Management and exploitation of Intellectual Property and Inventions (IP Policy)

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<tr>
<th>Author:</th>
<th>Senior R&amp;D Manager</th>
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| Responsible Lead Executive Director: | Director of Public Health *(includes any interim post-holder as appropriate)*  
A nominated deputy may take on specified aspects of this role as described within this policy, insofar as the Board’s Scheme of Delegation allows |
| Endorsing Body: | Research & Development Committee |
| Governance or Assurance Committee | Healthcare Quality Assurance & Improvement Committee (HQAIC) |
| Implementation Date: | October 2018 |
| Version Number: | 5.2 |
| Review Date: | April 2023 |
| Responsible Person | Senior R&D Manager |
CONSULTATION AND DISTRIBUTION RECORD

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<td>• Open consultation notified to all NHS Lanarkshire staff via Staff Bulletin</td>
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<td>• Interim Director of Public Health at time of issuance of this policy – referenced as ‘Director of Public Health’ throughout this document (Executive Lead)</td>
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<td>• Stakeholders: Refer to section on ‘Scope’.</td>
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CHANGE RECORD

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1. INTRODUCTION
This policy sets out how NHS Lanarkshire encourages the development and commercial exploitation of Intellectual Property (IP), and in particular Inventions, developed by its staff.
For completeness, the IP Policy defines Copyright Work and other forms of IP in the Glossary.
Please refer to the Board’s Copyright Policy for issues related to Copyright.

2. AIM, PURPOSE AND OUTCOMES
• Define various types of Intellectual Property that may be generated within NHS Lanarkshire.
• Clarify the ownership of Intellectual Property
• Provide guidance for staff about how to protect NHS Lanarkshire’s Intellectual Property
• Describe the help available to identify and develop NHS Lanarkshire Intellectual Property to improve patient care and, if possible, to generate income that will help the Board deliver services
• Describe how any income that may arise from commercial exploitation of Intellectual Property will be distributed.

3. SCOPE
3.1. Who is the Policy intended to Benefit or Affect?
• All NHS Lanarkshire staff are covered by the terms of this IP Policy; it applies if they generate Intellectual Property arising from the work they carry out as an employee of NHS Lanarkshire.
• Other non-NHS Lanarkshire staff or organisations that may generate IP through work carried out in collaboration with NHS Lanarkshire, such as students, University staff or other external researchers.

3.2. Who are the Stakeholders?
• NHS Lanarkshire staff, or others, who generate IP as described in 3.1 above.
• NHS Lanarkshire as an organisation, and its individual departments, who may benefit from the exploitation of IP generated by staff.
• The Director of Public Health who has executive responsibility for Intellectual Property within NHS Lanarkshire. Any disagreements about the application of this policy will be referred to the Director of Public Health.
• The Director of Planning, Property & Performance, who has the role of Innovation Champion, will support and advise the Senior Research & Development (R&D) Manager in fulfilling his role.
• The Senior R&D Manager, who advises and provides supports for staff who wish to develop Intellectual Property.
• Scottish Health Innovations Limited (SHIL), who will provide expert advice and support to help NHS Lanarkshire identify, develop and exploit IP.
NHS Lanarkshire takes care to ensure your personal information is only accessible to authorised people. Our staff have a legal and contractual duty to keep personal health information secure, and confidential. In order to find out more about current data protection legislation and how we process your information, please visit the Data Protection Notice on our website at www.nhslanarkshire.scot.nhs.uk or ask a member of staff for a copy of our Data Protection Notice.

4. INTELLECTUAL PROPERTY (IP) - PRINCIPAL CONTENT

4.1. What is Intellectual Property (IP)

Intellectual Property, or ‘IP’, can result through research, innovation or other work, and is the name given to new Inventions, ideas or concepts with practical application that the law recognises has value by providing legal protection.

It is possible in certain circumstances that IP can be developed into products that may benefit patients and generate revenue for the NHS if protected and harnessed properly.

Where commercial exploitation is not appropriate or practical, the sharing of IP with appropriate acknowledgement may also help patients and enhance the reputation of the Board as an innovating organisation.

NHS Lanarkshire therefore encourages the development of IP with a view to, where appropriate, its commercial exploitation for the mutual benefit of NHS Lanarkshire patients and all staff involved.

This IP 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.

This IP Policy is particularly intended to provide guidance to aid in the management of Inventions that are capable of commercial exploitation. Throughout the Policy, use of the term ‘Invention’ can be taken to mean any other form of Intellectual Property (IP)

4.2. Identifying and registering IP

Innovation, and the development of IP, can occur naturally through the work of any member of staff. 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 a Research & Development (R&D) project.

NHS Lanarkshire may, from time to time, ask its employees through surveys – called Technology Audits - if they have any ideas that they think may be IP. However, at any time, any member of staff with an idea they think is, or may be, IP resulting from their activities should register it as soon as possible. The three recommended routes are:

- Complete the Invention Record Form (Appendix 1) and submit it to the Senior R&D Manager – you can get a copy of the form from the R&D Department
- Register your idea on the Scottish Health Innovations website on their ‘Submit your idea’ link: https://www.shil.co.uk/submit-your-idea
- Respond to any Technology Audits carried out by NHS Lanarkshire

Any of these routes will ensure that potential IP will be properly registered as belonging to NHS Lanarkshire. It will also allow the Senior R&D Manager to get expert help for staff to assess the IP and, if appropriate, developing it further.
Staff must not under any circumstances, sell, assign or otherwise trade NH Lanarkshire’s Intellectual Property without NHS Lanarkshire’s agreement.

4.3. Ownership of IP

An Invention (or any other form of IP) produced by / originating from a member(s) of NHS Lanarkshire Staff¹ shall be taken to belong to NHS Lanarkshire if it was made in the course of or in connection with the duties of the member(s) of staff and the circumstances were such that an invention (or any other form of IP) might reasonably be expected to result from the carrying out of their duties.

If there are any doubts, any type of IP created by NHS Lanarkshire Staff which is thought to be capable of protection and / or commercial exploitation should be discussed with the Senior R&D Manager; he may involve other colleagues as necessary in to review the ownership of the IP and the prospects for commercialisation.

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.

4.3.1. IP not owned by the Board

IP generated by NHS Lanarkshire employees who are acting entirely outside NHS duties will not be owned by the Board.

NHS Lanarkshire staff may carry out work on research studies that may involve the Intellectual Property of other organisations, such as the Research Sponsor. In these cases the ownership of the IP should be clarified through formal contract, such as a Clinical Trials Agreement. If no such contract exists, ownership should be discussed in the first instance with the Senior R&D Manager, who will seek further advice as necessary.

If staff from other organisations working within NHS Lanarkshire generates IP, the Board will discuss and form agreements with those organisations agreeing IP ownership, Royalty sharing and the input required from each organisation.

Students are not classed as employees and as such are not covered by the relevant provisions governing IP. NHS Lanarkshire may require that student sign an agreement assigning to the Board the rights for any IP arising from the activities in which they have been involved.

¹ Where a member of NHS Lanarkshire Staff’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 any income resulting from exploitation.
4.4. Protection of IP
Depending on the type of IP, there are a number of potential ways for it to be provided with legal protection against unauthorised copying or exploitation. The four main categories of IP protection are Patent Protection, Copyright, Design Rights, Trade Marks.
More information about the main categories of IP, the protections that apply, and advice about safeguarding IP are described in ‘Appendix 3: Protecting Intellectual Property’

4.5. Exploitation of IP

4.5.1. Commercial exploitation of IP
NHS Lanarkshire will have the right to determine the route of exploitation of any IP owned by NHS Lanarkshire. In most circumstances, this will be with the assistance of Scottish Health Innovations Limited (SHIL). SHIL works in partnership with NHS Scotland to identify, protect, develop and commercialise healthcare innovations to improve patient care.
Where it deems it appropriate, or where required under the terms of a contract with a third party, NHS Lanarkshire may assign or license IP to a third party on such terms as it deems fit.
A member of NHS Lanarkshire Staff may be required to sign a formal assignation in favour of NHS Lanarkshire of all IP made or created by that member of NHS Lanarkshire Staff (whether alone or in conjunction with others) that belongs to NHS Lanarkshire under the IP Policy.
It must be stressed, however, that the absence of such an assignation in no way indicates that any IP has been transferred from NHS Lanarkshire to that member of staff.
Further information and guidance about the approaches NHS Lanarkshire may take in exploiting IP is provided in ‘Appendix 4: Exploiting Intellectual Property’

4.5.2. IP that will not be commercially exploited
The vast majority of the IP developed within NHS Lanarkshire will not have the potential for commercial exploitation. This may include, for instance:

- Training courses
- Clinical guidelines
- Patient leaflets
- Some computer programmes or databases

Where IP of this nature is developed, the aim is usually to share it within the NHS for the wider benefit of patients, rather than for commercial gain. Where commercial exploitation is not possible, or desirable, IP is still protected by Copyright, as described previously.
Please refer to the NHS Lanarkshire Copyright Policy for further information.
4.6. Income arising from exploitation and commercialisation of IP

If any Invention (or other IP) is commercially exploited by NHS Lanarkshire under the terms of this policy, and unless an alternative specific arrangement has been agreed by the relevant parties, any resulting income arising from royalties or other income payable, after deduction of expenses incurred in exploiting the Invention (such as payments to SHIL made in relation to the initial stages of commercial piloting, etc., - the cost of which will be specified within separate agreements), will be fairly and equitably distributed on the following basis:

- Forty percent (40%) to NHS Lanarkshire
- Thirty percent (30%) to the Inventor (this proportion may be liable for personal taxation)
- Fifteen percent (15%) to the R&D Department to support further research, development and innovation activities in the Board
- Fifteen percent (15%) to the Inventor’s departmental endowment funds (which are to be used to promote/undertake/support additional research or similar activities).

In the event of NHS Lanarkshire commissioning research, or undertaking joint R&D with another provider (including other NHS bodies, Universities, other academic institutions, and commercial organisations), NHS Lanarkshire 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.

The income sharing arrangements do not affect the statutory rights of any member of staff in terms of The Patents Act 1977 (as amended), details of which can be found within the UK Intellectual Property Office website.

4.7. Where NHS Lanarkshire decides not to pursue exploitation of IP

Should NHS Lanarkshire decide not to pursue the exploitation of a piece of IP, on the basis of the information imparted by the Inventor, then the Inventor can request that ownership of the idea be assigned to them. If NHS Lanarkshire is satisfied that all important material facts were disclosed then it will confirm this transfer of IP ownership in writing.

The transfer of ownership will not be unreasonably withheld.

If any disputes arise in relation to this arrangement, they will be referred in the first instance to the Director of Public Health.

The inventor may wish to pursue exploitation of the Invention at his or her own expense, in which case any income generated from the Invention reverts to the individual.

NHS Lanarkshire will, however, be entitled to invoke its statutory rights in an Invention if it becomes evident that important material facts were not disclosed by the inventor when the decision was taken to assign the Invention.

As noted previously, students may be asked to assign to NHS Lanarkshire the rights for any IP arising from their work in NHS Lanarkshire. Where such an agreement is in place, the student will be regarded as an employee in respect of sharing income earned from exploitation of the IP generated.
5. ROLES AND RESPONSIBILITIES
The various roles and responsibilities are as described throughout Section 4 of this Policy. In summary:

- **NHS Lanarkshire staff:**
  - may develop IP that requires protection, or that may be commercially exploited
  - are required to inform NHS Lanarkshire of their IP

- **Senior R&D Manager, Innovation Champion or other nominated employees of the Board:**
  - Provide appropriate advice and support for staff, in line with this Policy, including drawing on external expertise where required, including but not limited to Scottish Health Innovations Limited
  - Where there has been identified potential for commercial exploitation, usually following receipt of external advice, escalate to the Director of Public Health for discussion and resolution as noted below

- **Director of Public Health with suitable expert input as required:**
  - Determine whether NHS Lanarkshire wishes to commercially exploit any specific element of IP developed by NHS Lanarkshire staff
  - Inform staff of the Board’s decision as required

6. RESOURCE IMPLICATIONS
There are no immediate resource implications associated with the implementation of this Policy. Support will be provided as required by the Senior R&D Manager.

NHS Lanarkshire reserves the right to review from time to time the resources and support required to effectively identify, manage and exploit its Intellectual Property for the benefit of NHS Lanarkshire, its patients, staff and NHS Scotland.

7. COMMUNICATION PLAN
The Policy will be endorsed by the R&D Committee, and circulated to other relevant Board Committees.

The Policy is published on the R&D Department FirstPort site, and is also posted alongside all other NHS Lanarkshire Policies via Knowledge and Library Services Manager.

All NHS Lanarkshire researchers are made aware of the Policy, and are directed to the Board’s Intranet site (FirstPort) to view it as part of their R&D Management Approval.

8. QUALITY IMPROVEMENT – MONITORING AND REVIEW
The content of the Policy will be reviewed and ratified by the Research & Development Committee.

The effectiveness of the Policy in ensuring dissemination is assessed by reviewing the content of the relevant portions of the Intranet and Internet sites by the Senior R&D Manager.
The effectiveness of the Policy may be further assessed through Internal Audit inspections, or by other means as determined by NHS Lanarkshire from time to time.

9. EQUALITY AND DIVERSITY IMPACT ASSESSMENT

This policy meets NHS Lanarkshire’s EDIA

10. FREQUENTLY ASKED QUESTIONS (FAQS)

The following questions are discussed in greater detail within the IP Policy and Appendices.

10.1. What is Intellectual Property (IP)?

Intellectual Property is the name given to new ideas or concepts with practical application that the law recognises has value by providing legal protection. It is possible in certain circumstances that IP can be developed into products that may generate revenue for the NHS and the originator/researcher, if protected and harnessed properly.

Where commercial exploitation is not appropriate or practical, the sharing of IP with appropriate acknowledgement may be useful in helping to enhance the reputation of the Board as an innovating organisation.

10.2. Who owns Intellectual Policy in NHS Lanarkshire?

An Invention (or any other form of IP) produced/originating from a member(s) of NHS Lanarkshire Staff shall be taken to belong to NHS Lanarkshire if it was made in the course of their duties and the circumstances were such that an Invention might reasonably be expected to result from the carrying out of those duties.

10.3. How can I protect Intellectual Property?

Depending on the type of IP, there are a number of potential ways for it to be provided with legal protection against unauthorised copying or exploitation. The four main categories of IP protection are Patent Protection, Copyright, Design Rights, Trade Marks.

10.4. Can I be paid for my Invention?

If any Invention (or other IP) is commercially exploited by NHS Lanarkshire, income after all deductions and expenses will be fairly and equitably distributed on the following basis:

Forty percent (40%) to NHS Lanarkshire
Thirty percent (30%) to the Inventor (this proportion may be liable for personal taxation)
Fifteen percent (15%) to the R&D Department to support further research, development and innovation activities in the Board.
Fifteen percent (15%) to the Inventor’s departmental endowment funds (which are to be used to promote/undertake/support additional research or similar activities).

10.5. Is IP only relevant if we are trying to sell an Invention?
No. In fact the vast majority of the IP developed within NHS Lanarkshire will not have the potential for commercial exploitation. This may include, for instance, training courses, clinical guidelines, patient leaflets, some computer programmes or databases. Where IP of this nature is developed, the aim is usually to share it within the NHS for the wider benefit patients, rather than for commercial gain. Where commercial exploitation is not possible, or desirable, IP is still protected by Copyright, as described in the IP and Copyright Policies.

11. REFERENCES

This document is not intended to act as a detailed guide to the protection and commercialisation of IP arising from research. Further information can be accessed online via the UK Intellectual Property Office http://www.ipo.gov.uk/


12. R & D DEPARTMENT CONTACT DETAILS
Senior R&D Manager
R&D Department
Corporate Services Building
13. APPENDICES

Appendix 1: Invention Record – Contact the R&D Department
Appendix 2: Confidentiality Agreement – Contact the R&D Department
Appendix 3: Protecting Intellectual Property
Appendix 4: Exploitation of Intellectual Property

GLOSSARY

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<td>“IP Policy”</td>
<td>means this Policy and the procedures for the ownership and exploitation of Intellectual Property, and in particular Inventions, within NHS Lanarkshire (as amended from time to time);</td>
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<td>“Invention”</td>
<td>includes any discovery, Invention, process, composition of matter, article of manufacture, know-how, design, model, technological development, technical formula or specification plan, or drawing;</td>
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<td>“Intellectual Property” or “IP”</td>
<td>means Inventions (whether or not they are able to be Patented), designs and design rights (whether or not they can be registered), Copyright Work, technical formulae, research or clinical results, trade or service names or marks or logos used in relation to any of the above and any other intellectual property rights (whether or not of the same nature);</td>
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<td>“Copyright Work”</td>
<td>includes any copyrightable material, such as printed material, computer software or computer databases, audio and visual materials, lecture or clinical notes, teaching aids, flexible or distance learning materials, computer generated works, circuit diagrams, architectural and engineering plans or drawings, musical or dramatic compositions, choreographic works, pictorial or graphic works and all other forms of literary, artistic or dramatic works;</td>
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<td>“Inventor”</td>
<td>means any person responsible, individually or in conjunction with others, for an Invention or Copyright Work;</td>
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<td>“NHS Lanarkshire Staff”</td>
<td>includes all full-time and part-time employees and appointees of NHS Lanarkshire, including persons paid (whether in whole or in part) by or through NHS Lanarkshire, including visiting fellows, and anyone working under NHS Lanarkshire auspices, but excluding employees of sub-contractors engaged by NHS Lanarkshire;</td>
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<td>“Director of Public”</td>
<td>means the Director of Public Health of NHS Lanarkshire, or any interim appointee to this role, who has responsibility, through the Board’s Scheme of Delegation, for R&amp;D-related commercial activities.</td>
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APPENDIX 1: INVENTION RECORD

INVENTION RECORD

Intellectual Property (IP) is the name given to new Inventions, ideas or concepts with practical application that the law recognises has value by providing legal protection. NHS Lanarkshire encourages the development of IP by its employees with a view to, where appropriate, its commercial exploitation for the mutual benefit of NHS Lanarkshire, its patients, and the staff involved.

In order to determine the facts relating to an invention, design or copyrightable material (all referred to as ‘inventions’ within this document) and to protect the rights of all members of staff and others who may be involved, it is important that a statement of inventorship is lodged with NHS Lanarkshire. The Invention Record serves an additional purpose of establishing an independent reference point in support of project notebooks as to when an invention was made.

Information provided on this form may be used as a basis of a statement of title in respect of a patent application. In some instances, incorrect information may lead to the patent not being granted or being declared invalid. The information given will be treated as confidential and will be used only for assessing the potential for protecting and commercialising the invention and, if appropriate, in seeking protection of the disclosed invention and its future exploitation.

Protecting any invention can be costly; each invention must be assessed on a case-by-case basis to determine whether the Board wishes to pursue commercialisation. NHS Lanarkshire is supported in
this process by Scottish Health Innovations Limited. SHIL is a private company with three shareholders – Scottish Minister's through the Chief Scientist Office (CSO), NHS Tayside and the Golden Jubilee National Hospital – they work in partnership with NHS Scotland to identify, protect, develop and commercialise healthcare innovations to improve patient care. More about SHIL’s role can be found here: www.shil.co.uk.

The initial stage will be to discuss the invention with SHIL who will provide NHS Lanarkshire with advice as appropriate. NHS Lanarkshire will keep the originators of the invention informed and involved at each stage in the process and will as far as possible take into account all relevant factors when taking any decision relating to this invention.

Title of Invention

Inventor(s)

When completed, please return this form to the Senior R&D Manager at the undernoted address:
Senior R&D Manager, R&D Department
Corporate Services Building, Monklands Hospital, Monkscourt Avenue, Airdrie, ML6 0JS

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Inventors / Other Staff / Students

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Note: 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. True inventorship may be determined at a later stage, with the help of the R&D Office, SHII, and others as required.
Date, place of invention & inventor

Invention was conceived:

<table>
<thead>
<tr>
<th>Date</th>
<th>Place</th>
</tr>
</thead>
</table>

Name(s)

Field of Invention

Field of the Invention (e.g. orthopaedics, rehabilitation, urology, surgery)

What does your invention relate to? (e.g. my invention is related to lifting patients; is related to haemodialysis etc)
### Background of the Invention

What problem is solved by your invention? (If more than one problem, give details of each.)

What solutions are currently available?

Why is your solution an improvement?

Include any papers etc. that relate to your invention or to its general field.

### Inventive Step

General statement of what you think is the Inventive Concept:

Describe your invention in general terms i.e. what is unique about your invention?
Full Description of Invention

Describe how your invention is made and how it is used. (Where possible, give enough detail to enable a third party to build and use your invention.) Include any diagrams and drawings and, if relevant, experimental details.

If appropriate, please attach typed A4 pages marked CONFIDENTIAL at the top of each page.

Indicate here the number of pages attached: ____

Describe any variants of your invention that could be developed. (Use rough sketch drawings to illustrate.)

List all possible applications of your invention.

Potential Commercial Use

Past Disclosure/Publication

Have details of the invention been disclosed or published? Yes/No

If ‘yes’, give details, indicate date of disclosure/publication and attach a copy of the publication

If ‘yes’, was a Confidential or Non-Disclosure Agreement in place? Yes/No

(Give details and, if not previously seen by the R&D Office, attach a copy.)

Intended Disclosure/Publication

Is it intended to disclose details of the invention in the near future? Yes/No

If ‘yes’, give details and indicate date of intended disclosure/publication
N.B. Details in any thesis submitted in respect of a degree at a higher educational institute or any other institutions; submissions to journals; conference papers; seminar contributions; poster presentations; correspondence; e-mails; any other disclosures should be listed. If any of these have been accepted for publication, indicate approximate date publication may occur.

**External Funding**

Give as many details as possible of ALL external funding which has been used in connection with this or related work, including grants, contracts, studentships etc. If there are two or more externally funded projects of relevance, please copy this page.

<table>
<thead>
<tr>
<th>Research Council</th>
<th>✔</th>
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<tbody>
<tr>
<td>Charitable Foundation</td>
<td>✔</td>
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<tr>
<td>Industry</td>
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<tr>
<td>European Commission</td>
<td>✔</td>
</tr>
<tr>
<td>Other Funding Body</td>
<td>✔</td>
</tr>
</tbody>
</table>

Name of funding body/company:

Type of funding (e.g. Link, etc):

Lanarkshire R&D Reference No:

Title of Project:

Name of Grantholder:

Commencement & completion dates:

**External Collaboration**

Has any of this work been carried out elsewhere? Yes/No

If ‘yes’ please tick as appropriate:

- another academic institution
- previous employment
- industrial collaborator

Please give details:

**Prior Art**

Please list all databases which you have searched.
I / We agree to co-operate with NHS Lanarkshire in seeking patent or other legal protection in the name of NHS Lanarkshire and in any exploitation of this invention either through licensing to a new party or through the creation of a new business.

Inventor (i) (ii) (iii)

Name

Signed

Dated

(This form should be signed by all those named as inventors.)

I have read the contents of this invention record and agree to its submission to the R&D Office.

Head of Department

Name

Signed

Dated

This form was received in the R&D Office on:

Date

R&D Manager

Name

Signed
APPENDIX 2: CONFIDENTIALITY AGREEMENT

NHS Lanarkshire

Confidentiality Agreement

between
___________________ (hereforth known as ______________) having its principal office at
______________________________________________

and

NHS Lanarkshire having its principal office at the NHS Board, Beckford Street Hamilton

WHEREAS:

I. NHS LANARKSHIRE exists to provide healthcare services to NHS Scotland patients. In the
course of this, it is developing a ____________________ which may improve the delivery and
quality of care.

II. (Company)__________ exists to provide a ______________________________________

III. __________ - and NHSLANARKSHIRE wish to enter into discussions with a view to
determining whether there are grounds for entering into a collaborative research and/or
development programme or other business endeavour. Any such programme or endeavour
would be subject to a separate agreement.

IV. During the course of discussions, negotiations or analysis, it may be necessary for one party (the
disclosing party) to disclose to the other party (the receiving party) certain data, drawings,
processes, patent applications, technological information, know-how, reports or other
confidential information or documentation relating to the business and technology of the
disclosing party.

Any information whether of a written, oral, electronic or visual nature disclosed by either party as a
result of this endeavor shall become THE INFORMATION.

NOW IT IS HEREBY AGREED AS FOLLOWS:

I. The receiving party agrees that any of THE INFORMATION which it has received or may
receive from the disclosing party shall only be used for the purpose described in WHEREAS
above and shall not be used for any other purpose without the prior written consent of the
disclosing party.
2. The receiving party shall treat THE INFORMATION received from the disclosing party as confidential and the exclusive property of the disclosing party, and agrees not to disclose THE INFORMATION or any part thereof to any third party without the prior written consent of the disclosing party.

3. The receiving party further agrees that it shall make no use of THE INFORMATION or any part thereof (other than as provided in Clause 1 above) unless a further agreement is concluded with the disclosing party concerning THE INFORMATION or any part thereof so disclosed.

4. The receiving party further agrees to use its best endeavors to ensure that none of the directors or other officers or employees of the receiving party shall use or disclose THE INFORMATION other than in accordance with the provisions of this Agreement.

5. The above provisions of confidentiality and non-use shall not apply to that part of THE INFORMATION which the receiving party is clearly able to demonstrate:

a) was fully and rightfully in its possession prior to receipt from the disclosing party; or
b) was in the public domain at the time of receipt from the disclosing party; or
c) became part of the public domain through no default of the receiving party, its directors, officers/or employees; or
d) was subsequently received by the receiving party from a third party having right to make such disclosure to the receiving party.

6. The receiving party agrees that, at the disclosing party’s request, the receiving party shall return to the disclosing party any and all parts of THE INFORMATION provided by the disclosing party in documentary or other tangible form and will return or destroy any copies thereof made by the receiving party, its directors, officers and/or employees. Any such destruction shall be certified in writing by a director or officer of the receiving party.

7. Nothing herein contained shall be deemed to grant to the receiving party any rights or licences under patents or patent applications or under any know-how, technology or invention.

8. The receiving party shall be responsible to the disclosing party for any damages arising from the breach by the receiving party of any of the covenants and obligations on its part to be observed or performed under this Agreement. Each party acknowledges that failure to comply with the Agreement might result in irreparable harm to the other party and that damages may not be an
adequate remedy. Each party shall therefore be entitled to the remedies of interdict and specific implement for any threatened or actual breach of this Agreement.

9. The obligation of the receiving party not to disclose THE INFORMATION as set forth in paragraph 2 hereof, shall remain in effect for a period of 5(FIVE) years from the date of disclosure of any of THE INFORMATION by the disclosing party.

10. This Agreement shall be governed by and interpreted in accordance with laws of Scotland and each party undertakes to submit to the non-exclusive jurisdiction of the Scottish Courts.

Signed for and on behalf of ______________________________
by:        Authorised Signatory

 Name:  
 Title:  
at 
on the day of 200
Witness: ______________________________  
Full Name: ______________________________
Address: ______________________________

______________________________
 ______________________________
______________________________

Signed for and on behalf of ______________________________
by:    Director/Authorised Signatory

 Name:  
 Title:  
at 
on the day of 200
Witness: ______________________________  
Full Name: ______________________________
Address: ______________________________
**APPENDIX 3: PROTECTING INTELLECTUAL PROPERTY**

**Inventions**
Inventions can be protected by a Patent

A Patent is a form of licensing that can be applied for, and that provides legal protection against others using a Patented Invention. To be eligible to be protected by a Patent, the Invention must:

- be new
- have an inventive step that is not obvious to someone with knowledge and experience in the subject
- be capable of being made or used in some kind of industry

**Patent protection process**
To ensure ideas for Patenting are processed as quickly as possible, the R&D Department provides an Invention Record (Appendix 1). This form should be completed by the Inventor and submitted to the Senior R&D Manager for assessment.

Alternatively, advice may be sought directly from SHIL via their ‘Submit-an-Idea’ web facility [http://www.shil.co.uk/submit-an-idea](http://www.shil.co.uk/submit-an-idea)

Only after advice on protection has been given should the idea be made public by publishing an article, giving a talk or poster presentation or disclosing to any outside organisation.

To be Patentable an Invention must be novel in some way 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. The only substantial reason for NHS Lanarkshire to process a Patent Application is to ensure that NHS Lanarkshire, and the NHS Lanarkshire Staff involved in the Invention, are in the best position to get full benefit of the Invention through proper exploitation by means of licence agreements or other arrangements.

If Patent protection is deemed to be desirable, NHS Lanarkshire may, at its discretion;

- Invite an outside commercialisation organisation – Scottish Health Innovations Limited (SHIL) - to undertake the protection and commercialisation on behalf of NHS Lanarkshire
- Apply for a Patent in the name of NHS Lanarkshire using a Patent Agent, and thereafter Licence out the Invention or Assign the Invention to a third party
- Take other such action regarding the IP that NHS Lanarkshire, at its sole discretion, deems appropriate

NHS Lanarkshire will usually adopt the first of these approaches, and will seek to work with SHIL in relation to Patent Protection through to commercial exploitation.

At NHS Lanarkshire’s discretion, however, it may contribute to any and all stages of the commercialisation process provided that there is reasonable likelihood that the Invention can be exploited. Contributions may include, but would not necessarily be limited to:

- Paying the costs of processing an initial Patent Application, up to the filing and examination stages - this will generally take the form of the Patent Application fee.
- Providing help in manufacturing pilot / prototype devices for Patenting purposes
- Providing help through sessional substitution to bring an Invention to Patentable form.

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 the Patent application.
**Designs / Trade Marks / Recorded works (written, video, audio)**

Copyright – automatically protects all written works, presentations, training courses, etc., as well as video and audio recordings, and broadcasts.

Registration – can protect:

- Designs (defined as being "the appearance of the whole or part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture or materials of the product or ornamentation")

- Trade Marks (defined as being “…a sign which can distinguish goods and services from those of competitors. It can be, for example, words, logos or a combination of both…”)

Please refer to the NHS Lanarkshire Copyright Policy for further information.

**Protection versus Publication**

Research activities funded by the NHS may result in the development of IP – usually an Invention – that can potentially be exploited commercially – e.g., the development of a new medical device, drug, treatment or assay.

It is also common for IP to arise outwith the context of any formal research, or other type of project – staff may simply have developed an idea for an Invention that could help address a problem that they have encountered in delivering patient care.

IP 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 IP such as this 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.

Researchers are obliged, as a condition of their NHS Ethics approval, to seek to disseminate their research results in national peer reviewed professional journals. Outwith the context of research, staff may be naturally keen to let people know that they have an idea that can potentially help patient.

If any research study or other activity or work has resulted in the IP that has the potential for commercial exploitation, it is important to ensure that suitable IP protection is in place, and that any publication of results or discussion or dissemination of an idea or Invention does not jeopardise this protection - see the following section.

**Maintaining confidentiality – safeguarding IP**

Public disclosure of results or information about an Invention, including publishing, will jeopardise the potential for protection of that Invention. 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.

Prior disclosure is one of the most common reasons why Inventions arising from academic research that would be otherwise Patenable - 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.

If you think you have made an invention, (or any other type of IP), you should not tell anyone until you have taken advice from the Senior R&D Manager.

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 that the NHS provides. Should a conflict arise, the best interests of the NHS and the country as a whole will prevail.
In order to protect the interests of NHS Lanarkshire during negotiations regarding commercial exploitation of IP, a non-disclosure agreement should be used. A template agreement is attached (Appendix 2); this should be completed in conjunction with the Senior R&D Manager.

In order to establish the date an Invention has been made, and who made it (two factors which are crucial to obtaining Patent protection) it is good practice to keep proper records of research or other work that lead to the Invention (e.g. laboratory notebooks).

It is recommended that each page of laboratory notebooks is dated and signed by the research worker and countersigned, perhaps once a week.

The R&D Manager will assess the IP, and may call upon the resources of the technology transfer staff of SHIL to assist with protection and subsequent commercialisation.
APPENDIX 4: EXPLOITATION OF INTELLECTUAL PROPERTY

Financial support from NHS Lanarkshire for exploitation of IP
NHS Lanarkshire is responsible for the cost effective exploitation of IP that it owns.

NHS Lanarkshire must minimise speculative financial investment from public funds. Therefore, as much as possible, a private partner should assume the financial risk of exploitation. To actively exploit IP and minimise the risks involved, NHS Lanarkshire will seek to assign or license IP to commercial, or other organisations, able and willing to meet all, or most, of the exploitation in return for a share of any subsequent income.

The executive responsibility for the decision to protect IP, and to commercialise it, rests with the Director of Public Health who will be advised by Scottish Health Innovations Limited.

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 spinout company in which the individual inventors may have equity and equity may be held on behalf of NHS Lanarkshire Board, and assigning or licensing the IP to the spinout.

The above options are not exclusive.

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

Contracts with external organisations
NHS Lanarkshire Staff must contact the R&D Department before any contract with an external organisation is entered into or negotiated, where IP will be 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 an authorised signatory of NHS Lanarkshire, such as the Director of Public Health, must sign all contracts to ensure that they have legal validity. NHS Lanarkshire must ensure that contracts with external organisations are on appropriate terms and that NHS Lanarkshire has obtained expert advice where necessary.

In many cases research and clinical work (Projects) will be undertaken either with the support of, or in conjunction with, organisations that are external to NHS Lanarkshire (whether such organisations are commercial, government agencies or charities). In these cases it is essential that a formal agreement be reached with the external organisation prior to work commencing.

The R&D Department, Innovation Champion, and other NHS Lanarkshire Departments or other party/parties acting on behalf of NHS Lanarkshire that NHS Lanarkshire deems appropriate, will be involved in the negotiation of such agreements.

Such agreements should provide for, as a minimum, the following:

- The input by NHS Lanarkshire and the parties involved in each Project

A mechanism for sharing profits which may arise from each Project, including the exploitation of any result that may have commercial value. NHS Lanarkshire 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 each Project
• The respective obligations of the parties to the agreement including the obligations of liability, confidentiality and publication procedures

**Alternative approaches to exploitation**

It is recognised that the initial planned route to exploitation of any Invention cannot be guaranteed to be successful. There are many potential barriers to successful commercialisation of products that can arise at any stage between the initial idea and a product coming to market, including, but not limited to:

• Patent applications
• Prototype development
• Contracting with third parties
• Production and marketing
• Sales and logistics.

In the event of any initially attempted route to commercial exploitation not being successful NHS Lanarkshire may, at its sole discretion, seek alternative approaches.

Any alternative approach will be subject to adherence to the existing terms and conditions of any agreements or contracts that it has entered into with third parties.