

Intellectual Property Policy for Research

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Document Abstract
<p>University Hospitals Bristol NHS Foundation Trust is committed to ensuring that innovative ideas and intellectual property (IP) arising from the full range of Trust activities is appropriately protected and exploited for the benefit of NHS patients and employees and for purposes of income generation. IP can arise within or outside of research activities.</p> <p>This Policy describes how IP that arises from research is managed, who owns it, why it needs to be protected, who is responsible for protecting it and where to go for further guidance and input. IP arising from non-research projects will be covered in a separate document.</p>

¹ Divide number of words (1226) by 240 for average reading time and add 25% for specialist content.

Document Change Control				
Date of Version	Version Number	Lead for Revisions	Type of Revision	Description of Revision
August 2007	1.0	Innovation Leader	Major	First draft
May 2011	2.0	Innovation Manager	Minor	Trust name; Revenue Sharing for beneficiaries; Information on Induction and contracts of employment; Equality Impact Assessment
October 2016	3.0	Research Grants Manager	Major	Revised to focus on research intellectual property

Table of Contents

1.	Introduction	4
2.	Purpose and Scope	4
	2.1 Purpose	4
	2.2 Scope	5
3.	Definitions	5
	3.1 Intellectual Property	5
	3.2 Background IP	6
	3.3 Foreground IP	6
4.	Duties, Roles and Responsibilities	6
	4.1 Divisional Management Boards	6
	4.2 Research and Innovation Department	6
	4.3 All Staff	6
5.	Policy Statement and Provisions	7
	5.1 Intellectual Property Rights and Ownership	7
	5.2 Protection process	7
	5.3 Copyright and moral rights	7
	5.4 Contracts of Employment	8
	5.5 Revenue sharing	8
	5.6 Disputes	8
6.	Standards and Key Performance Indicators	8
7.	References	8
8.	Appendix B – Dissemination, Implementation and Training Plan	10
9.	Appendix C – Document Checklist	11

1. Introduction

- (a) The NHS recognises that staff, from any discipline or activity, can generate new ideas, innovative solutions to problems, inventions or better ways of working which may lead to improvements in the delivery of healthcare.
- (b) IP generated from any source is recognised by the NHS as an asset of value which should be used in the best interests of the NHS and the country as a whole by those best able to do so. The Framework and Guidance on the management of IP in the NHS¹ sets out how NHS organisations can take appropriate steps to ensure that the IP, expertise and knowledge base are put to maximum use.
- (c) The Research Governance Framework for Health and Social Care² states that the protection and exploitation of IP is one of the responsibilities of a high quality organisation undertaking R&D and that agreements should be in place with NHS employees and research partners about ownership, exploitation and income from any IP arising from research.
- (d) A Policy Framework³ for the management of IP arising from research has been in existence since 1998, with the management of IP arising from research and development (R&D) being a contractual requirement for Trusts in receipt of NHS R&D Support Funding.
- (e) The current Framework and Guidance¹ extends the requirement of NHS Trusts to identify and exploit innovation arising from the full spectrum of NHS activity i.e. patient care, education and training, administrative and support functions, as well as R&D. An essential aim of wider-Government strategy⁴ is to capture and exploit innovations for the benefit of the UK economy.
- (f) Section 5 of the Health and Social Care Act 2001⁵ empowers NHS Trusts (and therefore employees of NHS Trusts), to participate in spin-out companies established for the purposes of income generation.

2. Purpose and Scope

2.1 Purpose

- (a) To enable staff to participate in research and resultant generation of IP as part of its commitment to deliver the best possible patient care through research. UHBristol will provide the necessary advice and support for handling IP in research projects, so that the outcomes from those projects can be disseminated and exploited to maximise the benefits to patients, staff and the NHS.
- (b) The policy is to provide a balance between the Trust's legitimate needs to protect its interests, and the provision of a facilitative and creative research environment for staff and collaborators from other institutions.

2.2 Scope

- (a) This policy describes what IP is within the context of research. IP arising outside of research will be covered under a separate policy (currently being drafted by the Transformation Director).
- (b) UHBristol Research and Innovation (R&I) Department will advise on what IP within the context of research needs to be protected, why this is important, and will seek external guidance where necessary.
- (c) R&I will ensure relevant contracts and/or other agreements are in place to allow discussion of research with external collaborators including commercial companies where relevant, and management of IP within research projects.
- (d) R&I will liaise with research funders and collaborators in consultation with the researcher to allow revenue sharing where appropriate.

3. Definitions

3.1 Intellectual Property

IP is the tangible output of any intellectual activity that is new or previously un-described. It has an owner, can be bought, sold or licensed, and must be adequately protected (restricted in its availability or dissemination) in order to ensure its appropriate development and ultimate use or exploitation. The following IP categories are relevant to the NHS:

Category	Protection	Examples
Inventions	Patents	New medical device, software system
Literary works	Copyright	Computer software, patient leaflet, journal article
Designs, drawings	Design rights	Medical illustration
Brand names	Trade marks	Trust logo
Trade secrets	Know-how, knowledge	Surgical technique
Research outputs	Copyright, creative commons licence	New clinical care pathways, new methodology, new treatments, questionnaires, patient reported outcome measures

Research grant applications frequently contain a section on the IP of a project. This can include:

- IP already owned by UH Bristol and the project collaborators,
- IP that will be developed during the project
- using other people's IP, for example, in standard assessment tools or questionnaires
- how IP will be managed throughout the project

3.2 Background IP

Any IP that will be used to input into a new research project, generated by either the researcher or by a third party. This can include any of the IP categories described above. If UHBristol does not own the background IP, we need to obtain permission from the owner before using it in a research project, or to establish that permission is not needed if the IP is already in the public domain.

3.3 Foreground IP

This is any IP generated during the course of the research. It can include any of the categories described in section 3.1 and includes improvements in methodologies. It is important to protect the foreground IP so that it can be exploited where appropriate, and also so that others cannot prevent it being exploited for patient benefit.

4. Duties, Roles and Responsibilities

4.1 Divisional Management Boards

This Policy document will be approved by Trust Research Group and the Senior Leadership team. Divisional Research Leads will disseminate to researchers as appropriate.

4.2 Research and Innovation Department

The R&I department will help to identify what IP will arise from your research, and what background IP might be required. Management and ownership of IP will normally be dealt with in research contracts, including collaboration and site agreements. R&I will liaise with all relevant funders and other institutions who own the background IP.

4.3 All Staff

When discussing a research idea, or preparing a research grant application, all staff have a responsibility to check they have the necessary permissions to use anyone else's research and IP for the development of their work. The R&I department can help obtain permission once the source has been identified.

Staff should refrain from discussing ideas with third parties before appropriate agreements including issues around confidentiality have been put in place. This is especially important when discussing your work with commercial companies.

5. Policy Statement and Provisions

5.1 *Intellectual Property Rights and Ownership*

- (a) IP, which arises during, or could reasonably be expected to arise from, the course of the normal contracted duties of a member of staff (including research), belongs to the Trust, unless alternative has been agreed in a contract with another organisation.
- (b) IP generated as a result of a research project will normally be captured as described in the research agreement with funder or collaboration agreement with other institutions or commercial partners involved. For research between members of Bristol Health Partners (BHP), the BHP IP Guidelines⁶ set out how IP ownership will be assigned unless covered under a separate project specific agreement.
- (c) IP generated by an employee, in his or her own time and which is unconnected with their normal contracted course of duties, will be owned by the employee. The employee is responsible for protecting such IP.

5.2 *Protection process*

- (a) Patents, trademarks and designs are protected through external registration with the Patent Office. Copyright is automatic, and does not need registration, but ownership can be established by attaching a copyright statement. Know-how is protected by keeping it secret and not disclosing it to a third party
- (b) If an invention has been disclosed, it cannot be patented. Disclosure means that the invention or any part of it has been published, given in a seminar or conference paper, or discussed with a potential collaborator. Development potential can be lost through prior disclosure.
- (c) Non-disclosure agreements (NDAs) can be put in place prior to any discussions with third parties to prevent loss of developmental potential.

5.3 *Copyright and moral rights*

- (a) Although copyright of any work produced by an employee in the course of employment belongs to the Trust, the Trust will normally grant to the author, a free licence to the copyright of any work published in a recognised scientific, technical, professional or management journal or book. The Trust will not grant such a licence for materials created by a member of staff during the course of and related to their employment, including but not limited to:
 - Course or training materials
 - Patient information
 - Software programmes
 - Designs, specification or other works, which may be necessary to protect rights in commercially exploitable IP
- (a) The Trust will respect the moral rights of its employees to be named as authors in copyright materials

5.4 Contracts of Employment

- (a) The Trust includes a statement about IP in the contract of employment for all new staff. Existing staff will be informed of the existence of this policy and how it relates to them (see Appendix B).
- (b) Temporary staff supplied via external Employment Agencies will be covered by an agreement drawn up between the Trust and External Employment Agencies. In addition these individuals will be asked to sign a non-disclosure agreement.

5.5 Revenue sharing

- (a) The Trust system for revenue sharing encourages the development of new ideas and inventions, and shares revenue on a consistent basis
- (b) The Trust will agree with any external organisations or partners that contribute to generation of IP how revenue will be shared between the parties. The split between parties may be changed dependent on the level of involvement of each partner, and will be agreed between each of them as the IP develops.
- (c) Unless otherwise agreed at the outset, revenue will be shared on an equal share basis (one third to the inventor(s), one third to the department, one third to the Trust). Values are net after deduction to cover any patent and legal expenditure incurred.
- (d) On death of the innovator, the beneficiary will continue to receive such IP payments for the life time of the agreement

5.6 Disputes

Where no alternative arrangements have been documented (for example in research contracts), the Trust's legal department will advise on the process for resolving IP disputes between individual staff, other organisations and the Trust. The Trust may take external legal advice when this is appropriate

6. Standards and Key Performance Indicators

Research contracts and other agreements relating to IP are written and reviewed by the UHBristol R&I department and UHBristol legal team, and if necessary by external advisors.

The time for contracts to be agreed and reviewed can be a barrier to research, and R&I department reviews the time taken to put in place collaboration agreements for NIHR funded grants at monthly KPI reviews.

7. References

1. The NHS as an innovative organisation: a framework and guidance on the management of Intellectual Property in the NHS. 2002. Department of Health Publication 29030
<http://www.nic.nhs.uk/Pages/NHSIPGuidance.aspx>

2. 'Research Governance Framework for Health and Social Care' Department of Health. 2001.
3. HSC 1998/106 'Policy Framework for the management of Intellectual Property within the NHS arising from research and development'
 - 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.
 - Handling inventions and other Intellectual Property: a guide for researchers. NHS Executive. 1998.
4. 'Creating Knowledge Creating Wealth: Realising the Economic Potential of Public Sector Research Establishments'; *Baker Report (Treasury)*
5. 'Health and Social Care Act 2001'. 2001
6. 'Bristol Health Partners IP Guidelines' available from the Research and Innovation Department:

8. Appendix B – Dissemination, Implementation and Training Plan

8.1 The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Research Grants Manager, Research and Innovation
This document replaces existing documentation:	Not Applicable
Existing documentation will be replaced by:	Not Applicable
This document is to be disseminated to:	All Trust research staff
Training is required:	No
The Training Lead is:	N/A

Additional Comments
This Policy will be obtainable from the UHBristol website. It will be disseminated to all Trust staff through Newsbeat and through the R&I department's research e-newsletter. Any staff who have queries relating to the policy or research IP can contact R&I and will be dealt with on a per case basis.

9. Appendix C – Document Checklist

- 9.1 The checklist set out in the following table confirms the status of ‘diligence actions’ required of the ‘Document Owner’ to meet the standards required of University Hospitals Bristol NHS Foundation Trust Procedural Documents. The ‘Approval Authority’ will refer to this checklist, and the Equality Impact Assessment, when considering the draft Procedural Document for approval. All criteria must be met.

Checklist Subject	Checklist Requirement	Document Owner’s Confirmation
Title	The title is clear and unambiguous:	Yes
	The document type is correct (i.e. Strategy, Policy, Protocol, Procedure, etc.):	Yes
Content	The document uses the approved template:	Yes
	The document contains data protected by any legislation (e.g. ‘Personal Data’ as defined in the Data Protection Act 2000):	No
	All terms used are explained in the ‘Definitions’ section:	Yes
	Acronyms are kept to the minimum possible:	Yes
	The ‘target group’ is clear and unambiguous:	Yes
	The ‘purpose and scope’ of the document is clear:	Yes
Document Owner	The ‘Document Owner’ is identified:	Yes
Consultation	Consultation with stakeholders (including Staff-side) can be evidenced where appropriate:	Yes
	The following were consulted:	Trust Director of Transformation University of Bristol tech transfer manager
	Suitable ‘expert advice’ has been sought where necessary:	Yes
Evidence Base	References are cited:	Yes
Trust Objectives	The document relates to the following Strategic or Corporate Objectives:	Research and Innovation Strategy 2014-2019
Equality	The appropriate ‘Equality Impact Assessment’ or ‘Equality Impact Screen’ has been conducted for this document:	Yes
Monitoring	Monitoring provisions are defined:	Not Applicable
	There is an audit plan to assess compliance with the	Not Applicable

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
	provisions set out in this procedural document:	
	The frequency of reviews, and the next review date are appropriate for this procedural document:	Yes
Approval	The correct 'Approval Authority' has been selected for this procedural document:	Yes

Additional Comments
None