

# Management of Intellectual Property

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<b>Approved by:</b>	NHS GGC Innovation Governance Group, Central Management Team, Financial Planning & Performance Committee, Area Partnership Forum
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## 2. Introduction

- 2.1 Research and innovation (R&I) gives rise to the generation of intellectual property (IP) rights. NHS organisations are obliged to manage their R&I to improve patient care and to achieve best value for money. An important aspect of this is the protection and exploitation of IP.
- 2.2 Innovation is not the sole preserve of those involved in R&I, and occurs naturally through the work of all employees. Innovation could occur through the delivery or the management of patient care, in the education or training of employees or through the more traditional route of an R&I project.
- 2.3 The Board wishes to be at the forefront of NHS IP initiatives by capturing and encouraging the development of IP. Innovation can be used to improve the health service in one of two ways. First, after suitable evaluation, it can be freely disseminated across the NHS by knowledge transfer processes. Second, the evaluation may show that the innovation has commercial potential. The Board's main priority when developing IP is patient benefit; as such, innovations capable of providing health or service improvements to patients across the NHS are at least as important as those capable of generating income.
- 2.4 The Board will maintain a balance between the legitimate needs of the Board to protect its interests and the provision of a creative environment for employees in which to work.
- 2.5 The Board will actively encourage awareness of IP.
- 2.6 This policy embodies the principles of the Registered Designs Act (1949), the Patents Act (1977), Copyright, Designs and Patents Acts (1988) and the NHS Research Governance Framework for Health and Community Care, 2001 and is consistent with the Scottish Executive Health Departments' Policies on NHS Intellectual Property Management, MEL(1998)23 and HDL(2004).
- 2.7 This policy aims to:
  - Define IP
  - Outline the process of identifying IP
  - Clarify the ownership of IP
  - Detail the management of IP
  - Establish the principle of benefit sharing with respect to IP developed under collaborative projects (e.g. with industry or University) where the Board has contributed to, but does not own, IP.

## 3. Scope

This policy covers NHS Greater Glasgow and Clyde.

- 3.1 Staff covered by this Policy:
  - All staff with substantive contracts of employment with the Board.
  - Staff with a contract of employment with the Board whose payroll costs are partially or wholly funded by another party (e.g. a medical charity, government department, commercial sponsor) unless the contract between the Board and that party assigns ownership of all IP to that party.
  - Staff who have a part time contract of employment with the Board.
  - Trainees hosted by the Board for training purposes are, unless otherwise agreed, subject to the management arrangements for IP of Board staff.

- Staff who generate IP outside normal working hours and/or away from the place of work, where the IP relates to their normal course of duties.
- Board staff seconded to another organisation or employees of another organisation hosted by the Board under contract, subject to the arrangements for the ownership of IP agreed between the Board and that organisation.

**3.2** Students are not classed as employees and as such are not covered by the relevant provisions governing IP. Prior to any student placement or activity at the Board's premises, an agreement must be signed by the student assigning to the Board the rights for any IP arising from the activities in which they have been involved. A student who assigns IP will be entitled to benefit from income generated from the commercial exploitation of the assigned IP.

## 4. Roles and responsibilities

**4.1** Directors are responsible for ensuring that all members of staff within their Departments have an up-to-date copy of the IP Policy and that every student within their Departments is made aware of the IP Policy and its main provisions. The R&I Directorate is available for managers to explain or clarify any aspect of the IP Policy. To avoid conflicts of interest, employees should register all interests which they have in accordance with the Boards code of conduct.

**4.2** The Board is responsible for cost effective exploitation of IP that it owns. An IP officer or designated steering committee will decide the most appropriate exploitation route for the IP taking into account that the Board 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.

**4.3** The Board will nominate officers who have, as a component of their job, the remit to act as the primary points of contact for IP. These officers could be within research & innovation management or a technology based department such as the Department of Clinical Physics, Medical Device Unit and UKAS accredited NHS Laboratories. The IP officers will be proactive in promoting IP awareness and will provide advice and support for members of staff coming forward with potential IP.

**4.4** The R&I Directorate has management responsibility for IP generated by Board staff. The R&I Director will report to the NHS GG&C Innovation Governance Group on IP issues. This group will in turn report to the Financial Planning and Performance Committee on matters relating to IP.

**4.5** Staff should not take any steps to exploit IP, nor set up a company with a view to commercial exploitation, without the specific approval of the IP officer and R&I Director, as may be advised by Innoscot Health (formally known as Scottish Health Innovations Limited) or an alternative board contracted organisation.

**4.6** Staff are required to cooperate with the IP officer in carrying out its management and exploitation responsibilities for IP.

**4.7** The Board will ensure that provisions are made for IP in line with the provisions of this Policy document in all new Board employment contracts, including honorary contracts.

## 5. Body of Policy

### 5.1 Definitions

**5.1.1 IP** defines a novel or previously un-described activity. IP has an owner and can be bought, sold, licensed and should be adequately protected. The owner of the IP can control and be rewarded for

its use and by doing so can encourage further innovation bringing benefit to all. The owner of IP has legal rights, although in some cases the owner has to register for those rights to subsist. The principal forms of those rights are **patents, copyright, design, trademarks** and **know-how**.

- 5.1.2 **Patents** are generally intended to cover products or processes that possess or contain new functional or technical aspects. A patent gives the applicant a means of preventing others for a limited period from making, using or selling the invention. When a patent is granted, the invention becomes the property of the applicant.
- 5.1.3 **Copyright** covers literary and artistic works including computer software, films, videos, and training documents and other written documents. Copyright comes into effect immediately, as soon as something that can be protected is created and "fixed" in some way e.g. on paper, on film, via sound recording or as an electronic record on the Internet. It is an unregistered right (unlike patents, registered designs or trade marks). Examples of works that copyright protects include original literary works e.g. novels, instruction manuals, computer programs, lyrics for songs, articles in newspapers, some types of databases, but not names or titles.
- 5.1.4 A **registered design** is a monopoly right for the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture, materials of the product or its ornamentation.
- 5.1.5 **Unregistered design rights** cover engineering components and architectural drawings.
- 5.1.6 A **Trademark** is a badge of origin, used so that customers can recognise the product of a particular trader.
- 5.1.7 **Know-how** can be a procedure, process, a trade secret, knowledge of doing things, or a formula that cannot be patented but where some aspects are confidential.

## 5.2 Ownership of Intellectual Property

- 5.2.1 An invention (or any other form of IP) made by an employee of the Board shall be taken to belong to the Board if it was made in the course of or in connection with the duties of an employee of the Board and the circumstances were such that an invention (or any other form of IP in question) might reasonably be expected to result from the carrying out of their duties.
- 5.2.2 Acting "*in the course of or in connection with the duties of an employee*" can be construed quite widely and may include work carried out in the employee's spare time or at home; However, IP generated by an employee in his/her own time and unconnected with his/her NHS duties will not normally be owned by the Board.
- 5.2.3 The Board will have exclusive exploitation rights in any IP owned by the Board. Where the Board deems it appropriate or where so required under the terms of a contract with a third party the Board may assign or license IP to a third party. Within the constraints of maintaining front line clinical services, the Board will endeavour to make time available for inventors to continue to provide their specialist expertise to the development of the IP.
- 5.2.4 In collaborative projects, or during a secondment IP may be generated by employees from different organisations. As such, prior to the commencement of any collaborative project or secondment, the Board will discuss and form agreements with the other organisation(s) agreeing IP ownership, royalty sharing and the input required from each organisation.

5.2.5 Copyright can protect written information, databases, computer software and films/video and is achieved automatically when IP is created. Despite the statutory provision determining that copyright in any work produced by an employee in the course of his/her employment belongs to the employer, the Board licenses the copyright in such work back to the author for the purposes of publication in textbooks or in articles published in academic journals.

The Board does not grant such a license to the copyright to the author in materials comprising:

- i. course or training materials or
- ii. patient information leaflets produced by an employee in the course of employment for the Board and which are produced, used or disseminated within or outside the Board,
- iii. any software generated by an employee in the normal course of their employment  
(iv) any designs, specification or other works which may be necessary to protect rights in commercially exploitable IP.

5.2.6 The Board reserves the right to claim for expenses incurred in the use of facilities belonging to the Board if they were used in the development of IP not belonging to the Board.

5.2.7 Where the Board is involved in the procurement of an Innovation Partnership under the Public Contracts (Scotland) Regulations 2015, the procurement documentation will detail the position on ownership of IP. Staff are required to work with the Procurement Team to ensure proper processes are followed and the usual procurement rules shall apply.

### 5.3 Identification and Management of IP

5.3.1 Staff must first discuss the IP with one of the designated IP officers at the earliest opportunity and, in any event, before disclosure (either orally or in writing) of the IP to any party outside of the Board. Identification of these officers will be via the R&I Directorate or the R&I web site. In the case of potentially patentable IP, prior public disclosure (unless under a confidentiality agreement) will invalidate any subsequent patent application and reduce the commercial value and benefit to the Board and inventor.

5.3.2 If the Board decides not to seek to patent an invention or to exploit the know-how, on the basis of the information imparted by the inventors, they will be informed of this in writing. The inventors will be advised at that point if permission is granted for them to proceed with protection / exploitation on their own account and whether any conditions attached to such permission, such as the Board being entitled to use the IP for its own internal non-commercial purposes and/or to receive any royalty or profit share or to recover its costs in connection with the IP from revenues generated by its exploitation. The Board will be entitled to invoke its statutory rights in an invention if it becomes evident that important material facts were not disclosed as required in this policy by the inventor when the decision was taken to assign the invention.

5.3.3 If the Invention is considered to be Intellectual Property the IP officer will request that the Inventors document the idea on the Invention Summary Form (Appendix 1). This form will be signed and dated by the Inventors and countersigned and dated by the IP officer. This is to ensure that if the Inventors have not already documented the idea in the appropriate way the date of the countersignature will be regarded as the date of the invention. This is important for patents in the United States of America where the owner of an invention is described as “first to invent”. In the rest of the world the owner of an invention is described as “first to patent”.

5.3.4 The Board may contract with an advisor organisation, such as InnoScot Health (formally known as Scottish Health Innovations Limited) to assess the potential of IP, support the development and or

commercialisation of individual NHS innovations or to assist in fostering an infrastructure to support such commercialisation (including technology auditing, awareness raising and staff development). Inventors should be aware that they may be required to enter into additional legal agreements with ISH and/or the Board in order to support the protection and commercialisation of inventions.

5.3.5 The R&I Director will ensure the maintenance of a register of all IP rights owned by the Board, which have been licensed or assigned to a third party where an employee is a named inventor or originator. Details of these IP rights and the income they generate will be given to the Scottish Governments Chief Scientist Office (CSO) from time to time on request.

## 5.4 Record Keeping

5.4.1 Inventors should keep detailed records of the invention including details of any development work. Ideally these records will be signed and dated by the Inventors and countersigned and dated by an independent third party who understands the invention. If this has not happened the completion of the Invention Summary Form with signatories will be taken as the date of the invention.

## 5.5 Exploitation of Intellectual Property and Risk Management

5.5.1 The choice of commercialisation route will depend on the nature of the IP and the perceived market for it. Importantly, the chosen commercialisation method and subsequent agreement should be in the best interest of NHS patients and the decision making process, which should include the management of risk, must be transparent and defensible. It is therefore essential that an advisor organisation, such as ISH, are fully involved in this process.

5.5.2 Should the calculated risks outweigh any potential benefits, the Board may also decide to take no further action to protect or exploit IP. Should the Board decide not to support the idea then the ownership of the idea will revert to the inventors who may wish to pursue exploitation of the invention in their own time and at their own expense, in which case any income generated from the invention reverts to the individual. The inventor must not utilise Board time, Board resources, or Board or NHS name or logo in connection with the exploitation of the invention, nor shall the inventor use or seek to use their position within the Board to publicise or endorse the invention or to provide a quality approval for the invention.

5.5.3 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 however should be undertaken *after* consideration by the IP Officer or designated local steering group of the potential for protecting and/or exploiting IP.

5.5.4 IP may be exploited by:

- Outright sale of the IP to an existing company (possibly with the retention by the Board of its right to use the IP for its own internal non-commercial purposes)
- Licensing or assigning the IP to an existing company in return for up-front fees and/or royalties
- Licensing or assigning the IP to a spin-out company set up specifically to exploit the IP in return for fees, royalties or equity. (n.b. Scottish NHS Boards are not able to form or participate in the formation of companies, nor invest in companies for income generation purposes. As such, the equity route is only available should the IP be assigned to a company such as ISH, where ISH may take equity in a spin-out company).
- Further development of the IP. Appropriate sources of funding will be investigated to allow the development work to take place.
- Dissemination of the idea with no further development or commercial exploitation.



## 5.6 Patent Protection

- 5.6.1 Patentable inventions must be new and involve a novel step (i.e. a step not obvious to someone skilled in the subject) and it must be capable of industrial application.
- 5.6.2 Non-disclosure is essential for patent protection. 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 an informal discussion with a potential industrial collaborator.
- 5.6.3 If patent protection is deemed to be desirable, the Board may;
- Apply for a patent
  - Invite an outside commercialisation organisation to undertake the protection and commercialisation on behalf of the Board or,
  - Take other action such as delaying filing of the patent until development work has been completed and the appropriate funding is in place. This will prevent additional filing costs and reduce the patent upkeep costs prior to commercialisation.

## 5.7 Contracts with External Organisations

- 5.7.1 In many cases research and clinical work will be undertaken either with the support of or in conjunction with organisations that are external to the Board (whether such organisations are universities, commercial, government agencies or charities). In these cases it is essential that an agreement, negotiated by an IP officer (or such other party on behalf of the Board), is reached with the external organisation prior to any work commencing. These agreements will ensure that adequate provision is made for the ownership and the exploitation of arising IP with the Board retaining or obtaining ownership where appropriate. Employees should ensure that they understand their position and obligations within these agreements.

## 5.8 Types of Agreement

- 5.8.1 **Confidentiality Agreement.** Prior to legal protection of an innovation the idea should not be disclosed. Disclosure includes publishing results, poster or paper presentations and casual conversation. Prior to discussions with external groups or individuals during the development or exploitation process and to protect the interests of the Board, a Confidentiality Agreement should be brought into use (after discussion with the IP officer).
- 5.8.2 **License Agreement.** The Board may elect to licence its IP to a third party permitting it to utilise and develop the Board's IP. A licence may be exclusive (only the licensee can exploit the IP), sole (where both the licensor and the licensee can use the IP), or non-exclusive (where the licensor can appoint other licensees).
- 5.8.3 **Joint IP Agreements.** Joint IP Agreements can be made with other organisations that may have rights to a share in the commercialisation of the IP e.g. University, Funding Body, ISH. The agreement should contain sections on ownership, decision-making, project management structure, contributions, cost recovery and revenue sharing.
- 5.8.4 **Assignment.** Employees of Greater Glasgow Health Board must not assign Intellectual property to a third party without the consent of the Board.



5.8.5 **Benefit Sharing Agreement.** Benefit Sharing Agreements detail the benefit to be received by the Board where the Board has contributed to IP but does not own the IP. Benefit sharing may take the form of a share of royalties or preferential licensing agreement terms, or such other benefit as may be agreed. While the specific terms of the benefit sharing arrangement may be set out in a separate benefit sharing agreement, the agreed principle of benefit sharing should be included within the collaboration agreement to ensure the Board’s contribution to the IP is recognised and its interest in receiving appropriate benefit in return for its contribution to the IP is protected.

## 5.9 Income Arising from Exploitation and Commercialisation

5.9.1 Prior to initiating actions to exploit IP, the Board and appropriate staff must seek written agreement on the terms for subsequent revenue sharing. Where income is received in relation to inventions, inventors will be identified by the declaration made in the relevant Invention Summary Form.

5.9.2 Depending on the exploitation route and the legal agreements formed (joint IP, license etc) the Board requires that any royalties or other income arising out of the commercial exploitation of IP belonging to the Board is fairly and equitably distributed between the inventor(s), and Board on the following basis:

	<b>Inventor</b>	<b>Board</b>
<b>Net Income up to First 500k</b>	<b>50%</b>	<b>50%</b>
<b>Net Income between 500K-2M</b>	<b>33%</b>	<b>67%</b>
<b>New Income between 2M-10M</b>	<b>25%</b>	<b>75%</b>
<b>Net Income &gt;10M</b>	<b>20%</b>	<b>80%</b>

**“Development Expenses”** means all expenditure incurred by the Board in the protection, development, enhancement and exploitation of IP including (but not limited to) patent filing fees, design or trademark registration fees, costs of applying for, prosecuting and maintaining in force any IP, marketing expenses, research costs, travel and subsistence costs, legal and other professional fees associated therewith and any royalties or other sums paid to any third parties (including without limitation, the research funder, ISH (or its affiliates or any of their successor bodies)).

Not included as “Development Expenses” are NHS staff salaries (with the exception of formal IP development sessions funded through R&I and incorporated into the individual’s job plan) and general overheads of the Board.

**“Gross Income”** means proceeds from the licence, sale, lease, transfer, assignation or other conveyance of IP by the Board, such as licence fees, royalties and other sums paid to the Board by a licensee/assignee in respect of such IP; but all excluding dividend, or other income derived from equity held by ISH or its affiliates or any of their successor bodies).

**“Net Income”** means Gross Income less Development Expenses.

The income sharing arrangements will be kept under regular review by Senior Management of the Research and Innovation Directorate.

The income sharing arrangements do not affect the statutory rights of any member of staff in terms of the Patents Act 1977.

## 5.10 Disagreements

Any disagreement arising from the interpretation of this document, which cannot be mutually resolved, will be referred to the R&I Director. If the Parties are unable to settle a dispute arising out of or in connection with this Policy, the same shall be referred to a group comprising the Medical Director, the Finance Director and a non-Executive Director. The decision of this group can be by majority, and a written report outlining the reasons for the finding will be issued.

## 6. Review

This policy will be reviewed every three years by the authors who sit within the R&I Directorate. This document is not intended to act as a detailed guide to the protection and commercialization of IP.

## 7. References

- 1) Handling Inventions and Other Intellectual Property. A Guide for NHS Researchers. 1998. (NHS Executive).
- 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. 1998 (NHS Executive).
- 3) Policy Framework for the Management of Intellectual Property within the NHS Arising from Research & Development. NHS MEL (1998) 23. (Scottish Executive).
- 4) Patent Protection. The Patent Office. 1998.
- 5) How to Prepare a UK Patent application. The Patent Office. 1997.
- 6) The Patents Act. 1977.
- 7) The Copyright, Designs and Patents Act. 1988.
- 8) Intellectual Property in the Public Sector Research Base. Office of Science and Technology. Stationery Office Books Ltd. 1992.
- 9) Intellectual Property. David Bainbridge. 4<sup>th</sup> edition. Financial Times Management Ltd. 1998. Intellectual Property Law. Tina Hart. Macmillan Publishers Ltd. 1997.
- 10) Management of Intellectual Property in the NHS. HDL (2004) 09 (Scottish Executive)
- 11) The Baker Report "Creating Knowledge Creating Wealth" Realising the economic potential of the public sector research establishments (HM Treasury).
- 12) British Standards Institute (2011). Specification for the provision of services relating to the commercialisation of intellectual property rights (BS 8538:2011).
- 13) Department of Health (2002) The NHS as an innovative organisation. A Framework and Guidance on the Management of Intellectual Property in the NHS. Department of Health Publications.

**Title of the invention:** \_\_\_\_\_

**Name(s) of Inventor(s) and % inventive contribution** (n.b. the total inventive contribution must equal 100%). If more than three inventors, please attach additional pages providing details of all inventors.

<b>Name</b>	
<b>Employer</b>	
<b>Department</b>	
<b>Work Address</b>	
<b>Work Email</b>	
<b>% inventive contribution</b>	

<b>Name</b>	
<b>Employer</b>	
<b>Department</b>	
<b>Work Address</b>	
<b>Work Email</b>	
<b>% inventive contribution</b>	

<b>Name</b>	
<b>Employer</b>	
<b>Department</b>	
<b>Work Address</b>	
<b>Work Email</b>	
<b>% inventive contribution</b>	

**Please identify which inventor (above) will act as the principal point of contact (“Lead Inventor”):**

\_\_\_\_\_

**Summary of invention: (to be completed by Lead Inventor)**

Please attach a full description of the invention including diagrams, photographs, drawings, sketches or other descriptive materials.

Please also provide information on possible commercial applications and benefit to the NHS, including information regarding the problem the invention solves, whether similar inventions exist and if so, how this invention differs.

All attached pages (Papers Apart) should be signed and dated by the Lead Inventor.

**Where and when was the invention first conceived?**

**Place:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Funding: Please list all funding sources that have contributed to the invention:**

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**Materials: Have you supplied any material relating to the invention to any collaborator?** “collaborator” includes researchers within NHS Scotland as well as those at other institutions, universities and/or companies.

**If yes, was a Material Transfer Agreement (MTA) in place? Yes/No**

**Did you use any materials supplied by others to make your invention? Yes/No**  
**If yes, were the materials supplied under an MTA? Yes/No**

**Research Tools:** In developing the invention, did you make any use of research tools (e.g. gene editing platforms, image analysis tools, etc) that are restricted to research only use or may include restrictions on the commercial exploitation of their outputs? **Yes/No**

**If yes, were the materials supplied under an MTA or other legal agreement? Yes/No**

**Public Disclosures: Has the invention or any part of it been disclosed in a publication, abstract or presentation?** If so, please attach a copy of the disclosure and provide the date of disclosure.

**Please provide the names of any companies you believe may be interested in the invention.**

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**Declaration**

I/We confirm that I/we have read the above summary and any attached Papers Apart to which it refers and agree that this describes our invention.

Our relative contributions to the invention are as indicated above.

Signature of Inventors

\_\_\_\_\_  
Name                                      Signature                                      Date

\_\_\_\_\_  
Name                                      Signature                                      Date

\_\_\_\_\_  
Name                                      Signature                                      Date

Witnessed by employee of the Board

Signed..... Date.....

Full Name..... Base location .....

\_\_\_\_\_

N.B. An inventor is a person who has made an intellectual contribution to the inventive step(s) involved in the creation of the invention described in the invention record. Staff and students working under supervision and not making a positive intellectual/creative contribution to the inventive step are unlikely to be inventors. Inventorship is a matter of fact under patent law. True inventorship may be determined at a later stage, with the help of the R&I team and/or patent agents.

