

Policy for Management of Intellectual Property

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1.0 INTRODUCTION:

The following is a statement of NHS Lothian's (NHSL) policy that covers all aspects of its Intellectual Property ownership and the ownership of such rights by others. This Policy attempts to set forth NHSL's position regarding the use of the Intellectual Property (IP) Rights and the policies regarding such use.

2.0 DEFINITION OF INTELLECTUAL PROPERTY

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.

- 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.
- 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, articles in newspapers, some types of databases, but not names or titles.
- 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.
- Unregistered design rights cover engineering components and architectural drawings.
- A Trademark is a badge of origin, used so that customers can recognise the product of a particular trader.

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.

3.0 SCOPE

Staff Covered by Policy:

- ♦ All staff with substantive NHSL contracts of employment.
- Staff with NHSL contracts of employment whose payroll costs are partially or wholly funded by another party (e.g. a medical charity, a government department, a commercial sponsor), unless the contract between NHSL and that party assigns ownership of all Intellectual Property to that party.
- ♦ Staff who have a part-time NHSL contract and who are self-employed or otherwise employed part-time. Trainees hosted by NHSL for training purposes are, unless

otherwise agreed, subject to the management arrangements for Intellectual Property of NHSL staff.

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

Ownership of any IP made or created by a member of staff whether in the course of the performance of his/her duties or field of responsibility as a member of staff, or in the 'Normal Course of Employment' specifically assigned to him/her by NHSL or whilst making use of NHSL funds, resources, equipment, materials or information belonging to NHSL shall belong to and be the property of NHSL, entailing exclusive ownership and exploitation rights, unless an over-riding contract with a sponsor over-rules this. The phrase 'In the Normal Course of Employment' can be construed quite widely and may include work carried out in one's spare time or at home; However Intellectual Property generated by an employee, in his or her own time and which is unconnected with their normal course of NHS duties, will normally be owned by the employee.

If staff are in any doubt about whether or not an idea falls within the remit of this policy, NHSL Research and Development Office will carry out an initial assessment of the idea on a confidential basis.

NHSL 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.

NHSL will have exclusive exploitation rights in any IP consequently or originally owned by NHSL that may be of commercial value. Where appropriate or where so required under the terms of a contract with a third party, NHSL may assign or license IP to a third party on such terms as it at its sole discretion deems fit.

If they are not otherwise employees, students are not classed as employees simply by virtue of the fact that they are undertaking activity on NHSL premises. As such they are not covered by the relevant provisions governing IP. Preceding any placement or activity at NHSL, an agreement must be signed by the student assigning to NHSL the rights for any IP arising from the activities in which they have been involved.

Any student assigning IP will be entitled to participate in the income sharing arrangements set out in Section 14 of this document. NHSL shall have the discretion, in special circumstances, to waive its rights in favour of a Member(s) of Staff and/or Student(s) on such terms as NHSL shall deem fit.

All Staff and students involved in work with NHSL are under an obligation to;

- Report any potentially exploitable results and/or other intellectual property to NHSL.
- Unless otherwise agreed with NHSL, keep key information confidential until it is
 protected or released into the public domain with the approval of the principal
 investigator or supervisor (unless first released by a third party through no fault of the
 University). Any queries as to confidentiality should be referred to the R&D Office.
- Report any potential conflicts of interest to NHSL via the Research and Development Office.

4.0 AIMS:

NHSL policy is to encourage and enable staff to participate in the generation of IP as part of its commitment to delivering the best possible patient care. The policy is to maintain a balance between the legitimate needs of NHSL to protect its interests, and the provision of a creative working environment for staff. NHSL has agreed that revenue generated by successful exploitation of Intellectual Property can be shared with the originators, that is, the members of staff responsible for the innovation. For further details of this please reference 7.4

NHS Lothian policy aims to:

- **A.** To support and encourage the development and application of Research, wherever possible contributing to improvements in clinical care;
- **B.** To act in a fair and reasonable manner in determining the rights and interests of all Staff and Students, with adherence to broader principles of academic freedom;
- **C.** To ensure efficiency and transparency in the commercialisation of research, with particular regard to the distribution of income between Schools, The Research Institute, individual researchers, students and Universities.

5.0 ROLES AND RESPONSIBILITIES:

The R&D Office has management responsibility for Intellectual Property generated by NHSL staff.

Key Points of Contact as Regards the Management of IP within NHSL are -

Contracts Manager (Research and Development)
Research and Development Office Room E1.12
NHS Lothian
The Queen's Medical Research Institute
47 Little France Crescent
EDINBURGH EH16 4TJ

Or

Business Development Associate (Edinburgh BioQuarter) Research and Development Office Room E1.05 NHS Lothian The Queen's Medical Research Institute 47 Little France Crescent EDINBURGH EH16 4TJ

The R&D Director, nominated by NHSL, is responsible for the management of IP and commercial exploitation of ideas will report to the R&D Management Group on IP issues. Inventors must first discuss the potential IP with one of the designated IP officers (see above). Identification of these officers will be via the R&D central management office or the R&D web site.

The local R&D Office is available for managers to explain or clarify any aspect of the IP Policy. 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 an example of which is attached as Schedule 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.

NHSL may contract with an advisor organisation to assess the potential of IP, or to support the development and/or commercialisation of individual NHS innovations.

6.0 PROCESS

Staff are required to notify the R&D Office of any idea or other form of Intellectual Property that they have developed and which falls within the remit of this policy at the earliest opportunity, and, in any event, before disclosure of the idea to any party outside NHSL, either orally or in writing. Prior public disclosure (other than under explicit terms of confidentiality) will invalidate any subsequent patent application and diminish both potential commercial value and benefits accruing to NHSL and the originator. (The R&D Office can provide Confidentiality Disclosure Agreements to enable staff to discuss their Intellectual Property with external parties. Disclosure without entering into undertaking of confidentiality may prejudice negotiations of commercial arrangements with a company.)

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.

The R&D Office will, from time to time, arrange for an audit of NHSL R&D activity to identify Intellectual Property of potential commercial value. Staff are required to co-operate fully with this activity.

The R&D Office will maintain a register of all Intellectual Property owned by NHSL or where a member of NHSL staff is a named inventor or originator. A record will be kept of the date and time on which a member of staff reports to the R&D Office that s/he is the inventor of a creative product. Records will also be kept of arrangements entered into by NHSL for the protection and subsequent use of the Intellectual Property.

7.0 ADDITIONAL INFORMATION

7.1 Protection of Intellectual Property by Patenting

The decision to protect Intellectual Property by patenting rests with NHSL but is delegated to the Head of R&D for UK patent applications and to the Director of R&D/Chief Executive for all other patent applications. NHSL is the vehicle for holding patents and other Intellectual Property, but is free at its absolute discretion to engage another organisation to exploit its Intellectual Property on its behalf.

7.2 Commercial Exploitation Activity

All commercial exploitation activity is coordinated by the R&D Office of NHSL. Members of staff who are the originators of Intellectual Property are expected to co-operate fully, and to correspond in a timely manner, with those responsible for its exploitation so that maximum possible benefit is obtained.

The decision to exploit, license or assign Intellectual Property (defined above), whether to a commercial company or to an employee of NHSL or to agree contractual terms with a technology transfer company and/or other commercial partner(s), rests with NHSL but is delegated to the Chief Executive.

Should the calculated risks outweigh any potential benefits, NHSL may also decide to take no further action on a project. Should NHSL 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.

Methods of Exploitation by NHSL may include, but are not limited to;

- Outright sale of the IP to an existing company (possibly with the retention by NHSL 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.

Staff are reminded that no steps should be taken, including the establishment of companies, to exploit any Intellectual Property belonging to NHSL without the specific approval of NHSL and that they are required to cooperate with the R&D Office in carrying out its management responsibilities for Intellectual Property.

In dealing with an external organisation, it is important to keep full records, including copies of all correspondence and notes of telephone conversations and meetings, in order to provide detailed accounts of the progress of discussions relating to any Intellectual Property. All records and notes must show the relevant date(s) and action(s) agreed.

Wherever possible, commercially funded research contracts should provide for NHSL retaining ownership of any resulting Intellectual Property to enable the management of its proper exploitation.

7.3 Pricing of Commercial Funded Research Contracts

In pricing commercially funded research contracts, regard must always be given to the value of the resulting Intellectual Property and the rights to the Intellectual Property which are granted to the sponsor, as well as the value of existing background Intellectual Property (especially software or patented inventions) which may be used in furtherance of the research project.

7.4 Revenue Sharing of Intellectual Property

The current basis of sharing with NHSL staff the revenue from the successful exploitation of Intellectual Property is given in the following Table:

	Inventor	Division/Office	NHSL /R&D Fund
Net income up to £50k	50%	30%	20%
Net income > £50k	35%	35%	30%

Notes

- Net income refers to the income remaining after recovery of patenting and other out of pocket costs incurred by NHSL in identifying, protecting, developing and exploiting the Intellectual Property. (NHSL costs include: the costs incurred by the researcher, the clinical Office within which the researcher works, the R&D Office and/or any NHSL departments directly contributing resources to the development process.)
- Where there is a contractual agreement with a funding sponsor to share the revenue from successful exploitation of Intellectual Property arising from research funded by that

sponsor, the Cumulative Net Income to NHSL is the income from exploitation remaining after deduction of the sponsor's share.

Despite the statutory provision whereby the copyright in any work produced by an employee in the course of employment belongs to the employer, NHSL normally grants a free licence to the copyright in any work to be published in a recognised scientific, technical, professional or management journal or book to the author. NHSL will not grant such licence to the copyright in materials created by a member of staff during the course of and related to their employment, comprising:

Course or training materials;

- ii Software programs;
- iii Any designs, specification or other works which may be necessary to protect rights in commercially exploitable Intellectual Property.

NHSL retains the right to use, make copies of and disseminate any of these publications for its own non-commercial purposes, including research and training.

NHSL will not normally take any action to diminish or remove the Moral Rights of NHSL employees in respect of copyright material (i.e. the right to be named as author).

Where Intellectual Property arises from a research group containing both University and NHSL employees, management and revenue-sharing arrangements will be determined on a case-by-case basis with the University.

7.5 Disputes Over Intellectual Property Ownership

Where there is dispute about the inventor(s) of Intellectual Property, dated written records associated with the generation of the Intellectual Property will be used to establish the inventor(s) of the Intellectual Property and to determine their level of contribution/remuneration. In the absence of documentary evidence, a committee comprising the Chairman and R&D Director of NHSL together with a Senior Partnership Representative appointed by the Employee Director of NHSL shall decide, taking such professional advice as appropriate, and their decision will be final.

In the event of any dispute about the interpretation of this policy, NHSL employees have recourse to NHSL grievance procedure to resolve the dispute.

8.0 Review of Policy

The effectiveness of this policy will be reviewed by NHSL Research and Development Office after a period of two years in operation.

Schedule 1



NHS Lothian Invention Disclosure Form

1 Title of Invention					
		n 3 inventors, please a pution must equal 100%		neets)	
Name:					
Employer:					
Department:			Work address:		
Work Phone:					
Work Fax:					
Work Email:					
%	inventive				
contribution					
Name:					
Employer:					
Department:			Work address:		
Work Phone:					
Work Fax:					
Work Email:					
%	inventive				
contribution					
-	<u>, </u>				
Name:					
Employer:			1	1	
Department:			Work address:		
Work Phone:					
Work Fax:					
Work Email:					
%	inventive				
contribution					
Name of the in	nventor that	will act as the principa	l contact person		

3 Description of invention

Please attach a summary of the invention being disclosed. Include photographs, drawings, sketches or any other descriptive material.

Please try to answer the following questions:

- (1) What problem does the invention solve?
- (2) Do similar inventions exist?

(3) If so, how does your invention differ?						
4 Please indicate exactly where and when the invention was first conceived						
Date: Place:						
5 Funding Sources						
Please list all sources of funding that have contributed to the invention						
6 Information on intellectual property						
(a) Public Disclosure						
Has the invention or any part of it been disclosed in a publication, an	Yes	No				
abstract or a presentation? If yes, please attach a copy and write the						
date of the disclosure on the material						
(b) Materials						
i. Have you supplied any material relating to the invention to anyone	Yes	No				
outside your research group? Please include researchers within NHS						
Lothian as well as those at other institutes, universities and						
companies.						
Y6	Yes	No				
If yes, was the material supplied under a Material Transfer Agreement						
(MTA)?	X 7	NI.				
ii. Did you use any materials supplied by other researchers?	Yes	No				
If yes, were the materials supplied under an MTA?	Yes	No				
(c) Commercial Interest						
Are you aware of any companies that might be interested in this	Yes	No				
invention?						
If yes, please list names						
7 General						
Are there any other details required to enable a full assessment of the id	ea? Please	detail below.				

8 Signature of Inventors Print Name Signature Date Print Name Signature Date

Signature

Date

Confidential / Not to be copied

Print Name