

Supporting Innovation in Health and Social Care in Northern Ireland

Innovation Policy

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This document was produced by *HSC Innovations* on behalf of the HSC Research and Development Office and the Northern Ireland Department of Health, Social Services and Public Safety (DHSSPSNI). Any feedback or requests for further information should be directed through:

HSC Innovations
Clinical Research Support Centre
1st Floor
Education and Research Centre
Royal Hospitals
Grosvenor Road
Belfast
BT12 6BA

Tel: 028 9063 5794
Fax: 028 9063 3328
E-mail: innovations@crsc.n-i.nhs.uk
Web: www.crsc.n-i.nhs.uk/innovations

1. Summary

Innovation in the HSC is highlighted as an essential activity, leading to both improvements in health and wellbeing, and to improvements in infrastructure. Such innovation occurs naturally from the work and creativity of its employees and may arise from both within and outside specifically identified research and development activities.

DHSSPSNI wishes to embed innovation at the centre of HSC activities, to ensure that every opportunity to derive benefit for service users, the Northern Ireland health and social care system and the economy of the region is maximised.

The main premise of this policy is that innovations arising from HSC research and clinical activities are identified; and IP is protected, managed and developed in the interests of patients and society as a whole. This policy clarifies the rules of ownership of IP arising from HSC employees' work, and sets out the procedures to be followed, to ensure appropriate identification, protection, development, and sharing of income generated through exploitation. *HSC Innovations* will provide the necessary support to ensure that HSC Bodies are able to fulfil the obligations of this policy.

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3. Glossary of Terms

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| Confidential Disclosure Agreement (CDA) | Legally binding document that enables you to record the terms under which confidential (or secret) information is exchanged between different organisations. Also known as Confidentiality Agreements (CA) or Non-Disclosure Agreements (NDA). |
| Copyright | Legal right that can be used to protect written information, databases, computer software and audiovisual materials. |
| Clinical Research Support Centre (CRSC) | The Clinical Research Support Centre was established to provide comprehensive advice and practical help to clinical researchers in Northern Ireland. |
| Design right | Legal right that can be used to protect against deliberate copying of the shape or configuration of an object. |
| Disclosure | Giving out information about an innovation. Disclosure before the innovation has been protected, or without the protection of a confidential disclosure agreement, can jeopardise commercialisation of the innovation. |
| DHSSPSNI | Department of Health, Social Services and Public Safety Northern Ireland |
| HSC | Health and Social Care, the name applied to public sector health and social care providers in Northern Ireland. |
| <i>HSC Innovations</i> | The innovation management service providing advice and support for the development of innovations arising from within Northern Ireland's Health and Social Care organisations. |
| Innovation | The successful development of new ideas, products or methods that deliver healthcare benefits. |
| Intellectual Property (IP) | Asset resulting from intellectual or creative activity e.g. information and knowledge. |
| Intellectual Property Rights (IPR) | Rights obtained to protect and use intellectual property. |
| Invention Disclosure Form (IDF) | This form captures data, research findings, and background information relating to an idea. |
| Inventor | Person who devises, creates or designs a new process, device or other invention. |
| Material Transfer Agreement (MTA) | Legally binding document that is used to control how a material is used, and the ownership of any work carried out using the material, when it is transferred from one organisation to another. |
| National Health Service (NHS) | The National Health Service is the national publicly funded healthcare system. |
| Patent | Legal right that can be used to protect inventions. |

| | |
|------------------------------------|---|
| Publication | Article published in a journal that is aimed at a wide audience and that details the findings from research and development activity or clinical practice. |
| Regional Innovation Strategy (RIS) | <i>think/create/innovate - the Regional Innovation Strategy for Northern Ireland</i> was published in June 2003 by an Inter-Departmental Working Group comprising all Northern Ireland Government Departments and Invest Northern Ireland. The vision of the RIS is to 'create a culture and environment within which Northern Ireland will prosper by using its knowledge, skills and capacity to innovate'. |
| Revenue Sharing Agreement | Agreed distribution of any revenue generated by the commercialisation of intellectual property. |
| Trademark | Legal right that can be used to protect a sign or symbol which is used to distinguish a product or service. |

4. Introduction

4.1. Innovation Policy Drivers

The importance of innovation in generating service improvement and economic benefit is now a central tenet of Government policy. The drive to secure an innovative culture within the public sector is backed by numerous policy initiatives both nationally¹⁻³ and regionally⁴⁻⁵.

The Regional Innovation Strategy (RIS) for Northern Ireland (NI)⁴, entitled '*think, create, innovate*' has a vision to '*create a culture and environment within which Northern Ireland will prosper by using its knowledge, skills and capacity to innovate.*' The RIS involves all stakeholders within the region including the public sector, academia and the private sector.

On behalf of the Department of Health, Social Services and Public Safety for Northern Ireland (DHSSPSNI), the Research and Development Office for the HSC (R&D Office) is required to co-ordinate Health and Social Care (HSC) research and innovation policy. The R&D Office aims to improve linkages between public and private sector research and development (R&D) and to develop opportunities to both apply and commercialise publicly funded research.

4.2. Value of Intellectual Property for Health

Innovation in the HSC is an essential activity, leading to both improvements in health and wellbeing, and to improvements in infrastructure⁶. Such innovation occurs naturally from the work and creativity of its employees and may arise from both within and outside specifically identified research and development activities.

DHSSPSNI wishes to embed innovation at the centre of HSC activities, to ensure that every opportunity to derive benefit for service users, the Northern Ireland health and social care system and the economy of the region is maximised.

4.3. Identification and Management of Intellectual Property

The Government recognises that intellectual property (IP) arising from public sector research establishments is a valuable asset and that such IP must be properly protected and managed. The Research Governance Framework for Health and Social Care⁷ requires the HSC to identify, and where appropriate protect, manage and exploit, IP generated from HSC R&D and other clinical practice. The Research Governance Controls Assurance Standard⁸ highlights the importance of innovation and IP within the HSC as a means of ensuring that advances in health and social care are developed and made available to patients. Innovation is also included as one of the five strategic priorities of the HSC R&D Strategy⁹. It is the objective of the R&D Office to '*support the identification, assessment and management of IP, with the aim of generating improved technologies and treatments for service users.*' Proper management of IP is a requisite for effective innovation through the successful application and exploitation of new ideas, which help to secure real improvements in health and social care practices throughout the HSC.

4.4. Sources of Innovation in Health and Social Care

The HSC recognises that innovation occurs naturally from the work and creativity of its employees. This innovation arises from both within and outside specifically identified R&D activities, and can take a number of forms, for example: a novel therapy; a novel diagnostic procedure; a new or improved device; a new drug or its new use; data; software; training material; a treatment protocol; or a new management system¹⁰⁻¹¹. The development and adoption of such new ideas, technologies, design or best practice through the innovation process leads to significant improvements in the delivery of health and social care for the benefit of all involved in the process.

4.5. Supporting an Innovation Culture

The HSC seeks to encourage all of its employees to make innovative contributions. Whereas the primary driver of this policy document is the proper protection and management of IP arising from formal HSC R&D, the policy and support mechanisms apply equally to IP and innovations irrespective of their source within the HSC. All innovations/IP arising from any HSC sector or activity should be appropriately developed. This may be achieved by a number of mechanisms, ranging from dissemination throughout a Trust, the HSC, or the wider NHS, to commercial exploitation in order to gain access to a wider market and other healthcare systems. IP is the key that unlocks innovation for the benefit of both current and future health and social care.

4.6. Health and Social Care Innovation Policy

The main premise of this policy is that innovations arising from HSC research and clinical activities are identified; and IP is protected, managed and developed in the interests of patients and society as a whole. This policy clarifies the rules of ownership of IP arising from HSC employees' work, and sets out the procedures to be followed, to ensure appropriate identification, protection, development, and sharing of income generated through exploitation.

4.7. Health and Social Care Innovations

The policy has been produced by *HSC Innovations* in consultation with the relevant local and national stakeholders on behalf of the R&D Office. *HSC Innovations* is based within the Clinical Research Support Centre (CRSC), and provides one of a number of services provided by the CRSC in support of HSC clinical research¹². As such, *HSC Innovations* is an important regional resource for support and advice relating to all aspects of the identification and management of IP and other innovation activities.

5. Intellectual Property and Intellectual Property Rights

5.1. What is Intellectual Property?

Intellectual Property (IP) is the output of any intellectual activity (e.g. knowledge, design, a way of doing something, a technology, device, or treatment) that is new or previously un-described. It has an owner, and it can be bought, sold or licensed. Once it is in the public domain (thus disclosed) it can no longer be protected (controlled and restricted in its availability or dissemination). Therefore, before any IP is made public, it must be adequately protected in order to ensure that it can be further developed and bring ultimate benefit to the HSC and the wider health and social care community.

Intellectual Property Rights (IPR) are the rights obtained to both use and protect these IP assets. Appendix B provides an overview of the different types of IP.

5.2. Categories of Intellectual Property

The following IP categories are relevant to the HSC.

| Category | Protection Method | Examples |
|-------------------|---------------------|---|
| Inventions | Patents | New medical device, medicinal substance |
| Literary works | Copyright | Computer software, patient leaflet, journal article |
| Designs, drawings | Design rights | Medical illustration, medical device |
| Brand names | Trade marks | Trust logo, equipment logo |
| Trade secrets | Know-how, knowledge | Surgical technique |

To further develop innovations, IP must be available, unpublished and protected by IPR. Appendix C contains a flow chart outlining the steps involved in taking an idea through the innovation process to healthcare benefits and potential revenue generation.

5.3. Publication of Research Findings

Successful commercial development often depends upon the protection of IP or commercial confidentiality at critical points in the research and development pathway as part of the innovation process. The timing of the publication (for example: manuscript, book, conference, presentation, internet, and conversation) of research findings needs to take account of this, as the publication of these research findings prior to IP assessment and protection will mean that the opportunities for and benefits of further development will not be realised, and therefore potential benefits to healthcare lost.

6. Ownership of Intellectual Property

The ownership of IP, in most cases, will reside with the employing organisation of the person(s) who generated it. This applies to all IP produced by HSC employees in the course of their normal duties. IP generated as a result of activities that fall outside of the normal duties of the employee (and that are undertaken outside HSC time and facilities), will belong to the employee. The only exception to this rule is where an employee is directed to perform other duties as part of their employment and generation of IP might reasonably be expected to result. This is in accordance with the Patents Act 1977¹³ and the Copyright, Designs and Patents Act 1988¹⁴.

Contracts of employment should address IP issues, including ownership and revenue sharing arrangements. Revenue sharing arrangements are an important means of encouraging staff to think about innovation and the importance of IP in developing new healthcare products and also promote an innovation culture.

6.1. Contracts of Employment

An IP clause will be included in the contract of employment for all new staff. For existing staff, the policy will be incorporated into their terms and conditions of employment. Temporary staff supplied via external employment agencies will be covered by an agreement drawn up between the HSC Body and the external employment agency. In addition, where appropriate, these individuals will be asked to sign a confidentiality agreement.

6.2. Collaborative Projects

If work/research is conducted by an employee in partnership with another organisation, a formal agreement stating ownership (or sharing) of generated IP is required. *HSC Innovations* should be consulted when developing IP sharing agreements between HSC staff and collaborating institutions. In the instance where there are a number of projects involving a third party (for example: University of Ulster or Queen's University Belfast), a framework document will be put in place between the HSC Body and the third party detailing the principles of assessment of contribution, ownership, and revenue share resulting from the exploitation of any IP generated.

This fulfils the requirements for good research governance as outlined in Criterion 13 of the Research Governance Controls Assurance Standard⁸.

6.3. Shared Materials

Materials are defined as equipment, reagents and biological materials, including cell lines, tissues, proteins, antibodies, bacterial strains, plasmids and viruses. In the course of research projects, materials may be obtained from another organisation/collaborator or donated by a company for use within the HSC.

Materials that are generated within the HSC may also be transferred to other organisations or companies to be used within their research programmes. When the transfer of such materials occurs they should be subject to a Material Transfer Agreement (MTA). This agreement should define the limitations of use of the material, and recognise the interest in the IP that may arise from its use. This agreement must be in place prior to distribution and use of the material, and all exchange of material must comply with legislation, for example; the Human Tissue Act (2004). The use of trade marks and design rights associated with the aforementioned materials should also be the subject of this agreement.

6.4. Disputes of Ownership

The importance of identifying IP early, engaging with *HSC Innovations* and putting in place the necessary agreements will usually mean that IP ownership is not disputed.

However, if the ownership of IP is disputed, dated written records relating to the IP in question will be assessed to establish the inventor(s) and their proportionate contribution. If such material is not available, the Director of Research in the relevant Trust, in consultation with *HSC Innovations* lead, will make a final decision, taking professional advice if necessary.

7. Persons Covered by this Policy

7.1. HSC Employees

This policy applies to all members of HSC staff, specifically including the following groups:

- (a) All staff that are full or part time employees of any HSC Body. This includes HSC Staff who generate IP outside normal working hours and/or away from their place of work, where the IP relates to their area of employment within the HSC Body.
- (b) Staff with HSC contracts of employment whose payroll costs are partially or wholly funded by another party (e.g. medical charity, a government department, or university) unless the contract between the HSC Body and that party assigns ownership of any IP to that party.
- (c) Staff who have a part-time HSC contract and who are self-employed or otherwise employed part-time. Where IP is generated during this non-HSC employment, and which is within the specialist area of the HSC Body employment, the HSC Body will own the IP. (Flexibility will be exercised where the non-HSC employment gives a greater opportunity for IP to arise).
- (d) Trainee professionals hosted by the HSC Body who generate IP during the course of their training.
- (e) HSC staff seconded to another organisation, or employees of another organisation hosted by the HSC Body under contract, are subject to the arrangements for the ownership of IP agreed between the HSC Body and that other organisation.

In some instances, the HSC may decide not to prosecute its IP rights and may assign ownership of the IP to the relevant inventor or lead investigator. In this circumstance, costs would be borne by the assignee, and the employee may pursue and exploit patents in their own time and without utilising HSC or Trust facilities and resources.

7.2. Students and Other Researchers

Students who are not employees of the HSC are not subject to the provisions in the 1977 Patent Act or in the Copyright, Designs and Patents Act 1988. However, students engaging in research within the HSC will sign a confidentiality agreement. This agreement will also require the student to disclose details of any invention and assign the associated rights to the HSC Body on request. In consideration of all issues relating to IP, the student is treated on a par with HSC staff.

Other researchers working within the HSC Body, who are neither staff nor students e.g. Senior Research Fellows and other emeritus staff, will be included within the scope of this agreement.

7.3. Responsibilities of Inventors/Employees

Employees have an obligation to inform their employing organisation (i.e. any of the following: the HSC Trust Research Office, Director of Research, or the *HSC Innovations* lead) about identified or potential IP resulting from their activities. They are also strongly advised to contact *HSC Innovations* at the earliest opportunity to ensure that any potential IP arising from research or other activity can be appropriately protected and developed. An employee must not under any circumstances disclose before protection, sell, assign, license, give or otherwise trade IP without the prior agreement of their HSC Body. Appendix D outlines the key areas employees should be aware of.

7.4. Responsibilities of Employers

To fulfil the requirements for good research governance, HSC Bodies must ensure that employees are aware of the potential for IP arising from both research and clinical practice, and the support available to them (Research Governance Controls Assurance Standard⁸). Employers must also ensure that IP is identified and assessed, and where appropriate protected, managed and exploited. Support for this activity is available through *HSC Innovations* in CRSC (see section 8.1). Appendix E outlines the key areas employers should be aware of.

8. Exploitation of Intellectual Property

The development and exploitation of IP involves both costs and risks. Consequently, it will not always be appropriate or cost effective to seek to protect and exploit potential IP. Where this is the case, research and clinical findings may be disseminated via publication in peer reviewed journals, conference proceedings or by sharing best practice.

8.1. Provision of IP Skills

HSC Innovations will provide all HSC Bodies and all members of staff with a number of services to support innovation and IP activities, which include:

- IP and innovation management services.
- Efficient identification, assessment, and management of IP assets through protection and technology development processes.
- Development of an innovation culture through training and education.
- Training in the management and development of HSC IP assets.
- Acceleration of potential products to market and revenue streams.
- Links with the healthcare industry – both access to and commercialisation of IP.

An Innovation Lead will be identified for each HSC Body. These Innovation Leads will work closely with *HSC Innovations* and the HSC Trust Research Offices, to provide innovation support and act as 'technology scouts' within their respective organisations.

8.2. Identification of Innovations

HSC Innovations will assist HSC staff with the identification of IP by increasing awareness about what IP is, how it originates, and how it should be managed. In some cases, where it would be beneficial to probe more thoroughly into specific areas, *HSC Innovations* will undertake innovation audits (opportunity surveys). IP management tools will also be made available (e.g. advice leaflets; IP registration, evaluation, and both confidentiality and material transfer agreements).

8.3. Decisions on Exploitation

It is the role of *HSC Innovations* and the appropriate contact within the HSC Body (for example the Research Office), in consultation with the inventor and other specialists, to decide on the potential for an idea/invention to be exploited. For a strong case to be made, the information reported should effectively demonstrate the potential market and the likelihood of success of the venture.

As indicated in the flow chart in Appendix C there are a number of stages ('Stop/Go' points) in the innovation process where a decision on whether to proceed will be made. When the outcome of the decision-making process is that an invention will not be taken forward for exploitation, for example either because of IP issues or because it is not possible to demonstrate a market for the idea, the inventor will always be informed of the rationale behind the decision. In addition, ownership of the project will be offered back to the inventor(s) or their collaborators/funding bodies, as appropriate.

In cases such as this, where it is not appropriate or cost effective to proceed with the protection and exploitation of potential IP, the research and clinical findings may be disseminated via publication in peer reviewed journals, conference proceedings or by sharing best practice. As outlined in Appendix C, publication and dissemination of research and other findings can proceed after IP protection is in place. By seeking advice early and preparing

manuscripts for publication concurrently with securing IP rights, it is not necessary to delay dissemination processes.

8.4. Contract Negotiations

Contracts for research will be processed by the relevant person (R&D Manager/Director of R&D/Contracts Manager) for the HSC Body, and should be scrutinised for clauses relating to IPR¹⁵. All clauses should be negotiated to be fair and equitable. When material/equipment is used from a third party, Material Transfer Agreements (MTA) should always be in place, clarifying the interest of the third party in any resulting IP. *HSC Innovations* will assist with this process.

Any IP that is licensed, sold or otherwise transferred to another organisation will be negotiated in the best interests of the HSC by *HSC Innovations* with assistance from professional advisers arranged by *HSC Innovations* as required.

8.5. Revenue Sharing with Inventors

The HSC wishes to encourage full participation of employees in the creation and commercial exploitation of IP. The policy will therefore be to reward members of staff that have contributed substantially to the generation of IP, which has subsequently provided revenue through exploitation. Such revenue will be shared between the HSC Body and the inventor according to an agreed revenue sharing formula. In cases where several members of staff have been involved in generating the IP, the proportion of income allocated to inventors will be divided between them on the basis of their relative inventive contributions.

The initial £1000 (gross) from any revenue generation will be distributed to the inventor(s) without deduction of any protection and exploitation costs. All further revenue sharing will be net of any protection and exploitation costs (e.g. patent costs). Revenue in excess of £1000 will be distributed as outlined in the table below.

HSC revenue sharing from IP

| Cumulative Net Income | Inventor(s) | Inventor's Department | HSC Body |
|-----------------------|-------------|-----------------------|----------|
| £1000 to £10,000 | 80% | 10% | 10% |
| Over £10,000 | 34% | 33% | 33% |

Notes:

- (a) This revenue sharing policy is similar to that applied by universities, in order to minimise the potential for conflict within inter-HSC/university groups.
- (b) Revenue (before distribution) is to the HSC body per se, but it will be shared with the inventor and the inventor's Division/Department in a consistent and continuing way that encourages the development of new ideas and inventions.

Appendix A References

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14. *Copyright, Designs and Patents Act 1988*, <http://www.ipo.gov.uk/cdpact1988.pdf>.
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Appendix B Intellectual Property Protection

This appendix includes a very brief overview of some aspects of IP protection. It must be noted that the law is complex, and members of staff are advised to contact *HSC Innovations* in CRSC, at the earliest opportunity, to discuss in more detail any circumstances in which IP protection may be required.

B.1. Copyright

Written information (such as leaflets, articles, assessment tools and training packs), images, databases, computer software and films/videos can all be protected by copyright. Copyright is achieved automatically when the IP is created. However, it is advisable to attach a statement to emphasise the protection, such as:

© HSC Trust 2008. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner.

B.2. Patents

Patents can be used to protect inventions that embody a new idea and are capable of being made or used by industry (such as devices, processes or methods of operation). There are some inventions for which patent protection cannot be obtained, such as methods of treatment of humans/animals by surgery or therapy, and methods of diagnosis. *HSC Innovations* can provide advice on what may or may not be patented. An invention must not have been made public anywhere in the world prior to the patent filing date (including publication in journals or on the internet, oral or poster presentation at meetings etc.) and must not be obvious, compared to what is already known to someone who is experienced in the relevant field.

B.3. Design Rights

Design Right protects against deliberate copying of the shape or configuration of an article. Design Right may exist in addition to other forms of protection such as Patent, Copyright or Trademark.

(a) **Unregistered Design Rights**

Unregistered Design Rights are not directly associated with appearance. The Right can protect internal and external features, but only gives protection against copying of features of shape and configuration (e.g. physical design of computer chips, engineering components and architectural drawings).

(b) **Registered Design Rights**

In some new products the novelty lies not in a new idea or principle, but in their appearance. Registered Design Rights usually cover commercial objects with a unique or aesthetic appearance.

B.4. Trademarks

A trademark is a sign or symbol that is used to distinguish a product or service from that produced or supplied by another business. It could be the design of a label or the shape of a product's packaging (for example, the Coca-Cola bottle). The term 'sign' includes logos, slogans, words, colours and 3-D shapes.

Registering a trademark protects the owner from competitors also trying to use that brand to promote their own products. Trademarks can be very valuable in maintaining a brand as a market leader.

B.5. Know-How

Confidential information or 'know-how' is information that may be commercially or technically valuable, and is regarded as secret. It may, for example, include information on industrial processes, or be a list of clients.

In all cases, the 'know-how' will only retain its value if it is managed effectively. All exploitation partners, business partners and collaborators should be bound by conditions of confidentiality through a Confidential Disclosure Agreement (CDA). This may be a reciprocal agreement whereby confidential information is both disclosed and received. Advice on CDAs may be obtained from the *HSC Innovations* and your organisation's R&D Office or Manager.

Know-how and confidential information can be bought, sold and licensed like any other form of IP and persist indefinitely, as long as they remain 'secret'.

B.6. Importance of IP protection

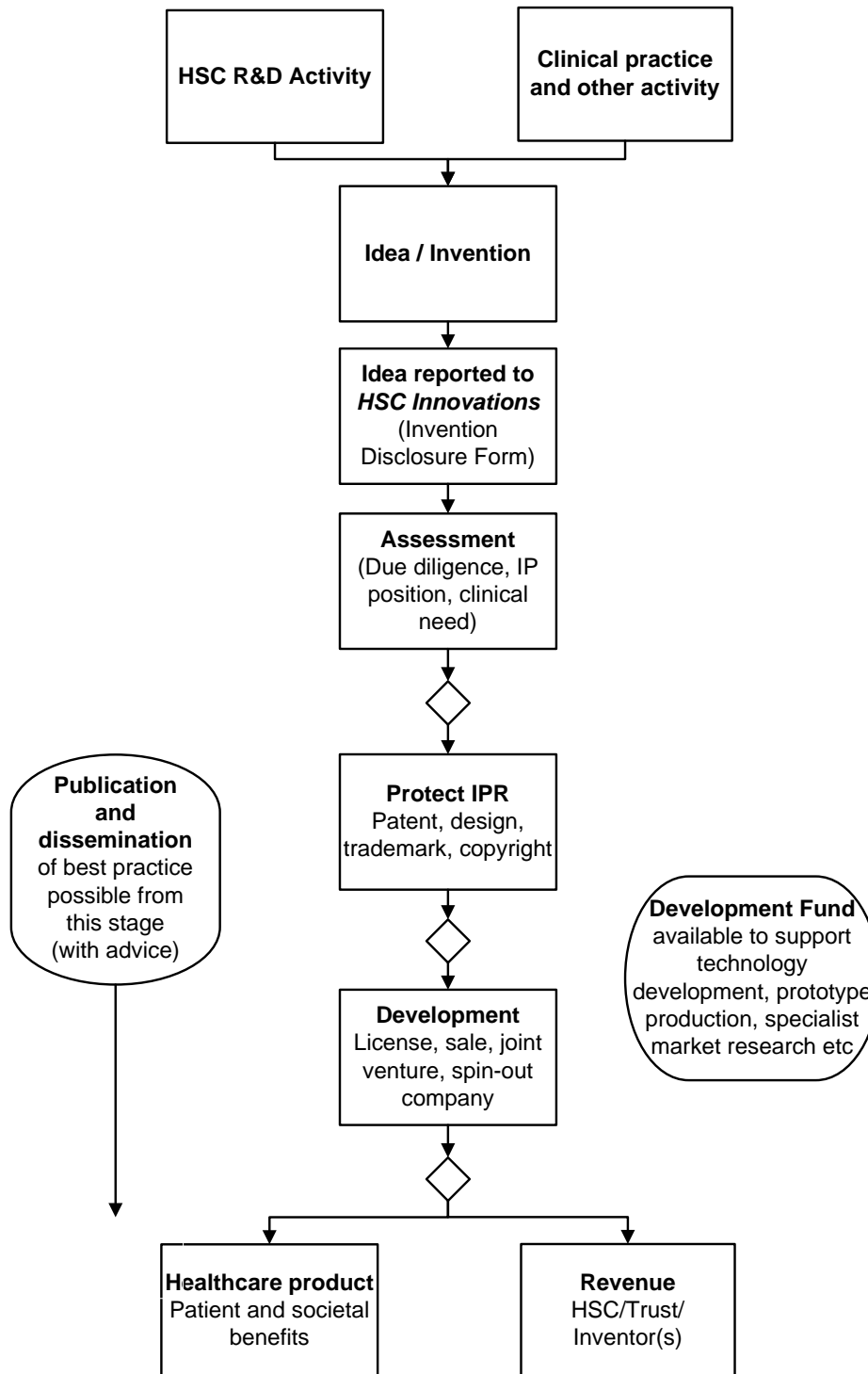
If you have an idea for a new or improved device, what should you do? If a prototype for the device is to be made, it should first be protected, preferably through a patent or registered design right. A commercial manufacturer is unlikely to make your device in future, however good it is, unless the IP is protected. They will need to know that the improvement has not been publicly disclosed, and that the prototype or the design organisation has been working under conditions of confidentiality. The basis of IP protection in this example applies to other innovations as well. To develop innovations, IP must be available, unpublished and protected.

B.7. Example of Local Innovation

A local example of realising innovation, which you may be familiar with, is that of world's first mobile defibrillator. In 1965, at the Royal Victoria hospital, Belfast, a team led by Professor Frank Pantridge converted a mains defibrillator to operate from two car batteries in the back of an old ambulance - it weighed 70 kilos. This invention was the forerunner of what was to become the portable defibrillator which has saved the lives of countless cardiac patients over the past 40 years. The technology had significant IP associated with it and was protected by a family of worldwide patents. This IP protection contributed significantly to its successful exploitation.

Appendix C Innovation Flowchart

Flowchart showing the process of developing an idea to obtain healthcare benefits.



◇ STOP/GO decision point. If 'STOP' decision made, the invention will be offered back to the inventor (or funding body/collaborators if appropriate). If 'GO' decision made, the invention is progressed to the next stage of the process.

Appendix D Staff Responsibilities

D.1. Publications

It is HSC policy to actively encourage employees to publish their work and HSC Bodies will not normally object to an employee's right to be named as an author of copyright material. However, if IP is to be exploited, all work needs to be kept confidential until it is correctly protected.

The peer-review process for many scientific and clinical publications does not protect any confidential information contained within articles submitted for consideration. It is therefore essential that protection for IPR is sought before papers are submitted to journals.

Many funding bodies have a policy to ensure that information contained within grant applications is kept confidential. Funding bodies may, however, wish to publish extracts from the application on their website or other promotional materials in order to communicate how their money is being spent. Care should be taken not to disclose any confidential information in sections that may be used for such purposes.

Advice should be sought from *HSC Innovations* before publicly disclosing any work, including the submission of publications and grant applications.

D.2. Confidentiality

Any IP with the potential to be exploited must not be disclosed to anyone outside the HSC Body (including presenting papers or posters at conferences, abstracts, chapters in books or any other verbal or written communication) until IP advice has been sought from *HSC Innovations* (or your R&D Manager or Research Office). IP cannot normally be protected (especially in the case of filing patents) once prior disclosure has occurred, no matter how informal.

D.3. Record Keeping

It is important for HSC staff working on projects which generate IP, to keep written, dated records of their activities and results. This is especially important for patent application purposes in the US, since the US has a policy of 'first to invent' rather than the 'first to file' rule in the UK. When exploiting IP it is imperative that all correspondence, including emails, telephone conversations and meetings are logged to provide a detailed account of any discussions relating to the IP. This is in accordance with clinical governance, research governance and good clinical practice guidelines for R&D.

Research Offices are responsible for maintaining a register of all the IP owned by their HSC Body, including the date and time it was reported to the Research Office. Research Offices will share this register with *HSC Innovations*, who in turn will share information about new IP with the appropriate Research Office(s). It is also their responsibility to keep safe any important original documents, such as confidential disclosure agreements, relating to IP. It is advisable that key members of staff concerned should also retain copies of these documents.

D.4. Due Diligence

The due diligence process to be undertaken by *HSC Innovations* will include:

- Identification of inventors and their relative contributions.
- Confirmation of the employment status of the individuals concerned.
- Determination of the sources of funding of the invention, including the sources of salary support of the individuals concerned, and any obligations to external funding bodies, whether industrial or charitable.

- Discussion with the individuals about when, where and how the invention arose.
- The contributions and rights of third party research funders.
- The due diligence process will assist in determining (or confirming) the ownership of the invention and will identify the relative contributions of the interested parties. An equitable revenue sharing agreement will then be negotiated on the basis of the information provided (see section 8.5).

Appendix E Employer Responsibilities

E.1. Intellectual Property

HSC Bodies have a responsibility for ensuring the identification and assessment of intellectual property, and where appropriate its subsequent protection, management and exploitation.

E.2. Innovation Awareness

HSC Bodies have a responsibility for ensuring that employees are aware of the potential for intellectual property arising from both research and clinical practice, and the support available to them.

E.3. Agreements

HSC Bodies should ensure that there are agreements between them and the following:

- their staff;
- research funders;
- other care organisations;
- universities;
- industry; and
- any other 'third party'

to cover areas such as ownership, exploitation and income from any intellectual property that may arise from research or clinical practice conducted by their employees. They should also ensure that any material used for research (for example, cultures, cell-lines, proteins, antibodies, plasmids, pharmaceuticals and other chemicals) is covered under a Material Transfer Agreement.

The CRSC has a remit to provide advice and practical support in the conduct of clinical research within HSC. As such, support and advice for the management of intellectual property and other innovation activities will be delivered through *HSC Innovations* service at CRSC.