

NHS Greater Glasgow and Clyde Health Board
Policy on the Management of Intellectual Property

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Authorised by:

Date:

1 Introduction

- 1.1 NHS organisations are obliged to manage their Research & Development (R&D) to improve patient care and to achieve best value for money. An important aspect of this is the protection and exploitation of intellectual property (IP).**
- 1.2 Innovation is not the sole preserve of those involved in R&D, 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&D project.
- 1.3 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.
- 1.4 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.
- 1.5 The Board will actively encourage awareness of IP.
- 1.6 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)9.

2 Key Objectives of this Policy

This policy aims to:

- Define IP
- Outline the process of identifying IP
- Clarify the ownership of IP
- Detail the management of IP

3. Definition of IP

3.1 Intellectual Property (IP) defines a novel or previously un-described activity. IP has an owner and can be bought, sold or 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**.

3.1.1 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.

3.1.2 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.

3.1.3 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.

3.1.4 Unregistered design rights cover engineering components and architectural drawings.

3.1.5 A Trademark is a badge of origin, used so that customers can recognise the product of a particular trader.

3.1.6 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.

4. Identifying Intellectual Property

4.1 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 management or a technology based department such as the Department of Clinical Physics. Many IP disclosures concern health technologies. In these cases the nominated IP officer should have a health technology background. 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.

5. Ownership of Intellectual Property

- 5.1** 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** IP generated by employees acting outside NHS duties will not be owned by the Board.
- 5.3** 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.
- 5.4** When IP is generated by employees from different organisations, the Board will discuss and form agreements with the other organisations agreeing IP ownership, Royalty sharing and the input required from each organisation.
- 5.5** Students are not classed as employees and as such are not covered by the relevant provisions governing IP. 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.
- 5.6** Copyright can protect written information, databases, computer software and films/video and is achieved automatically when IP is created. The Board does not normally claim ownership of copyright in published textbooks or in articles published in academic journals by members of staff or students. However, the Board retains the right to right to use, make copies of and disseminate any of these publications for its own non-commercial purposes, including research and training. To protect and to establish ownership and copyright for each item of IP, members of staff are requested to state prominently on each page of the document the following statement “© [employee to insert year of creation] Greater Glasgow and Clyde Health Board”. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner”. The Board does not assign any of its other copyrights to the author including, without limit: course or training materials or 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, any software generated by an employee in the normal course of their employment, any designs, specification or other works which may be necessary to protect rights in commercially exploitable IP. [Copyright relating to academic papers is normally assigned to the publisher.](#)
- 5.7** 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.

- 5.8** 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.

6. Employment Contracts

- 6.1** 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.

7. Management of IP

- 7.1** The R&D Director, nominated by the Board, responsible for the management of IP and commercial exploitation of ideas will report to the R&D Management Group on IP issues.
- 7.2** Inventors must first discuss the potential IP with one of the designated IP officers. Identification of these officers will be via the R&D central management office or the R&D web site.
- 7.3** 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”.
- 7.5** The Board may contract with an advisor organisation, such as Scottish Health Innovations Limited (SHIL), 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).
- 7.6** The R&D Director for Commercialisation 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 Executive’s Chief Scientist Office (CSO) from time to time on request.
- 7.7** 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 local R&D Office is available for managers to explain or clarify any aspect of the IP Policy.

8. Record Keeping

8.1 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.

9. Risk Management of Intellectual Property

9.1 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.

9.2 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 SHIL, are fully involved in this process.

9.3 Should the calculated risks outweigh any potential benefits, the Board may also decide to take no further action on a project. 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 at their own expense in which case any income generated from the invention reverts to the individual.

10. Exploitation of Intellectual Property

10.1 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

10.2 The decision to protect IP and to commercialise it will be the responsibility of the IP officer or designated local steering group.

10.3 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.
- 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.

11. Patent Protection

11.1 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.

11.2 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.

11.3 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.

12. Contracts with External Organisations

12.1 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.

13. Types of Agreement

- 13.1 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).
- 13.2 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).
- 13.3 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, Scottish Health Innovations Limited. The agreement should contain sections on ownership, decision-making, project management structure, contributions, cost recovery and revenue sharing.
- 13.4 Assignment.** Employees of Greater Glasgow and Clyde Health Board must not assign Intellectual property to a third party without the consent of the Health Board.

14. Income Arising from Exploitation and Commercialisation

- 14.1** Prior to initiating actions to exploit IP, the Board and appropriate staff should 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.
- 14.2** Depending on the Exploitation route and the Agreements formed (joint IP, license etc) the Board will obtain a proportion of royalties. The net profit, after deduction of expenses incurred by the Board [including salary components where formal sessions have been agreed] will be distributed on the following basis:
- One **quarter** to the inventor(s) who generated the intellectual property (as described on the Invention Summary Form);
 - One **half** to an endowment fund selected by agreement between the inventors and the Board. This fund could be used to support further development work at the discretion of the inventors.
 - One **quarter** to the Board. The Board may elect to use this income for general IP or research project support.

16. Disagreements

- 16.1** Any disagreement arising from the interpretation of this document, which cannot be mutually resolved, will be referred to the R&D Director for Commercialisation. 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 HR 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.

17.1 This policy will be reviewed every two years.

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

18. IP Publications

- (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. 4th edition. Financial Times Management Ltd. 1998.
- (10) Intellectual Property Law. Tina Hart. Macmillan Publishers Ltd. 1997.
- (11) Management of Intellectual Property in the NHS. HDL (2004) 09 (Scottish Executive)
- (12) The Baker Report "Creating Knowledge Creating Wealth" Realising the economic potential of the public sector research establishments (HM Treasury)

Appendix 1

INVENTION SUMMARY FORM

Please complete and include a full description of the invention including diagrams, possible commercial applications and benefit to the NHS

Full Project Title _____

PROJECT NO. _____ *DATE RECEIVED* _____

to be completed by a designated IP officer

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

We confirm that we have read the above summary and any attached Papers Apart to which it refers (the first page of each of which we have each signed and dated) and agree that this describes our invention.

Our relative contributions to the invention are as indicated below.

Delete A or B as appropriate

A We confirm that we believe ourselves to be the only parties responsible for creating/designing or making the invention.

B We have created/designed or made the invention in association with partners listed below

Partners: **[state the name of each partner (whether an organisation or an individual) and the percentage contribution to the invention made by that partner. If applicable state the name, position and base location of each individual partner]**

Lead Inventor: Signed.....

Date.....

Full Name.....

Base location

My contribution to the invention is _____%

Witnessed by [employee of the Board]

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

Full Name.....

Base location

[Cut and paste this section for each inventor]