

Innovation and Intellectual Property Policy

Version 2.2

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Innovation and Intellectual Property Policy

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Associated documents

BHT Ref	Title	Location/Link

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1. Introduction

This document outlines this organisation's policy for the effective management of intellectual property (IP) and is based on Department of Health guidance. It gives a brief definition of what IP is, with information on who to contact if you have an invention/idea/innovation that you think may need protecting or if you require general advice on IP arising from your work. Buckinghamshire Healthcare NHS Trust (BHT) recognises that all colleagues during the course of their employment, and from any discipline, may generate new ideas and innovative ways of working that if developed could lead to improved clinical services or methods of working.

1.1 This supports the Trust's key strategic objective to provide outstanding patient care.

1.2 The Trust seeks to encourage and enable employees to participate in the generation of IP as part of its commitment to encourage innovation and to deliver the best possible patient care. BHT aims to maintain a balance between the legitimate needs of the Trust to protect its interests (IP is seen as an asset), and the provision of a creative environment for employees in which to work.

1.3 The UK Policy framework for Health and Social Care Research 2017, states the importance of protecting IP and the need for accountability for any IP arising from research.

2. Scope

2.1 This policy applies to all colleagues who are full or part time employees of the Trust, trainee professionals hosted by the Trust and agency colleagues contracted by the Trust and is in line with the terms and conditions of your employment contract with the Trust. This includes:

- Colleagues with Trust 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 the Trust and that party assigns ownership of IP to that party.
- Trainee professionals employed by the Trust (e.g., specialist registrars) hosted by the Trust who generates IP during the course of their training.
- Colleagues who have a part-time Trust contract or who are employed part-time elsewhere. Where IP is generated during this non-Trust employment, but which is within the specialist area of the Trust employment, the Trust has rights of ownership to all or part of the IP.
- Colleagues working at the Trust under an agency contract, the HR and contracts teams are responsible for ensuring agency contracts appropriately reference IP ownership.
- Colleagues 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/knowledge gained during their employment at the Trust.

- Where Trust colleagues are seconded to another organisation or are working in partnership with other organisations, the Trust will agree an arrangement for sharing IP and revenue.

Broadly speaking, IP is owned by its creator (i.e., the author of a copyright work, or the inventor of a patentable invention), unless otherwise agreed (in a contract for example).

The exception is where a person is an employee. If an employee creates something in the course of their employment, the general rule is that the IP will belong to the employer. Therefore, if an employee of the Trust creates a copyright work (such as a report or paper) or invents a patentable invention in the course of their employment with the Trust, the IP will belong to the Trust. This is the case even if the IP is created off Trust premises, outside normal working hours or using home equipment.

Where colleagues have joint or honorary contracts with another organisation (e.g., a university) IP will be managed under a partnership agreement.

3. Definitions

3.1 Intellectual Property (IP)

IP can be defined as products of innovative and intellectual or creative activity and can include inventions, industrial processes, software, data, written work, designs and images.

3.2 Intellectual Property Rights (IPR)

IP can be given legal recognition of ownership through intellectual property rights (IPRs) which also enable people to earn recognition and/or financial benefit from what they have invented or created. Examples of IP that may be developed in the NHS include: training manuals, clinical guidelines, books and journal articles, software packages, applications (APPs), new or improved designs, medical devices, equipment, new uses for existing drugs, diagnostic tests, and new treatments. IPRs which are most relevant to the Trust include:

- Patents (inventions)
Patents protect inventions, for example a novel compound for therapeutic use, a new use for a known compound, or a new type of medical instrument or device. A patentable invention is a product or process which is:
 - New (also known as novel);
 - Involves an inventive step;
 - Capable of industrial application; and
 - Not a subject matter which is excluded from patent protection by the law.

It should be noted that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded.

Patents must be registered in order to be protected.

It is important to note that disclosing the invention to third parties, or to the public at large is likely to mean that it is impossible to either obtain patent protection or protect the invention as confidential information.

- Copyright (original content)

Copyright protects original content (also known as 'works') such as literary works, software, photographs, films, and music. 'Literary works' can include such things as annual reports, website content, guidance notes, and blog entries, and 'software' of course has huge application in the health industry.

Copyright arises automatically on creation – it does not need to be registered.

- Design rights

A design right can protect the appearance of all or part of a physical product. However, it does not protect design concepts or drawings and methods of making the product. These may be protected by other IP rights such as patents or copyright.

Design rights can be registered or unregistered and give protection in the UK or in the EU. See appendix 1 for further detail.

- Trademarks (brands)

These protect brands and other signs which identify a business – for example works (e.g., Buckinghamshire Healthcare NHS Trust), letters (e.g., NHS), and stylised logos (e.g., the blue and white "NHS" logo). Trademarks can be registered or unregistered; however, it is more effective to register a trademark.

- Confidential Information (trade secrets and know-how)

This protects valuable information kept or received in confidence, such as know-how and trade secrets. Even if a patent cannot be obtained for an invention, it is possible to retain some degree of protection for the invention by maintaining it as a trade secret. Since the value of confidential information is maintained for as long as it is kept secret, whereas a patent has to be made public and gives monopoly protection only for up to 20 years, it can be preferable to protect some inventions as trade secrets.

3.3 Innovations which need to be developed commercially (and which should be to maximise the benefit to patients, the Trust and to the individual) are called inventions and the employee responsible for the innovation is called the inventor.

4. Roles and Responsibilities

4.1 The potential for commercial exploitation of IP is large and it is essential that colleagues are made aware of its importance. It is the Trust's responsibility to undertake this and to communicate this policy and to make it available on the Trust's intranet.

4.2 It is a responsibility of all colleagues that if there is IP that has potential for exploitation, then it should neither be discussed nor shown to any third party who is not under a legal obligation

to keep it confidential. This means that employees and their collaborators must not make IP public via publications, abstracts, presentations at meetings etc. until such time as a patent application is filed. They must maintain absolute confidentiality. The Research and Innovation Department Innovation Manager can advise and arrange for a Non-Disclosure Agreement to be in place prior to any discussions with external individuals or organisations.

Employees should ensure that they keep full records of their ideas, including copies of all correspondence and notes of telephone conversations and meetings; and mark all notes and journals with the date and time. This is important in cases where proof is required to assess novelty and therefore in the protection, exploitation and defence of IP.

Each employee should as part of their own work management practice keep full records for each invention or creation showing;

- What was invented or created
- Who invented or created it
- When was it created
- Who has the invention or creation been disclosed to
- Whether any other person's IP was used to generate the invention or work (and the associated licence agreement)
- Any other details the employee considers relevant

4.3 The Trust will maintain details of all IP rights owned by the Trust which have been licenced or assigned to a third party where an employee is a named inventor or originator. Details of these IP rights and the income they generate will be given to the independent regulator (Monitor) or the Department of Health, from time to time, on request.

4.4 The Research and Innovation Department is responsible for being the initial point of contact for advice and provides information to Trust employees on the policy at induction. They will provide details of the support available for the correct management of IP.

4.5 Employees have the responsibility of keeping accurate and dated laboratory notebooks, or records of their work, so that in the event of similar IP being generated elsewhere, the ownership of the invention can be legally attributed. Such notebooks can be important when applying for patents and also for identifying know-how.

4.6 Employees must take no steps to exploit any BHT IP without the specific approval of the Trust's Board of Directors on recommendations from the Research and Innovation Executive Committee or delegated representative.

4.7 The Director of Strategy and Business Development will be responsible for ensuring that formal legal advice is made available to protect and advise the Head of Research and Innovation and Innovation Manager on all innovations and IP rights issues.

5. Ownership

- 5.1 The Trust legally owns all IP (Copyright, Designs and Patent Act 1988) arising from the delivery of patient care, the education and training of employees and research and development programmes undertaken by its employees in the course of work for BHT unless such IP is subject to a separate written agreement with an external funding organisation or agreed otherwise.
- 5.2 The ownership of IP arising from activities undertaken jointly with another organisation will be assigned to either of the employing organisations by agreement unless subject to prior agreement with a third-party external organisation. The proportion of IP contributed by each party will be agreed by discussion between the parties as early in the process as possible.
- 5.3 In exceptional circumstances the Trust may without prejudice to its legal rights decide not to maintain its IPR and may assign ownership of the IP to the relevant inventors (assignees) with their agreement, the costs of such assignment to be borne by the assignee. In such cases, the assignees may pursue and exploit the relevant IP in their own time and without utilising Trust facilities and resources.
- 5.4 All service level agreements (SLAs) should include a clause on IPR, whether or not the agreement with BHT is for the provision or commission of services. All SLAs should protect the ownership of IP generated within the Trust and by its employees, with or without partner organisations. For instance, in some cases there will be contractual arrangements under which the arising IP belongs to a third party. Managers responsible for SLAs should ensure they are familiar with any relevant SLA so as to meet the requirements in relation to reporting and protection of IP.

6. Distribution of Income Generated from Exploitation of Intellectual Property

- 6.1 The revenue from successful exploitation, whether a lump sum, sale of shares or royalties, from option, licence, collaboration or assignments agreements are:
- First subject to repayment of external patenting (filing, searching etc.) and legal costs and execution of legal obligations or financial obligations to the funding body, to management charges incurred by the Research and Innovation Department and to pay Commercialisation Fees due to other Advisor Organisation(s).
 - Then between Inventor, Inventor Department, Research and Innovation Department and Trust and are subject to clause 6.4 below.
- 6.2 The inventor's share of net revenue may be treated as a discretionary gift by the Trust which is intended to continue for the inventor's lifetime or the expiry of the licence agreement, whichever event occurs sooner.

Any net revenue will be distributed as personal income (paid via payroll and which is subject to income tax). It should be noted that BHT expects any revenue sharing scheme to begin

from the point at which the innovation was registered with BHT and will not usually consider retrospective claims.

When licencing IP, the percentage will change as income accumulates from any given deal. Therefore, when paid in tranches, the inventor’s percentage will drop over time.

6.3 Section 5 of the Health and Social Care Act 2001 authorises Trusts to form or participate in the formation of companies and to invest in companies for income generation purposes. In particular, this enables them to participate fully in companies established to exploit Trust IP, including acquiring shares, subject to approval of a business case.

The Trust, together with its Advisor Organisation(s), may determine that the best route for exploitation of Trust IP is via the setting up of a new company (commonly called a spin-out company). The Trust and the inventor(s) will be eligible to own an equity share in the company. The size of the respective shareholdings will be decided on a case by case basis, taking into account the contributions of all parties and other funders. In the event that the inventor(s) are given equity in the new company, the revenue sharing provisions of clause 6.4 will not apply.

6.4 In the event that a colleague leaves the Trust, the institution retains its right to that material under express licence or ownership, as applicable.

If there is already a revenue share agreement in place this is likely to continue but this is subject to the terms and conditions of the revenue share agreement and the circumstances under which the colleague is leaving the organisation.

If IP is commercialised after a colleague has left and there is no existing revenue share agreement, this may result in a revenue share being agreed with the ex-colleague but this will be discussed on a case by case basis and will be subject to IP law and statutory rights to compensation.

Cumulative Net Revenue over lifetime of the IP	Inventor’s	Inventor Department	Research and Innovation Department	Trust
Up to £10,000	80%	5%	10%	5%
£10,001-£50,000	70%	5%	20%	5%
£50,001-£1,000,000	50%	5%	40%	5%
Over £1,000,000	35%	10%	50%	5%

Table 1-Distribution of Income Generated from Exploitation of IP

7. Employment Contracts

7.1 BHT recognises that some of its employees may hold employment contracts funded jointly by the NHS and another party or funded entirely by another party (e.g., university, medical charity, a commercial sponsor). The Trust will agree and thereafter formalise with the other party how IP generated during the employment is to be managed to the maximum benefit of the Trust and the employee.

7.2 A Trust employee may have a part time NHS contract and be employed part time for example in private practice. If IP arises during this period of NHS employment, it will be owned by the Trust if it is construed to relate to that employment. If there are circumstances which makes it clear that IP arises within the self-employment, then the Trust may agree with the employee alternative terms for the sharing of benefit and will set these out in a legal agreement.

7.3 A Trust employee may have an honorary contract with another organisation e.g., a university which recognises the research status of an employee. IP generated by such an employee will be owned by the Trust. Ownership of IP in other honorary contracts will need to be agreed as described above.

8. Commercial Exploitation

8.1 The Trust is the vehicle for holding patents and other IP, but is free at its absolute discretion to engage another party (e.g., Advisor Organisation) to exploit its IP on its behalf.

8.2 Employees who believe that their work will generate a patentable (or protectable) invention should notify the Research and Innovation Department at the earliest opportunity and in any event, before disclosure of the idea to any party outside BHT either orally, in writing, by e-mail or in any other disclosure.

8.3 When the invention is sufficiently advanced the Research and Innovation Department will arrange for a consultation with a project manager from the relevant Advisory Organisation to assess its patentability and commercial potential.

8.4 A decision to apply for IP protection e.g., patent will signal the need to contract the services of a patent agent and to start seeking a commercial partner. Such discussions may only take place after a confidentiality agreement is signed with a prospective commercial partner.

8.5 A decision not to apply for IP protection and exploitation of the invention will require BHT to determine whether to retain ownership of the IP. If not, the inventor(s) will be invited to meet the cost of legal transfer of ownership to the inventor(s) after which they can pursue the IP at their own expense and in their own time.

9. Disputes

9.1 An employee who believes the Trust has wrongfully claimed ownership of IP shall seek resolution by means of the Trust's grievance procedure. Advice will be available to transfer the IP to the Trust when this is agreed to be necessary. Without transfer of the IP, NHS resources will not be available to the employee to exploit the IP.

9.2 Where external organisations are involved, formal legal advice may be sought by the Trust.

10. Training and Awareness

10.1 Where external organisations are involved, formal legal advice may be sought by the Trust.

10.2 All colleagues will be made aware of this policy by a notice on CAKE. Copies will be available on the intranet. Training will be accessible to all and provided by the Research and Innovation Department.

10.3 Colleagues will receive a copy upon joining the Trust where it is felt particularly appropriate.

11. Equality

11.1 This policy and protocol will be equality impact analysed in accordance with the Trust Procedural Documents Policy, the results of which are published on our public website and monitored by the Equality and Diversity team.

12. Data Protection

12.1 The Data Protection Act 2018 protects personal data which includes information about colleagues, patients and carers. The NHS relies on maintaining the confidentiality and integrity of its data to maintain the trust of the community. Unlawful or unfair processing of personal data may result in the Trust being in breach of its data protection obligations.

13. Records Management

13.1 Employees should ensure that they keep full records of their ideas, including copies of all correspondence and notes of telephone conversations and meetings; and mark all notes and journals with the date and time. This is important in cases where proof is required to assess novelty and therefore in the protection, exploitation and defence of IP.

Each employee should as part of their own work management practice keep full records for each invention or creation showing:

- What was invented or created
- Who invented or created it
- When was it created
- Who has the invention or creation been disclosed to

- Whether any other person’s IP was used to generate the invention or work (and the associated licence agreement)
- Any other details the employee considers relevant

Records are created or received in the conduct of the business activities of BHT and provide evidence and information about these activities. All records are also corporate assets as they hold the corporate knowledge about the Trust. This is particularly relevant and important for IPR, see clause 4.5

The Trust has a Records Management Policy for dealing with records management. Compliance with and the application of this policy, will ensure that the Trust’s records are complete, accurate and provide evidence of and information about, the Trust’s activities for as long as is required.

14. Review

- 14.1 This policy will be reviewed in 3 years’ time. Earlier review may be required in response to exceptional circumstances, organisational change or relevant changes in legislation or guidance.

15. Monitoring

- 15.1 All colleagues will be made aware of this policy. It will be monitored by the Research and Innovation Department who may arrange an audit from time to time to review compliance.

16. Discipline

- 16.1 This policy will be managed through the Trust’s Research and Innovation Executive Committee.
- 16.2 Breaches of this policy will be investigated and may result in the matter being treated as a disciplinary offence under the Trust’s disciplinary procedure, and/or referred to the Trust’s Local Counter Fraud Specialist.

17. Monitoring/Compliance Table

Minimum requirement to be monitored	Process for monitoring e.g. audit	Responsible Individuals to undertake monitoring and production of a report.	Frequency of monitoring / audit	Responsible individuals receiving the monitoring report and for development of action plan.	Responsible committee for review of action plan	Responsible committee for Monitoring of action and audit to ensure satisfactory conclusions.
Yearly	Audit	Innovation Manager	Yearly	Research and Innovation Department Governance Team	Research and Innovation Executive Committee	Research and Innovation Executive Committee

APPENDIX A

Additional Definitions

Advisory Organisation

The advisory organisation is appointed to advise the Trust on matters relating to commercial exploitation of IP.

Assignment

The term given to the outright transfer of ownership of IPR from one person or party to another. It is often, but not always, done in return for a fee. Whilst transfer of ownership of physical property is achieved by delivery of the property from one person to another, IP must be transferred in a written document which is referred to as an assignment.

Commercialisation Fee

The exploitation fee received by the Advisor Organisation.

Copyright

An unregistered IPR, which arises automatically by operation of law in the UK when a protectable work is created by a qualifying author, and there is no registration required. ('Protectable' here describes the class of copyright work, these are: literary, dramatic, musical and artistic works, films, broadcasts and cable programmes. 'Qualifying' refers usually to whether the author is recognised under the Copyright, Designs and Patents Act 1988. Most authors are qualifying authors.) A copyright work must be original. ('Originality' has a relatively low threshold and is not to be confused in any way with whether a copyright work is novel or new. The term 'originality' only refers to the fact that the author must make some amount of effort to produce the work in the first place. The term 'literary' is merely a reference to a written work.) Computer software is treated as a literary work and as such is protected by copyright in the same way as literary and artistic works. Sometimes computer programs may also be protected as patents. Copyright is governed by the Copyright, Designs and Patents Act 1988.

Databases

Databases are protected in one of two ways. Some databases can be protected as copyright works (see above) when the person compiling the database is judged to have used sufficient skill, labour and judgment in devising the compilation. Other databases are protected by a separate Database Right. This lasts for 15 years. Databases protected by Database Right tend to protect the content, as opposed to the organisation and structure of a database. Even so, Database Right is a valuable IPR. It is governed by the Copyright and Rights in Databases Regulations 1997.

Goodwill or Know-how

Intangible assets of an organisation which may not be able to be protected by one or other of the above means but which, nonetheless, may also be of value to a third party and can be exploited through consultancy or licensing and can be protected through the law of confidentiality.

Licence and licensing

The terms given to the permission, which the owner of an IPR may give to any other person or parties to use that IPR. Someone using an IPR without a licence infringes that IPR. The owner may charge a fee in return for the grant of a licence and can impose terms and conditions on its use as part of a licence. There is no transfer of ownership, just a licensing of use and it can be thought of as similar to hiring or renting out other forms of property. Licenses are usually divided as follows. A non-exclusive licence means that the licensor himself can use the rights and he can have any number of licensees. A sole licence means that the rights owner can use the rights but can only create one licence in favour of his licensee. An exclusive licence means that the licensor himself cannot use the rights and only one licence can be created. As can be seen, an exclusive or a sole licence will tend to command more royalty rights or income than a non-exclusive licence.

Licence agreement

An agreement whereby ownership of IP is retained whilst a third party is given rights by the IP owner for development and marketing. Such an agreement sometimes involves payment of an initial lump sum to the owner of the IP, dependent on the commercial potential of the IP, plus royalties as products from the inventions are sold.

Ownership

IP generated by an employee in the normal course of duties belongs legally to the employer. The employer may decide on some kind of income sharing arrangement with the inventor(s) and their department upon successful exploitation of the IP. The employer may decide to waive rights in some cases e.g. copyright on books. In the event of the departure of the inventor(s) from the employing organisation, all IP rights remain with the employing organisation and cannot be transferred with the employee to the new organisation unless by prior agreement.

Patent

Protect original inventions (subject to some exclusions) with industrial application. They are one of the strongest forms of IPR, conferring a 20-year monopoly upon their proprietor and they are infringed even if there is no conscious copying. They have to be applied for and are granted by the state through the Patent Office. They must pass through a rigorous vetting procedure for compliance with the legal requirements before they are granted. Patents are governed by the Patents Act 1977. One of the most important aspects of patent protection is that an invention must be 'novel' meaning that it must be new. Novelty can very easily be destroyed by disclosing the nature of the invention before a patent application is made. For this reason, an invention or details about it should not be disclosed, for example in a scientific paper, poster, presentation (oral or written) or exhibition before an application is made to protect the invention.

Registered design and Design rights

Design Rights under English law can exist in unregistered or registered form. There are differences to UK unregistered and UK registered design right, namely that UK registered design right can protect both two-dimensional and three-dimensional designs, whereas UK unregistered design right can only protect three-dimensional designs and not surface decoration.

UK registered designs protect the shape, configuration, pattern or ornament of an article to the extent that they are new and have "individual character". The main legislation in the UK is the Registered Designs Act 1949.

UK unregistered design right arises automatically by operation of law and, as its name suggests, it does not require to be registered anywhere. Unregistered design right is a proprietary right which subsists in an original design. "Design" for these purposes means the "design of the shape or configuration (whether internal or external) of the whole or part of an article." Unregistered design right does not subsist unless and until the design has been recorded in a design document or an article which has been made to the design. Unregistered Design Rights are governed by the Copyright, Designs and Patents Act 1988. Community design rights afford designs protection throughout the European Union.

Technology transfer

This covers the transfer of ownership of IP or allows a third party to develop and exploit the IP whilst ownership is retained. It is often more broadly defined as the management arrangements under which IP is identified, protected and exploited.

Trademark

Trademarks are signs, such as a distinctive name, emblem or logo which distinguishes the goods and services of one organisation from those of another. It provides protection for the goodwill and reputation of an organisation in its products and services. Registration confers greater protection and there is no time limit.