Procedure for the management of intellectual property

|  |  |  |
| --- | --- | --- |
| **Document Control** | **Number** | **GP/I1-1** |
| **Policy Manual/System** | **General Procedure** |
| **Author** | Research & Development Manager  | **Version No** | 8 |
| **Reviewer** | Research & Development Commercial Manager, Research & Development Manager  | **Implementation Date** | 01/10/2013 |
| **Approved By Responsible Director** | Medical Director  | **Next Review Date** | 13/10/2022 |
| **Last Review Date** | 13/10/2019 |

General Note

NHS Fife acknowledges and agrees with the importance of regular and timely review of policy/procedure statements and aims to review policies within the timescales set out.

New policies/procedures will be subject to a review date of no more than 1 year from the date of first issue.

Reviewed policies/procedures will have a review date set that is relevant to the content (advised by the author) but will be no longer than 3 years.

If a policy/procedure is past its review date then the content will remain extant until such time as the policy/procedure review is complete and the new version published, or there are national policy or legislative changes.

**1. FUNCTION**

1.1 NHS Fife has a responsibility to capitalise on opportunities to exploit Intellectual Property (IP) from any of its core and research activities.

1.2 This procedure sets out the process for the effective management of IP within NHS Fife.

**2. LOCATION**

This procedure applies across NHS Fife and is applicable to the following groups:

2.1 Staff

2.1.1 All staff with NHS Fife contracts of employment, whether employed in Research and Development, clinical, managerial, administrative or support roles.

2.1.2 Staff with NHS Fife contracts of employment whose payroll costs are wholly or partially funded by another party (including, but not limited to: a commercial sponsor, government department, or medical charity); unless the contract of employment between NHS Fife and that party assigns ownership of IP to that party.

2.1.3 Staff who have a part-time NHS Fife contract or who are employed part-time elsewhere. Where IP is generated during this non-NHS Fife employment, but which is within the specialist area of NHS Fife employment, NHS Fife has rights of ownership to all or part of the IP. Flexibility will be exercised where the non-NHS Fife employment gives a greater opportunity for IP to arise.

2.1.4 Agency or consultancy staff employed within NHS Fife.

2.1.5 Non Executive Directors of NHS Fife who generate IP arising from their time spent within NHS Fife.

2.1.6 Members of the public who are representatives on NHS Fife's statutory groups under the Patient Focus Public Involvement Agenda, e.g. the Involving People Team.

2.1.7 Trainees and students hosted by NHS Fife for training purposes are subject to the management arrangements for IP of NHS Fife staff when appropriate agreements are put in place (see 2.2 below).

2.1.8 Staff who generate IP outside normal working hours and/or away from their place of work where the IP relates to their normal course of duties.

2.1.9 Where NHS Fife staff are seconded to another organisation or are working in partnership with other organisations, NHS Fife will agree an arrangement for sharing IP and revenue, based on the assumption that all IP generated by NHS Fife employees remains the property of the Board.

2.2 Trainees and Students

2.2.1 If they are not otherwise employees, students are not classed as employees simply by undertaking activity on NHS Fife premises. As such they are not covered by the relevant provisions governing IP ownership.

2.2.2 It will be the responsibility of Line Managers who have students engaging in work on behalf of NHS Fife to ensure that they sign a confidentiality and assignation agreement that will require the student to disclose details of any invention and assign the rights to NHS Fife on request.

2.2.3 In consideration of all issues relating to IP the student is treated on a par with NHS Fife staff.

2.2.4 Other researchers in NHS Fife who are neither staff nor students e.g. Senior Research Fellows and other emeritus staff, will normally be brought within the scope of this agreement.

2.3 Independent Providers of Services (including Independent Contractors)

2.3.1 Reference should be made to HSC 1998/106 and clauses 2.69 – 2.72 Framework & Guidance on the Management of Intellectual Property in the NHS 2002.

2.3.2 Independent Providers of Services who generate IP from NHS Funded R&D are required to share benefits of its commercialisation with the Scottish Executive Health Department.

2.3.3 Independent Providers of Services who generate IP from delivery of their contracted service in the area of patient care can exploit this IP independently, provided no further NHS resources are utilised.

2.3.4 Independent Providers of Service who assign IP generated by them to NHS Fife will be eligible for all benefits under the sharing scheme of that organisation.

**3. RESPONSIBILITY**

3.1 **All staff**have the responsibility to ensure that they act in accordance with this procedure and under no circumstances will they disclose, sell, assign or trade IP without NHS Fife agreement.

3.2 It is the responsibility of all **Line Managers**to ensure that their staff have read, and comply with, this procedure.

3.3 The Assistant **Research and Development Director**, as the IP Lead, has overall responsibility for the management and exploitation of IP for NHS Fife. Responsibility includes ensuring that this procedure is implemented across the organisation.

3.4 The **Executive Lead for Research and Development**is responsible for overall implementation and review of the procedure.

**4. OPERATIONAL SYSTEM**

|  |  |  |  |
| --- | --- | --- | --- |
| 4.1 IP is the tangible output (new ideas or concepts) of any intellectual or creative activity that is new or previously un-described. IP can be owned and it can be bought, sold or licensed and must be adequately protected. IP can include inventions, industrial processes, software, data, written work, designs and images. IP Rights are the legally protected rights to the IP which can be exerted through patents, copyright, design rights, trade marks or know-how which allow the owners to exert monopoly control over the exploitation of these rights and prevent others exploiting the IP. Details of types of IP and the protection used for each are given in Table 1 below: Type of IP | Protection | Examples | Protection Method |
| Inventions | Patents | New diagnostic equipment, surgical tools, new drugs | Patent Office registration |
| Literary works, written information, computer software, original questionnaires, films & videos | Copyright | Leaflets, articles, training packs, photographs, computer based forms | Automatic but ownership is made clear by adding ©NHS Fife |
| Designs, design | Design rights | Illustrations, | Patent Office |

|  |  |  |
| --- | --- | --- |
| drawings, shape, configurations | aesthetic objects | registration |
| Sign, symbol, product brand names | Trade marks | Logo, slogan | Patent Office registration |
| Trade secrets | Know-how | Surgical technique | Keeping it secret |

Table 1: Examples of Intellectual Property, protection available and mechanisms of exerting protection.

4.2 Once protected, resources can be spent developing results into something useful and investment made in making the results more widely available, with the expectation of recovering that expenditure.

4.3 Generation of Intellectual Property

It is recognised that NHS Fife staff from any discipline or activity can generate new ideas, inventions, innovative solutions or new ways of working during the normal course of their employment.

If properly managed, these will lead to improvements in the running of hospitals / services or the delivery of healthcare, with improvements for patients and patient care. Innovation is not restricted to those involved in R&D, but occurs throughout the NHS and can involve novel treatments, new diagnostics, devices, new drugs or their new use, data, software, training material, treatment protocols or new management systems.

4.4 Ownership of Intellectual Property

4.4.1 In accordance with UK employment law, the Patents Act (1977) and the Copyright, Designs and Patents Act (1988), the right of ownership to any IP created by an NHS Fife employee during the course of their employment will normally reside with NHS Fife. Staff must not under any circumstances sell, assign or trade IP without NHS Fife agreement.

4.4.2 IP identified via audit or brought to the R&D Department’s attention will be required to be recorded in an Invention Record /disclosure form. Such IP will be assessed by the Assistant R&D Director who will discuss details of the IP with Scottish Health Innovations Ltd (SHIL), a Technology Transfer Office who provide the necessary support and advice in managing Intellectual Property for NHS Scotland. If it is decided to explore the potential further, a meeting will be arranged with the R&D Department, the inventor and SHIL to advise whether or not the NHS should exploit the IP, and if so, to discuss the routes for exploitation. Recommended outcomes will be reported to the Executive Lead for R&D, for final decision regarding NHS Fife selecting the IP for exploitation.

4.4.3 In circumstances in which NHS Fife chooses not to take up its rights to the Intellectual Property, the IP rights of ownership (IPR) may be assigned to the employee. IP which has been generated by an employee, in their own time, without NHS Fife resources and which is unconnected with their normal contracted course of duties, will normally be owned by the employee.

4.4.4 There are situations where IP will arise as a result of interaction with other institutions, including staff joint or Honorary appointments with other institutions. Specific exceptions regarding ownership may also occur where joint work is undertaken with other organisations such as: other NHS bodies; Universities; other academic institutions; and commercial organisations. In such circumstances, IP may be owned by an external sponsor or funding body where ownership of any resulting IP has been specifically defined and agreed in the contract to undertake that work.

4.5 Responsibility for Exploitation of Intellectual Property

NHS bodies are responsible for the cost effective exploitation of any IP which they own. However, exploiting IP can be expensive and NHS Fife may bear considerable financial risk in taking a project on. Any exploitation should be done in a way which minimises speculative financial investment from public funds and which does not detract from their primary role in the NHS. Generally, whenever possible, as much risk as possible should be borne by a private partner.

4.6 Staff Obligations

Employees identifying or creating IP thought suitable for protection and / or commercial exploitation whilst acting in the course of the employment, or at any other time using NHS Fife resources, are obliged to inform their Manager and the R&D Office at their earliest opportunity. Ownership of the IP and prospects for its commercialisation will then be discussed.

4.7 Dissemination

A natural reaction is often to publish findings as soon as possible in order to contribute to new knowledge and improvements in healthcare. However, early public disclosure can be counter-productive, especially when results could have led to a new treatment or drug. If details are published before the IP is protected it is unlikely that the product will be made or the process developed since exclusive rights to the IP would normally be a prerequisite. By avoiding disclosure and undertaking proper protection, new treatments will be developed and become available, with substantial royalties being paid for the new invention.

4.8 Safeguarding Intellectual Property - Confidentiality

4.8.1 The public disclosure of any IP with potential to be exploited, to anyone outside NHS Fife, will jeopardise the future potential for protection. Disclosure includes presenting papers or posters at conferences, abstracts, chapters in books, and any other written communication or even conversation. An invention needs to remain secret prior to any patent application and know-how must remain confidential if it is to be exploited. IP cannot normally be protected once prior disclosure has occurred, no matter how informal. Publication of any work relating to an invention or know-how must be avoided until advice has been sought from the R&D Office.

4.8.2 Confidentiality is generally protected by using written agreements and an NHS Fife Non Disclosure Agreement (Appendix 1) can be used to safeguard unprotected IP. Agreements are available from the R&D Office which, when completed, will enable staff to then discuss their IP with external parties.

4.9 Record Keeping

4.9.1 An NHS Fife Invention Record (Appendix 2), available from the R&D Office, should be used to register your invention/idea. Once completed, this should be submitted to the R&D Office for assessment on how best to proceed and will ensure ideas for patenting are processed as quickly as possible. After assessment it may be possible to make public the nature of the idea by publishing an article, giving a talk or poster presentation or disclosing to any outside organisation.

4.9.2 The R&D Office will maintain a register of all IP owned by NHS Fife where a member of the organisation’s 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 they are the Inventor/Author of a creative product. Details will also be kept of arrangements entered into by NHS Fife for the protection and subsequent use of the IP.

4.10 Decisions on Exploitation

In consultation with the Inventor, NHS Fife, any patent organisations and other specialists (e.g. SHIL), it is the role of the R&D Office to advise on the potential for a new invention/idea to be exploited. Their recommendation will be made to the Executive Lead and the final decision to protect IP by patenting or other means rests with the Fife NHS Board.

4.11 Financial Arrangements -

Revenue Sharing with Inventors/Distribution of Residual Income

4.11.1 Although there is no legal requirement to share income from IP exploitation with employees who created it in the normal course of their duties, NHS Fife wishes to encourage full participation of employees in the commercial exploitation of IP.

4.11.2 NHS Fife takes every step to recognise staff who have contributed substantially to the generation of the IP. Such individuals will be named as the Inventor on a patent or Author on copyright material and will also be due a share of any net revenue received from the commercialisation of the Intellectual Property Rights. Shared revenue will be net of all costs involved in the protection and exploitation of the IP (e.g. patent costs, fees due to SHIL for their role in IP exploitation).

Income will be allocated between NHS Fife and the Inventor/Author according to the revenue sharing formula given below in Table 2:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Cumulative Net Income | Inventor | Inventors Department | R&D Department | Fife NHS Board |
| First £50,000 | 50% | 10% | 20% | 20% |
| Next £100,000 | 40% | 10% | 25% | 25% |
| Next £100,000 | 30% | 10% | 30% | 30% |
| Over £250,000 | 25% | 10% | 32.5% | 32.5% |

Table 2: IP Revenue Sharing Distribution Formula of *Net*Income.

4.11.3 In cases where several staff have been involved in generating the IP, the proportion of the income allocated to inventors will be divided amongst them by agreement on the basis of their relative inventive contributions. Discussions if required to be managed by R&D Director who will facilitate any disputes.

4.12 Intellectual Property Management Structure

4.12.1 It is the role of the appointed IP Lead to assume overall responsibility for the management and exploitation of IP for NHS Fife, reporting to the Executive Lead for Research and Development, who reports to the NHS Fife Chief Executive. The appointed IP Lead for NHS Fife is the Assistant R&D Director. The R&D office should be the first point of contact for staff seeking information and advice on IP issues.

4.12.2 A wide range of specialist skills are required to undertake the protection and exploitation of IP and external expert advice will be sought as required from a variety of sources including patent agents, local enterprise companies, and solicitors. A Services Agreement is in place between NHS Fife and SHIL, who provide the necessary support and advice in managing IP for NHS Scotland.

4.13 Agreements with Partner Bodies

Where learning institutions present agreements for entry into by NHS Fife, any clause relating to IP needs to be tested against NHS Fife policy. Agreements on IP will be included as appropriate within individual partnership agreements (e.g. Memoranda of Understanding (MOUs) with Universities).

4.14 Awareness Raising

It is crucial that all staff are aware of the issues arising from the management of IP and to this end raising awareness will be covered in the following ways. Whilst arrangements will be made to include information on IP in the NHS Fife Corporate Induction Programme for new employees, it is the responsibility of the local manager to ensure that this issue is also covered within the local departmental induction process. In addition, information will be contained within the NHS Fife website, R&D newsletter and Staff Handbook on an ongoing basis. IP will be included in the Induction Training with regular ongoing seminars and training events provided by the R&D Office to raise awareness across the organisation of the importance of identification, record keeping, protection and exploitation of IP. Internal communication mechanisms e.g. NHS Fife Newsletter and payslips will also be used as a route to raise awareness around IP. Scottish Health Innovations Ltd also provide IP advice clinics within the R&D Department or on request to discuss notional IP.

4.15 Intellectual Property Audits

Technology Audits (Opportunity Surveys) will be carried out from time to time by the R&D Office in order to identify any potential IP arising from staff activities and assess any commercial possibilities. Such audits will involve questionnaires and meetings with staff to discuss the technology transfer process and undertake a preliminary assessment of potential innovations suitable for exploitation. Identification of potential IP at an early stage is essential to ensure that correct action is taken to protect any IP which might later be developed.

4.16 Contracts of Employment

As part of their employment contract or honorary contract, staff will be made aware of the IP Policy. NHS Fife will include a statement referring to IP within the contract issued to all new staff. For existing staff, the policy will be incorporated into their terms and conditions of employment via the normal national and local collective bargaining arrangements and by the adoption of this policy. A statement will be included in the Licence to Operate agreement for those working on a Licence to Operate basis.

**5. RISK MANAGEMENT**

5.1 The adoption and implementation of this procedure will significantly reduce risks due to the unregulated development of IP within NHS Fife.

5.2 The risk will be further reduced through the links established by the Assistant R&D Director with SHIL which is recognised throughout the NHS as an organisation trained in IP protection and development and has a Framework Agreement with NHS Fife.

5.3 This procedure will be regularly reviewed as part of the implementation process.

**6. RELATED DOCUMENTS**

? Appendix 1: NHS Fife Non-Disclosure Agreement

? Appendix 2: NHS Fife Invention Record/Disclosure Form

**7. REFERENCES**

? Handling Inventions and Other Intellectual Property. A Guide for NHS Researchers. NHS Executive. 1998

? The Management of Intellectual Property and Related Matters. An Introductory Handbook for R&D Managers and Advisers in NHS Trusts and Independent providers of NHS Services. NHS Executive. 1998

? Policy Framework for the Management of Intellectual Property within the NHS Arising from Research & Development. NHS MEL (1998) 23

? Patent Protection. The Patent Office. 1998

? The Patents Act. 1977

? The Copyright, Designs and Patents Act. 1988

? Baker Report. ‘Creating Knowledge Creating Wealth’ - Realising the Economic Potential of Public Sector Research Establishments. 1999

? Research Governance Framework for Health and Community Care. 2006.

? Guidance for NHS Scotland is set out in "A Framework and Guidance on the Management of Intellectual Property in the NHSScotland" (HDL(2004)9).

**Related Publications**

* [GP-I1 -1 - Management of Intellectual Procedure - Appendix 1](https://intranet.fife.scot.nhs.uk/uploadfiles/publications/GP-I1%20-1%20%20-%20Management%20of%20Intellectual%20Procedure%20-%20Appendix%201.docx)
* [GP-I1 -1 - Management of Intellectual Procedure - Appendix 2](https://intranet.fife.scot.nhs.uk/uploadfiles/publications/GP-I1%20-1%20%20-%20Management%20of%20Intellectual%20Procedure%20-%20Appendix%202.docx)

**Related Policies**

* [GP/I1 - Management of Intellectual Property Policy](https://intranet.fife.scot.nhs.uk/atoz/index.cfm?fuseaction=policy.display&objectid=2AC5F2A2-B724-A4DD-185EB6120FD5075D)