/N)
Patients	N
Staff	Y
TSH Board	N
Carers	N
Volunteers	N

19. Communication, Implementation, Monitoring and Review of Policy

This policy will be communicated to all stakeholders within The State Hospital via the intranet and through the staff bulletin. The Research Committee as Advisory Group will be responsible for the implementation and monitoring of this policy. This policy will be reviewed every three years or earlier if required.

This document is not intended to act as a detailed guide to the protection and commercialisation of IP arising from research.

20. Intellectual Property Publications for further guidance

1. Handling Inventions and Other Intellectual Property. A Guide for NHS Researchers. NHS Executive. 1998.
2. 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.
3. Policy Framework for the Management of Intellectual Property within the NHS Arising from Research & Development. NHS MEL (1998) 23.
4. '[A Framework and Guidance](#) (PDF) on the Management of Intellectual Property in the NHS. DoH. 2002
5. Patent Protection. The Patent Office. 1998.
6. How to Prepare a UK Patent application. The Patent Office. 1997.
7. The Patents Act. 1977.
8. The Copyright, Designs and Patents Act. 1988.
9. Intellectual Property in the Public Sector Research Base. Office of Science and Technology. Stationery Office Books Ltd. 1992.
10. Intellectual Property. David Bainbridge. 4th edition. Financial Times Management Ltd. 1998.
11. Intellectual Property Law. Tina Hart. Macmillan Publishers Ltd. 1997

21. Research and Development Department Contact Details

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