

Intellectual Property Rights

UCLH policy

Policy number	086/CLN/T
Issue number	1
Issue date	13/02/17
Approved by	Executive Board
Responsible Director	Medical Director, Corporate
Policy Author	Director of Research Support, Joint Research Office
Review Body	Research Board
Documents to read in conjunction with this policy	None
Complete review by date	31/01/2020

Table of contents	Page Numbers
--------------------------	---------------------

1.	Summary	2
2.	Policy Statement	2
3.	Objectives and Scope	3
4.	Duties	4
5.	Persons Covered by this Policy	4
6.	Ownership of IP	5
7.	Licence	9
8.	Joint Authorship	9
9.	Externally Sponsored or Funded Work	9
10.	Publication	9
11.	Revenue Sharing	10
12.	Assignment of IPR to Trust Staff	12
13.	Collaborative Research	12
14.	Leaving the Trust	12
15.	Agreements with Suppliers	12
16.	Disputes and Appeals	12
17.	Monitoring and Audit	13
18.	References	13
Appendix 1: Definitions		14
Appendix 2: Background		16

1. Summary

- 1.1 This policy sets out for its staff the approach to identifying and exploiting intellectual property (IP) that will be taken at University College London Hospitals NHS Foundation Trust (UCLH).
- 1.2 **Intellectual Property** or IP can be defined as products of innovative, intellectual or creative activity. This includes inventions, industrial processes, software, data, written work, designs and images. In a healthcare environment intellectual property may include training manuals, clinical guidelines, books and journal articles; PowerPoint presentations, inventions, new or improved designs, medical devices, equipment, new uses for existing drugs, diagnostic tests, and new treatments.
- 1.3 This policy defines IP ownership and the types of IP that might be developed in a large NHS tertiary teaching hospital like UCLH (see section 6 and [Appendix 1](#)).
- 1.4 UCLH will own intellectual property created by its staff in the course of their employment. Section 5 provides a definition of UCLH staff and who will fall within the scope of the policy. IP created in the course of employment is explained in paragraph 6.1.2. The policy also covers what happens where UCLH ownership may not be claimed e.g. in the case of specific academic activities UCLH may waive ownership of copyright. **Copyright** is right which automatically arises by operation of law when a protectable work is created and there is no registration required. For more on copyright, see paragraph 6.1 and [Appendix 1](#).
- 1.5 IP is a complex area of law and the UCLH Innovation Office is there to assist staff with intellectual property matters. Staff are advised to contact the Innovation Office with any queries by e-mail ucl-tr.innovation-office@nhs.net or by calling: **020 7679 6639**. Staff can find detailed information about IP in an easy to understand format in the guide: '**UCLH Innovation Office - A staff guide**' which is available on Insight.
- 1.6 Staff must adhere to the UCLH (and UCL for joint appointments) policy on declarations of interest when managing any conflicts that may arise in relation to IP.
- 1.7 All the terms used in this IP Policy are defined under [Appendix 1](#) and background of this policy stated under [Appendix 2](#).

2. Policy statement

- 2.1 UCLH is committed to encouraging the successful exploitation of Intellectual Property and maximising the value of Intellectual Property for the benefit of all. The Trust seeks to promote the recognition, protection and exploitation of potentially valuable IP produced by its staff.

3. Objectives

3.1 The objectives of this policy are to:

Ensure that innovation arising from Research and Development, day-to-day service provision and healthcare delivery which is generated by staff in the normal course of employment is developed and exploited appropriately.

Ensure that IP ownership is safeguarded and IP is adequately protected in the interests of UCLH and where commercialisation has the potential to generate income for UCLH while ensuring that any revenue is shared fairly with employee inventors. (Details of the revenue sharing arrangements to be applied at UCLH can be found at section 12).

Make staff aware of their obligation to inform UCLH (via the Innovation Office) about identified or potential IP resulting from their activities and the need to keep detailed written records.

Scope

3.2 **Intellectual Property** (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.

3.3 IP has an owner and can be bought, sold or licensed and is given legal recognition through a number of different rights such as patents, copyright, design rights, trademarks or know-how (Appendix 1 contains detailed definitions of these rights). Some of these require a registration; others arise automatically. **Licence** and **licensing** are terms given to the permission which the owner of an IPR may give to any other person or parties to use that IPR. Further details can be found under section 7.

3.4 This policy applies to UCLH staff as described in section 5 below and others identified in paragraph 5.2.

4. Duties

4.1 Innovation Office

The Innovation Office will provide support to UCLH departments in raising awareness of IPR matters and also provide specific support in evaluating, developing and exploiting new ideas.

4.2 Staff Obligations

- 4.2.1 Individuals covered by this policy have an obligation to inform the Trust (via the Innovation Office) about identified or potential IP resulting from their activities as soon as practically possible, and to cooperate with all reasonable requests made by UCLH in relation to such IP.
- 4.2.2 UCLH staff must not, under any circumstances, disclose, transfer, sell, assign, license, give or otherwise trade in IP without prior UCLH written agreement (via The Innovation Office) or unless in accordance with any licence granted by UCLH.
- 4.2.3 It is essential that staff working on projects that are likely to generate IP keep detailed written, dated records of their activities and results. It is important that all correspondence, including emails, telephone conversations, and meetings are logged, to provide a detailed account of any discussions relating to the IP.

5. Persons Covered by this Policy

5.1 This policy covers the following persons:

- 5.1.1 All staff who are full or part time employees of the Trust – ownership of IP generated will be determined in accordance with Section 6 of this policy;
- 5.1.2 Staff with Trust contracts of employment whose payroll costs are partially or wholly funded by another party (e.g. medical charity, government department) – ownership of any IP generated will be determined in accordance with Section 6 of this policy unless the contract between the Trust and that party assigns ownership of any IP generated by such staff to that party;
- 5.1.3 Trainee professionals employed or hosted by the Trust (e.g. specialist registrars) – ownership of any IP generated will be determined in accordance with Section 6 of this policy;
- 5.1.4 Staff who have a part-time Trust contract of employment and who are self-employed or otherwise employed part-time (e.g. private practice) – ownership of any IP generated will be determined in accordance with Section 6 of this policy;

- 5.1.5 Trust staff seconded to another organisation, or employees of another organisation hosted by the Trust under contract – ownership of IP generated will be determined in accordance with Section 6 of this policy subject to the arrangements for the ownership of IP agreed between the Trust and that organisation;
- 5.1.6 Staff with joint or honorary contracts with another organisation (e.g. a university) – ownership of IP generated will be determined in accordance with Section 6 of this policy: that is, IP generated during the course of an individual's work for UCLH will be owned by UCLH, whoever the substantive employing organisation is. This applies to University College London (UCL) staff except where a more specific agreement is reached between UCL and UCLH, or is explicit within individual honorary contracts. UCL staff should note that UCLH and UCL have an agreement to share equally any commercial or financial benefits of exploiting IP generated through research.

who are together referred to in this policy as "Staff".

- 5.2 Where someone other than Staff may create IP, the UCLH person responsible for the recruitment of that person should ensure that a contract is entered into with that person which includes appropriate provisions relating to the ownership and/or licensing of IP. This includes interns, students, free-lancers, contractors and those operating through service companies.
- 5.3 If there is a question regarding applicability of this policy to an individual, please contact the Innovation Office.

6. Ownership of IP

6.1 Copyright

- 6.1.1 Please see [Appendix 1](#), paragraph ii of this policy for a definition of "copyright". Under the Copyright, Designs and Patents Act 1988, the Trust will be the first owner of any copyright subsisting in works created by Staff in the course of their employment. The Trust does however recognise its employees' "moral rights" in the copyright works they create (please see [Appendix 1](#), paragraph x for a definition of "moral rights"). **Moral rights** allow the author/ director of a copyright work to assert rights to be known as the author/ director of the work.
- 6.1.2 Whether works have been created in the course of employment will depend upon a number of factors, including the terms of Staff employment contracts, honorary contracts or secondment agreements etc. The Trust policy is that work will be considered to have been created in the course of employment even where Staff create such work outside normal working hours and/or away from their place of work. This will be reflected in any employment contract issued by the Trust.

- 6.1.3 The Trust shall, with respect to personal lecture notes and thesis papers, waive its rights to copyright in favour of the staff member who created, made, or developed the relevant IP.

As a condition, however, of any such waiver of rights by the Trust, Staff may be required to grant the Trust a licence to use the copyright work on the terms set out in Section 8 of this policy.

- 6.1.4 The Trust shall, with respect to journal articles and seminar papers, waive its rights to copyright in favour of the relevant Staff member who created, made or developed the relevant IP

As a condition, however, of any such waiver of rights by the Trust, Staff may be required to grant the Trust a licence to use the copyright work on the terms set out in Section 8 of this policy.

- 6.1.5 The Trust shall, with respect to scholarly books, waive its rights to copyright in favour of the relevant Staff member who created, made or developed the relevant IP.

As a condition however of any such waiver by the Trust, Staff may be required to grant the Trust a licence to use the copyright work on the terms set out in Section 7 of this policy.

- 6.1.6 The requirements for the Trust to assign ownership or grant any licence in Sections 6.1.3 to 6.1.5 shall not apply where the copyright work created by Staff in the course of their employment as set out in Section 6.1.2 consists of training or course materials, software, or clinical evaluation tools, or where the Staff member has been specifically assigned to create the copyright work. **Materials** are physical items of IP that may or may not be subject to IPRs.

- 6.1.7 Where course materials are to be produced by staff for third parties, then Staff should seek advice on copyright ownership from the Innovation Office before preparing the materials or entering into any contract with third parties. Where course materials are to be produced by the Trust Staff outside what the Staff members consider to be their normal duties, then the individual should also seek advice on copyright ownership from the Innovation Office before preparing the materials or entering into any contract with third parties.

- 6.1.8 The standard revenue sharing arrangements will apply in relation to the exploitation of copyright (see Section 12, Table 1 of this policy). All activity in relation to the commercialisation of copyright should be discussed with the Innovation Office (Email: ucl-tr.innovation-office@nhs.net, Tel: **020 7679 6639**).

6.2 Registered and Unregistered Design Rights

- 6.2.1 Please see [Appendix 1](#), paragraph iv of this policy for a definition of "design rights". These rights protect two- and three-dimensional designs and may

co-exist with copyright. Under UK and European Community legislation, the Trust will be the first owner of design rights created by staff in the course of their employment (for UK unregistered and registered design rights) and developed in the execution of their duties or following instructions given by the Trust (for European Union design rights).

- 6.2.2 UCLH policy is that ‘in the course of employment’, or ‘developed in the execution of duties or following instructions given by the Trust’ will encompass the broadest interpretation or understanding possible within the context of the Trust’s day-to-day activity. For example, a design related to the Trust’s field(s) of expertise will still be created in the course of employment, or developed in the execution of duties, even where Staff create or develop such design outside normal working hours and/or away from their place of work. As such any design rights arising under such circumstances shall accrue to the Trust.
- 6.2.3 The standard revenue sharing arrangements will apply in relation to the exploitation of design rights (see Section 12, Table 1 of this policy). The commercialisation of design rights should be discussed with the Innovation Office (Email: ucl-tr.innovation-office@nhs.net, Tel: **020 7679 6639**).

6.3 Databases

- 6.3.1 Database means a collection of data and information managed, updated and accessed. Databases are capable of protection through copyright for the arrangement of data or through database rights for the substantial investment in collecting the constituents (Copyright and Rights in Databases Regulations. SI 3032/1997). The ownership of the copyright vests as detailed in Section 7.1 of this policy above. Please refer [Appendix 1](#) for details.
- 6.3.2 Under the Copyright and Rights in Databases Regulations 1997, the Trust will be the first owner of database rights in databases created by Staff in the course of their employment.
- 6.3.3 Whether databases have been made in the course of employment will depend upon a number of factors, including the terms of Staff employment contracts, honorary contracts or secondment agreements etc. The Trust policy is that a database will be considered to have been made in the course of employment even where Staff make such database outside normal working hours and/or away from their place of work. As such any database rights arising under such circumstances shall accrue to the Trust.
- 6.3.4 The standard revenue sharing arrangements will apply in relation to the exploitation of databases (see Section 12, Table 1 of this policy). The commercialisation of design rights should be discussed with the Innovation Office (Email: ucl-tr.innovation-office@nhs.net, Tel: **020 7679 6639**).

6.4 Patents

- 6.4.1 Please see [Appendix 1](#) paragraph xi for a definition of "patents". Under the Patents Act 1977, the Trust will be the first owner of patents in inventions made by Staff in the course of the normal duties of Staff or in the course of duties outside of normal duties to which Staff have been specifically assigned.
- 6.4.2 The standard revenue sharing arrangements will apply in relation to the exploitation of patents (see Section 12, Table 1 of this policy). All activity in relation to patents, patentable work and commercialisation of technology should be discussed with the Innovation Office (Email: ucl-tr.innovation-office@nhs.net, Tel: **020 7679 6639**).

6.5 Materials and Know-How

- 6.5.1 Please see [Appendix 1](#), paragraphs ix and vii for definitions of "materials" and "know-how." Materials and know-how can also be commercialised, either separately or with patents.
- 6.5.2 Ownership of physical materials will vest in the Trust subject to funding conditions and should only be transferred from the Trust under an appropriate agreement and under specific guidance. For more information about transfer of materials contact the following: i. for materials that fall under HTA regulations contact the Trust Pathology lead; and ii. for other materials contact JRO Contracts & Legal Affairs Manager of the Joint Research Office.
- 6.5.3 Ownership of know-how created by Staff in the course of their employment will vest in the Trust. The Trust policy is that work will be considered to have been created in the course of employment even where Staff create such work outside normal working hours and/or away from their place of work. Know-how can be exploited and protected through the law of confidence. Staff are reminded that it is necessary to keep know-how secret and to disclose it to third parties only in circumstances of confidence and pursuant to an appropriate non-disclosure agreement. For more information, contact JRO Contracts & Legal Affairs Manager.
- 6.6 The standard revenue sharing arrangements will apply in relation to the exploitation of materials and know-how (see Section 12, Table 1 of this policy). The commercialisation of materials and know-how should be discussed with the Innovation Office (Email: ucl-tr.innovation-office@nhs.net, Tel: **020 7679 6639**). Trade marks. Please see [Appendix 1](#), paragraph xiii for a definition of "trade mark". Staff must not apply to register any mark relating in any way to the Trust or its logo, name or brand, or any of the materials, works or inventions where IP rights are owned by the Trust, without the Trust's prior written consent (via the Innovation Office).

7. Licence

- 7.1 Where the Trust waives its ownership of IPR under Sections 6.1.3, 6.1.4, and 6.1.5 of this policy in favour of the Staff member who created, made or developed the relevant IP, the Staff member may be required to grant the Trust a free, unconditional, irrevocable, perpetual, non-exclusive worldwide licence to use such IPR, for academic and commercial purposes, including academic and teaching materials in all formats (now known or yet to be devised), including the right to sub-licence.

8. Joint Authorship

- 8.1 Where joint authorship is planned with an author(s) who is/are not a UCLH employee(s), the member of Staff should declare his/her copyright obligations to the co-author(s) and obtain a prospective agreement from the co-author(s) that the Trust will own copyright in that member of Staff's contribution or, where the Trust waives copyright ownership to that member of Staff in accordance with Sections 6.1.3 – 6.1.5, that the co-authors agree to the Trust's licensing rights to the materials in accordance with Section 7 of this policy.

9. Externally Sponsored or Funded Work

- 9.1 Ownership of IP in a project that is sponsored must be covered by the terms of the research contract between the sponsor and the Trust, and Staff must be informed of the terms of that contract by the Head of Department at the start of the project. If the research contract involves ownership of IP by the sponsor, Staff shall, where required, assign IPR to the Trust to enable the Trust to comply with its obligations under the contract.
- 9.2 UCLH, as appropriate. Specific information may be found in ***UCLH Innovation Office - a Staff Guide*** and by contacting the Innovation Office directly.
- 9.3 Where the Trust owns IP in accordance with Section 7 of this policy and the Trust commercialises such IP, standard revenue sharing arrangements will apply, as set out in Table 1 below.

10. Publication

- 10.1 Staff shall ensure that all copyright works contain an appropriate copyright notice, approved by the Innovation Office.
- 10.2 Staff shall ensure that any disclosure of the details of potential IP to any third party is made pursuant to an appropriate confidentiality agreement and with the prior written agreement of the Trust (via The Innovation Office).
- 10.3 UCLH encourages its staff to assert personal copyright over material submitted for research publication or scholarly publications, where copyright has been assigned by UCLH to the member of staff.
- 10.4 Where clinical evaluation tools form part of any publication, UCLH must not put specific information about the tool in the publication to avoid putting confidential information into the public domain, and should not grant copyright in the tool to the

publisher. Such material may be included only with the prior written consent of UCLH (via The Innovation Office) and by stating that permission is granted by the authors for the specific tool to be included but copyright in that specifically vests with the authors (where copyright has been assigned by UCLH to the authors) or UCLH, as appropriate. Specific information may be found in ***UCLH Innovation Office - a Staff Guide*** and by contacting the Innovation Office directly.

11. Revenue Sharing

11.1 Income from successful exploitation of IP, through sale or licensing of IP, through dividends or sale of shares, will normally be received by UCLH. In achieving this income, UCLH and the adviser organisation may have incurred expenditure for patent or legal work. This expenditure will be recovered as a first charge on income.

11.2 In Table 1 above, the following phrases have the following meanings:

11.2.1 "Net Cumulative Income" is Gross Cumulative Income less patent, legal, and research and development costs as well as other costs incurred by the Trust or its Advisor Organisation in bringing the product to market. Where there is an agreement with a funder or sponsor to share revenue from exploitation of IP arising from research funded by that sponsor, the sponsor's share of revenue will also be taken from the Gross Cumulative Income;

11.2.2 "Gross Cumulative Income" is the cumulative sums received by the Trust in respect of the commercialisation of the relevant IP (excluding VAT and any amounts received by THE TRUST in respect of the research and development of the IP, as distinct from the commercialisation of the IP);

11.2.3 "Advisor Organisation" is the advisor organisation appointed UCL Business PLC to advise the Trust on matters relating to commercial exploitation of intellectual property; and

11.2.4 "Commercialisation Fee" is the amount received by the Advisor Organisation in consideration for leading the commercialisation of the IP and managing the development project.

11.3 The Net Cumulative Income allocated to inventors/authors is shared on the basis of their contribution to the Intellectual Property. For example, equal inventors/authors would each receive half of this income. Where a product derives partly from any works or inventions created by a staff member, then a fair apportionment will be made taking into account all relevant factors and ownership rights.

Revenue Sharing Arrangements

Table 1: Trust's formula for sharing revenue with staff where advisor organisation

(UCL **Advisor organisation reclaims direct costs

*** Trust reclaims direct costs including obligations to funders

Business PLC) or the Trust lead commercialisation of UCLH IP development

Net cumulative income **	Commercialisation Fee	Inventor(s)/Authors (all)*	Trust Central Funds*	Clinical Department*
1) Advisor organisation (UCL Business PLC) leads commercialisation and manages development project and takes on patent filing costs, patent attorney costs, legal costs, provides accounting services, proof of concept or translational funding, marketing services. *each category is under Trust responsibility for distribution ("Trust Responsible Funds"). For the purpose of this policy, Trust Responsible Funds are calculated exclusive of VAT. VAT (where applicable) will be paid by the Trust at the applicable rate.				
≤£100,000	10%	80%	5%	5%
>£100,000 but ≤£1m	30%	50%	15%	5%
>£1m	40%	30%	20%	10%
Net cumulative income **	Commercialisation Fee	Inventor(s)/Authors (all)*	Trust Central Funds*	Clinical Department*
2) Trust Leads commercialisation and advisor organisation provides management of IP, legal services, commercial advice or evaluates the intellectual property position, provides market scoping information and advises of possible routes to commercialisation or other project end point ***				
≤£100,000	Nil	88%	6%	6%
>£100,000 but ≤£1m	Nil	72%	21%	7%
>£1m	Nil	50%	35%	15%

**Advisor organisation reclaims direct costs

*** Trust reclaims direct costs including obligations to funders

12. Assignment of IPR to Trust Staff

- 12.1 Where UCLH chooses not to exploit IPR arising from the work of Trust staff, it will, in most cases (subject to terms/conditions/claims of external bodies such as funders), assign such IPR back to the inventor(s). As a condition of any such assignment, staff may be required to grant UCLH a licence to use the IPR, in accordance with Section 7 of this policy.

Assignment is 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. Intellectual property must be transferred in a written document which is referred to as an assignment.

13. Collaborative research

- 12.1 It is important before embarking on research in collaboration with other organisations that IP ownership and licensing issues are agreed by the parties and documented in an appropriate written agreement.

14. Leaving the Trust

- 14.1 In the event that a member of Staff leaves the Trust, the Trust retains its rights to any IPR under express licence or ownership, as applicable.

15. Agreements with Suppliers

- 15.1 **It is important to ensure that all agreements with suppliers of goods and services** relating to research or day to day service provision and healthcare delivery, in addition to complying with the Trust's Standing Financial Instructions (SFIs) and related procurement policies and procedures, **contain appropriate provisions relating to the ownership and/or licensing of IP.**

16. Disputes and Appeals

- 16.1 Any dispute regarding the assignment of staff IPR should be discussed with the Innovation Office and will be referred thereafter, as appropriate, to the Trust Research Director to arbitrate. Appropriate Trust policies shall be referred to and complied with if the relevant member of staff wishes to appeal following arbitration by the Trust Research Director.

17. Monitoring and Audit

1. Key process/part of this policy for which compliance or effectiveness is being monitored	2. Monitoring method (i.e. audit, report, on-going committee review, survey etc.)	3. Job title and department of person responsible for leading the monitoring	4. Frequency of the monitoring activity	5. Monitoring Committee responsible for receiving the monitoring report/audit results etc.	6. Committee responsible for ensuring that action plans are completed
Effectiveness of tracking intellectual property opportunities by way of a database.	Quarterly review of portfolio and policy adherence by Innovation Office Group.	Research Director and Director of Research Support	At least annually.	Research Board	Research Board

18. References

1. HSC 1998/106. 'Policy Framework for the Management of Intellectual Property within NHS arising from R&D'
2. Department of Health, 1998. 'The Management of Intellectual Property and Related Matters'.
3. Department of Health, 1998. 'Handling Inventions and other Intellectual Property – A Guide for NHS Researchers'.
4. Department of Health, 2001. 'Research Governance Framework for Health and Social Care'.
5. Department of Health, 2002. 'The NHS as an Innovative Organisation. A Framework and Guidance on the Management of Intellectual Property in the NHS'.
6. Department of Health, 2000. 'The NHS Plan 2000. A Plan for Investment. A Plan for reform'.
7. Department of Health, 2011. Innovation, Health and Wealth. Accelerating Adoption and Diffusion in the NHS.

Appendix 1: Definitions

- i. **Assignment:** is 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. Intellectual property must be transferred in a written document which is referred to as an assignment.
- ii. **Copyright:** is an unregistered intellectual property right, which arises automatically by operation of law in the UK when a protectable work is created, and there is no registration required. 'Protectable' here describes the class of copyright works, these are: literary, dramatic, musical and artistic works, films, broadcasts and cable programmes. Certain categories of 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 '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 in certain countries be protected as patents. Specialist guidance on this should be sought from The Innovation Office. Copyright is governed by the Copyright, Designs and Patents Act 1988.
- iii. **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. However, databases can also be protected by a separate Database Right, which exists separately of the copyright (if any) in a database. Database Right lasts for 15 years. Database Rights protect the content from extraction or re-use, as opposed to the organisation and structure of a database. Even so, Database Right is a valuable intellectual property right. It is governed by the Copyright and Rights in Databases Regulations 1997.
- iv. **Design Rights:** under English law design rights can exist in unregistered or registered form. EU legislation also provides for Community Design rights that afford protection throughout the European Union, both for registered and unregistered designs. Please see the definitions of "Registered Design Rights" and "Unregistered Design Right" at paragraphs xii and xiv of this Appendix
- v. **Intellectual Property (IP):** is the generic term given to the bundle of various legal rights to protect innovation and creativity.
- vi. **Intellectual Property Rights (IPR):** are the legal rights that exist in Intellectual Property. IPR include the following related areas: copyright, patents, designs, trademarks, plant variety rights, database right and analogous rights.
- vii. **Know-How:** refers to technical expertise or practical knowledge that is not in the public domain and can encompass a broad and vague body of knowledge. In some cases this may be commercially valuable and can be exploited through consultancy or licensing and can be protected through the law of confidentiality.
- viii. **Licence and licensing:** are the terms given to the permission, which the owner of an intellectual property right may give to any other person or parties to use that IPR. Someone using an intellectual property right without a licence infringes that intellectual property right. The owner may charge a fee in return for the grant of a licence and can impose terms and conditions on use of the intellectual property right 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. Licences 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 for a particular category of use 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.
- ix. **Materials:** Physical items of property, that may or may not be subject to IPRs, created by staff in the course of their employment or using their employer's premises, equipment,

facilities or resources, including but not limited to biological materials, chemical compounds, prototypes, models, drawings, progeny, derivatives and modifications.

- x. **Moral Rights:** allow the author/director of a copyright work to assert rights to be known as the author/director of the work (the "paternity right") and to object to any derogatory treatment of the work ("the integrity right"). The moral right is usually asserted where copyright is assigned and the assertion binds the assignee. Moral rights are governed by the Copyright, Designs and Patents Act 1988.
- xi. **Patents:** protect original inventions (subject to some exclusions) with industrial application. They are one of the strongest forms of intellectual property right, conferring a 20-year monopoly upon their proprietor and they are infringed even if there is no conscious copying provided the patent is valid. They have to be applied for and are granted by the state through the UK Intellectual Property 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.
- xii. **Registered Design Rights:** can be used to protect three-dimensional designs as well as two-dimensional designs or surface patterns. 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 governing registered design rights in the UK is the Registered Designs Act 1949. Community design rights can also, separately, be registered across all member states of the EU.
- xiii. **Trade Marks** can be registered or unregistered. A registered trade mark is often much more valuable than an unregistered trade mark which can only give the owner a right to sue for passing off. It is more difficult and expensive to bring an action for passing off than for straightforward infringement of a registered trademark; so possession of a registered trademark is highly desirable. Registered trade marks are governed in the UK by the Trade Marks Act 1994. There is also a Community Trade Mark which gives a mark protection throughout the EU.
- xiv. **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 any aspect 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. In order to obtain unregistered design right protection, the design must be "original and not common place". Unregistered Design Rights are governed by the Copyright, Designs and Patents Act 1988.

Appendix 2

Background

1. In 1998, a Policy Framework¹ was launched requiring NHS organisations with R&D Levy funding to audit, protect and exploit their intellectual property (IP) arising from research and development (R&D). This Policy was accompanied by two guides^{2,3} written to assist NHS bodies and their researchers in fulfilling these obligations. Since 2001, management of IP has been a requirement of all NHS organisations carrying out research to comply with the Research Governance Framework⁴.
2. In 2002, the Department of Health (DOH) expanded on the existing guidance on management of innovation and IP⁵, the main points being that: IP from patient care as well as from R&D should be managed as an asset; statutory changes have occurred allowing NHS Trusts and PCTs to form or invest in spin-out companies to facilitate income generation; and a network of Advisor Organisations (hubs) were set up at that time to assist NHS bodies in managing their IP.
3. The 2000 NHS Plan⁶ highlights how the identification and exploitation of new technologies and developments can result in new products, improved interventions and services for health and social care.
4. Most recently, in 2011, the Department of Health policy document *Innovation Health and Wealth: Accelerating Adoption and Diffusion in the NHS*⁷ set out a delivery agenda that seeks to significantly ramp up the pace and scale of change and innovation.