

Reference Number: PHW81/CD01 Version Number: 1

Date of Next review: February 2027

#### INTELLECTUAL PROPERTY FRAMEWORK

#### **Introduction and Aim**

This framework supports the **Intellectual Property Rights Policy** and provides detailed instructions on the identification, referral and process involved in the exploitation and commercialisation of Intellectual Property Rights (IPR).

In addition, the framework also provides guidance for the protection, management and reporting of new ideas, creations or inventions – Intellectual Property - and the governance arrangements regarding income generation and the establishment of any spin-off companies.

## **Linked Policies, Procedures and Written Control Documents**

All corporate policies and procedures are available on the Public Health Wales website

- Intellectual Property Rights Policy
- Declarations of Interest, Gifts, Hospitality and Sponsorship policy and procedure

#### Scope

This framework applies to all intellectual property created by or on behalf of Public Health Wales by staff or others in all locations including those with honorary contracts, secondees and contractors working on behalf of Public Health Wales.

<b>Equality and Health</b>	An Equality and Health Impact Assessment (EHIA) was
<b>Impact Assessment</b>	completed for the overarching policy and can be viewed
	on the policy webpages.
Approved by	Leadership Team
Approval Date	28 February 2024
<b>Review Date</b>	28 February 2027
<b>Date of Publication:</b>	11/04/2024
Accountable	Board Secretary and Head of Board Business Unit
Executive	
Director/Director	
Author	Board Secretary and Head of Board Business Unit

## **Disclaimer**

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the <u>Board Business Unit</u>

Summary of reviews/amendments				
Version number	Date of Review	Date of Approval	Date published	Summary of Amendments
1	2023	28/02/24	11/04/24	PHW81 – Intellectual Property Rights Policy was developed as a new document and superseded the Velindre NHS Trust Black 90 Policy. An Intellectual Property Rights Guidance document (PHW81/CD01) was developed to support the policy. Legal advice sought and comments incorporated into document. Comments also received from Public Health Wales R&D department and wording added/amended to reflect those
				comments.

#### 1. Introduction

This framework provides detailed information on the identification, referral and process involved in the exploitation and commercialisation of Intellectual Property Rights.

The framework also provides guidance for the protection, management and reporting of new ideas, creations or inventions – Intellectual Property - and the governance arrangements regarding income generation and the establishment of any spin-off companies.

## 2. What is intellectual property?

In general terms, intellectual property (IP) or intellectual property rights (IPR) refers to intangible property that is the result of creativity, and includes, but is not limited to literary, artistic and scientific works; inventions; scientific discoveries; trademarks; copyrights; designs and logos; and know-how.

The IP has an owner, can be bought, sold or licensed, and must be protected in order to ensure its appropriate development, use or exploitation.

The following categories apply to Public Health Wales. A full list of types of IP can be found in Appendix 2:

Category	Protection	Examples
Inventions	Patents	New medical device,
		certain software systems
Literary or artistic works	Copyright	Computer software code, patient leaflet, journal article, medical illustration, photographs, books
Designs	Design rights	Usually relate to original, non-commonplace designs of the shape or configuration of articles and prevents deliberate copying
Brand names	Trade marks	Organisation logo
Know-how and confidential	Contracts, confidentiality	Also known as a "trade secret"
information	agreements, '	How to perform a
	common law duty of confidentiality	procedure or create a product or process

Some of these rights, such as copyright and unregistered design rights are automatic, there is no need to register the item in order to benefit from them. Others such as trademarks, patents and registered designs have to be applied for via a registration process.

Regardless of intellectual property rights, all data held by the organisation is subject to the provisions of the Data Protection Act 2018 and the Freedom of Information Act 2000. As such, in response to a request for data, the organisation may be required to release data to others (subject only the application of the statutory exemptions). Copyright or trademark status is not in itself sufficient to exempt release but all requests will be considered by on a case by case basis to ensure the organisation only releases the data necessary to comply with the statutory rights of data access. Commercial interests (which is a potential exemption under the Freedom of Information Act 2000) will adequately protected from disclosure where applicable.

## 3. Legal Framework

The Health and Medicines Act 1988 enables NHS Health Boards and Trusts to "develop and exploit ideas and exploit intellectual property". This is a key principle of the Research Governance Framework for Health and Social Care in Wales, which outlines the potential for the commercial exploitation of IPR. Welsh Government also released A Framework and Guidance on the Management of Intellectual Property in the NHS in Wales in 2005, which encourages the audit, protection and exploitation of IP. There is also in place a UK wide UK Policy Framework for Health and Social Care Research which also addresses the need to protect IP.

Successive acts of Parliament have provided a legal framework within which intellectual property may be protected and commercially exploited. The Patents Act 1977 (as amended) states that an invention belongs to an employer if:

- a) the invention was made in the course of either the employee's 'normal duties' or 'specifically assigned duties' and, in either case, an invention might reasonably be expected to result from the carrying out of the duties; or
- b) the invention was made in the course of the employee's duties and the employee has, because of the nature of the duties and

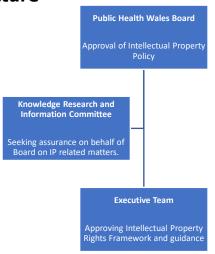
<sup>1</sup> Health and Medicines Act 1988, Section 7(2), applicable in Wales by virtue of the Government of Wales Act 2006.

-

the particular responsibilities arising from them, a special obligation to further the employer's interests.

Under the Copyright Designs and Patents Act 1988, where a literary, dramatic, musical or artistic work, or a film is made by an employee 'in the course of his employment', the employer is the first owner of any copyright (subject to any agreement to the contrary).

#### 4. Governance Structure



## 4.1. Reporting mechanisms

The National Director for Public Health Knowledge and Research is responsible for keeping a register of all patents owned by Public Health Wales and of those patents assigned to third parties where a member of staff is a named inventor. A report on IP activity will be provided to the Knowledge, Research and Information Committee on an annual basis.

#### 4.2. Roles and responsibilities

All Public Health Wales staff in all locations, including those with honorary contracts, secondees and contractors working on behalf of Public Health Wales, are responsible for being aware of the Information Property Rights Policy and the associated framework and guidance.

Staff awareness of IPR is important because it could avoid infringing other people's rights which could lead to a criminal prosecution or a civil claim for damages; and it protects Public Health Wales' and the individual's IPR and prevents IP belonging to the organisation and / or the individual being exploited by others.

Staff are asked to inform the Board Business Unit and the The National Director for Public Health Knowledge and Research about any potential IP they have developed that is connected with their work in and for Public Health Wales. You should refer to the provisions of your contract of employment regarding IP ownership issues. The Public Health Wales Terms and Conditions of Employment contain a section covering IPR (see **Appendix 1**).

Staff must not under any circumstances, disclose, sell, assign (transfer), license, give away or otherwise trade in IP before consulting the R&D Office and the Board Business Unit. This is to protect the possibility of being able to develop such IP, particularly technical inventions, and also to protect the Trust's and staff members' interest.

Specific roles and responsibilities are outlined below:

# National Director for Public Health Knowledge and Research : policy lead for Intellectual Property

- provide IP advice to innovators/ creators to seek out appropriate routes for application of IPR.
- In conjunction with the Lead Executive Director, will also determine whether patent/legal advice is required on a caseby-case basis.
- Responsible for keeping a register of all patents owned by Public Health Wales and of those patents assigned to or licensed to third parties where a member of staff is a named inventor or otherwise.

## **Deputy Chief Executive/Executive Director of Operations and Finance**

- In instances wherein patent/legal advice is required, resources will need to be considered on a case by case basis
- Recommending income sharing arrangements on each project to the Chief Executive

# Director of NHS Quality Improvement and Patient Safety/Director of Improvement Cymru

- Executive lead for Innovation
- Supporting patent/license applications as appropriate

## 5. Principles

## 5.1. Ownership of IP

As a general rule IP created by an individual in the course of their employment, or training arising out of their employment, belongs to the employer (Public Health Wales) and any benefits accrued in the work will belong to the organisation.

If the organisation decides to commercially exploit and protect the IP rights then it may be appropriate for members of staff who created or developed the IP to have a share in the benefits, for example, through royalty income or other recognition. In certain circumstances Public Health Wales may decide not to take up its rights and ownership may be assigned to the employee.

## 5.1.1. Joint working

Where employees have joint contracts with other organisations, where appropriate, a partnership agreement on IP will need to be developed. The organisation with the main contract will be responsible for protecting the IPR and for any commercialisation. Agreement should be reached at the beginning of the piece of work as to the way in which the costs and benefits will be split between the organisations. The Joint Working Framework should be used when entering into agreements such as this.

### 5.1.2. Other employment (eg private practice)

An employee may have a part-time NHS contract and be selfemployed part-time (for example in private practice). If IP arises during the period of part-time self-employment, it will be owned by Public Health Wales if it is construed to relate to that employment. If there are circumstances where the IP has arisen independently within the self-employment, the organisation may agree with the employee alternative terms for sharing the benefit and will set these out in an agreement.

### 5.1.3. Honorary contracts

An individual may be employed by Public Health Wales but have an honorary contract with another organisation. IP generated by such an employee during the course of their duties in Public Health Wales will be owned by Public Health Wales. IP generated by such an employee during the course of their duties under the honorary

contract with the other organisation will be governed by the provision set out in the relevant honorary contract.

An individual may be employed by another organisation and have an honorary contract with Public Health Wales. If IP arises during the course of their activities with Public Health Wales under the honorary contract, it will be owned by Public Health Wales, unless alternative arrangements have been made under the honorary contract.

#### 5.1.4. Hosted bodies

Ownership of IP generated as a result of activity undertaken by hosted bodies (e.g. the NHS Executive) will be subject to agreements set out in the respective hosting agreement. Any income from IP which is attributable to Public Health Wales will be subject to the provisions of this framework and procedure and will be owned by Public Health Wales.

#### 5.1.5. Contractors

Agreements entered into between Public Health Wales and third party contractors or consultants (with non standard terms of engagement) should take account of the need to identify ownership of IP rights in favour of Public health Wales.

## 5.2. Identifying and Protecting Intellectual Property

Staff at all levels need to be aware of the possibility that they may generate new IP during the course of their employment. They must have clear guidance on the procedures to follow if they feel that their ideas may provide wider benefit.

The most critical period for ensuring the protection of IP is the initial period from when the idea is generated until statutory IPR protection is in place<sup>2</sup>.

During this period, it is **essential** that staff:

- keep accurate records of the idea itself and any work performed to develop and prove the practical implementation of the idea;
- must refrain from any public disclosure of the idea or related development;

<sup>&</sup>lt;sup>2</sup> Note that protection arises, for example copyright on creation so no registration required, while trademarks, for example need to be registered to attract protection

• recognise their duty to the Trust and to colleagues to maintain confidentiality with respect to the IP.

Any member of staff wishing to discuss the protection of any idea or other form of intellectual property must discuss the matter with their line manager at the earliest opportunity. This must take place prior to disclosing the idea to any party outside terms of confidentiality or Public Health Wales, either orally or in writing. Staff are advised to complete a Non-Disclosure Agreement. Prior public disclosure (other than under explicit terms of confidentiality) will invalidate any subsequent patent application and diminish both potential commercial value and benefits accruing to Public Health Wales and the inventor(s).

A record will be kept of the date and time on which a member of staff reports that he or she is the inventor/ creator of the piece of work. The National Director for P{unlic Health Knowledge and Data is responsible for keeping a register of all patents owned by Public Health Wales and of those patents assigned or licenced to third parties where a member of staff is a named inventor or otherwise.

## **5.2.1.** Collaborative Research Projects

It is essential for Public Health Wales to establish at the outset whether any proposed activity requires access rights to IP generated from research activities.

#### 5.2.1.1. Externally sponsored research

In order to retain the confidence and support of the sponsors of its research, it is imperative that Public Health Wales complies with the terms and conditions under which such funding is made available.

Sponsored research contracts, with the exception of those that are 100% funded, will generally allow Public Health Wales to retain ownership of the arising IPR in order to enable Public Health Wales to control its commercial exploitation. Care must be taken in such contracts to ensure that adequate provision is made for the proper exploitation of arising intellectual property rights.

In pricing sponsored research contracts, Public Health Wales will give due consideration to the potential value of resulting intellectual property rights as well as the value of any pre-existing, background IPR, software or patented inventions which may be used in furtherance of the research project.

There will be occasions where Public Health Wales does not receive 100% of the funding for example as part of a collaborative project In these cases, Public Health Wales will agree in clear terms the nature of the relationship with the partner organisation(s). This agreement should be underpinned by two clear criteria:

- That the development and commercialisation of the IP delivers benefits to population health and Public Health Wales;
- That the inventor(s) retain the rights to receive an appropriate level of income in the event that commercialisation of the IP generates profits.

Public Health Wales may, on occasion, sponsor research via a research grant or through a non-financial agreement such as a Memorandum of Understanding. It is an important part of the grant process to establish ownership of IP.

Public Health Wales actively encourages its staff to work collaboratively with other organisations to promote research and innovation. It is widely recognised that the issue of IP in collaborative research can be complex. Public Health Wales aims to provide a framework whereby those that generate ideas are able to use them and are rewarded for their efforts whilst ensuring that the appropriate level of control is in place to ensure that any IP arising from collaborative research always benefits patients and facilitates the collaborative process.

It is therefore important before embarking on a collaborative venture that all parties, the researchers, contract managers and funders, agree the principles of the collaboration. These can be set out in a Heads of Terms (HoT) which allow research decision makers to identify in plain language what they regard as the key issues before instructing their lawyers to draw up a formal agreement (See Appendix 2).

## **5.2.2.** Pre-existing intellectual property

Staff should declare patents and other Intellectual Property Rights they hold (either individually or by virtue of their association with a commercial or other organisation), including where applications to protect have started or are ongoing, which are, or might be reasonably expected to be, related to items to be procured or used by the organisation.

Public Health Wales' <u>Declarations of Interests</u>, <u>Hospitality</u>, <u>Sponsorship and Gifts procedure</u> sets out the requirements in connection with employees' commercial interests. Where a member

of staff is a Director of a Company which owns IPR for which permission has been granted to Public Health Wales to utilise, a formal licence agreement must be put in place between the organisation and such Company to document the terms under which Public Health Wales can use the relevant IP.

## **5.2.3.** External Organisations

Do not involve external organisations or companies in testing or prototyping without a written agreement together with a confidentiality agreement being in place and have such agreements checked before commencement. Do not sign any contract or agreements or begin any related activities, including giving or selling samples, until they have been reviewed by the Board Secretary.

## 6. Exploitation of IP

Public Health Wales has taken the decision to own and engage with its staff in exploiting its IPR. Employees as part of their contracts of employment are not to disclose information which has arisen as a result of their duties of employment without Public Health Wales' approval. In the event a member of staff is requested to sign documentation which may transfer any IP rights, they should seek guidance and prior approval from the Research and Development team.

This approval will not be unreasonably withheld but may be deferred whilst IPR are applied for or registered. External organisations involved in projects will be required to sign Non-Disclosure Agreements (NDAs).

Exploitation of IP involves costs and risks. It may not therefore, always be appropriate or cost effective to seek to protect and exploit potential IP. In most cases copyright will suffice. However, in some cases patenting or licensing may be more appropriate. In those cases, negotiations will be undertaken on behalf of the inventor and Public Health Wales. In many instances the organisation may decide to use the product as an example of 'best practice' to be shared with other stakeholders including NHS bodies.

### **6.1.** Spin-out companies

Health legislation allows NHS Trusts to set up or invest in companies for the purposes of exploiting IP and for staff to participate in them.

Authorisation to set-up spin out companies will be dependent on a successful business case to the Welsh Government's NHS Finance

Division, as required by legislation. In taking a shareholding in the spin-out company a Public Health Wales employee will be nominated by the Chief Executive, to sit on the Board or as an observer to the Board, with a residual right to appoint a Director if it desires. The employee will have sole responsibility on behalf of Public Health Wales to support the development of the company, providing this does not give rise to a conflict of interest with their duties of employment.

In cases where creating a spin-out company may be appropriate the procedure set out in "Intellectual Property and Innovation in Health Care in Wales – a framework and guidance on the management of intellectual property in NHS in Wales" (2005), the NHS Wales Act 2006 and any applicable guidance will be followed.

## 7. Profit sharing

If Public Health Wales chooses to protect IP rights, then it is considered appropriate that the members of staff who have developed the IP (the inventors) should have a share of any benefits e.g. profit or royalty income.

Public Health Wales' share of royalty income is utilised to offset the annual costs of maintaining patents and licences and any under-recovery is found from the annual funding allocation made by Public Health Wales to the Executive Director of Finance and Operations.

Income from the successful commercial exploitation of IPR, through the transfer of IPR by assignment or licensing, receipt of dividends or profit shares or ownership of shares will normally be received by Public Health Wales. As an incentive to employees, Public Health Wales will grant its employees and respective departments an interest in revenues from the successful exploitation of IPR. If such commercialisation is to take place an agreement will be drawn up which details terms for the exploitation of the IP and the distribution of any revenues accruing from it. This will be in line with the NISCHR IP Principles and on a case by case basis.

Inventorship will be determined at the outset and inventors will warrant that they, and only they, have contributed to the generation of the IP in question.

Inventors may include non-clinical NHS staff, clinical, academic, nursing and allied health professionals and related staff and postgraduate and other students. Financial benefits from the exploitation of IP will not accrue to members of staff who are employed for the specific purpose of writing software, although consideration will be given, on a case by case basis, where a member

of staff is deemed to have made a contribution to the inventive step beyond that of software development.

Where Public Health Wales leads on a project then independent commercial advice should be obtained for all major projects. The allocation of royalty income will depend upon the complexity and size of the project. Where shares are to be issued or outside investors involved then the allocation is more complex and should be determined using professional advice.

Income generation for charitable purposes using NHS resources is strictly forbidden and therefore income from IP exploitation must not be directed to the charitable funds in line with Standing Financial Instructions. The income from IP exploitation will be managed centrally.

## 8. Assumption of Liabilities/Indemnities

The basis of assumption of liabilities/indemnities will be set out in each project and adequate indemnity/insurance cover provided where necessary. In certain instances, Public Health Wales may seek legal advice to confirm the liabilities to include financial, Intellectual Property (IP) warranties for breach of third-party IP infringement for example.

#### 9. Resources

This guidance largely reflects existing practice. In instances where patent/legal advice is required, resources will need to be considered on a case by case basis by the Board Secretary and the Deputy Chief Executive/Executive Director of Finance and Operations.

## 10. Reporting

A report on Intellectual Property activity will be provided to the Audit and Corporate Governance Committee on a bi-annual basis. This may include the Patents Register.

#### 11. Review

The guidance will be reviewed to reflect any changes in guidance or legislation. As a minimum it will be reviewed every three years after the date of approval.

## Appendix 1

# **Extract from Public Health Wales NHS Trust Contract of Employment**

# 28. <u>DISCOVERY AND INVENTIONS/OWNERSHIP OF</u> INFORMATION

Public Health Wales wishes to stress that all information generated during the course of your employment is the property of Public Health Wales and remains so, irrespective of origin or authorship.

Subject to the provisions of the Patents Act 1977 (as amended), any invention made by you in the course of your employment will belong to the Public Health Wales and you are required to co-operate fully with Public Health Wales to enable it to protect the invention by letters, patent or otherwise howsoever.

## **Appendix 2 Aspects of Intellectual Property**

This appendix includes a brief overview of some aspects of IP protection. More detail can be found on the Intellectual Property Office website 'types of IP' section <a href="www.ipo.gov.uk/types">www.ipo.gov.uk/types</a>. This should not be considered an exhaustive list and should be used for quidance only.

Intellectual property rights is a complex area of law and members of staff are advised to contact the Board Secretary in the first instance to seek advice on the relevance of IP protection to the proposed ideas and pieces of work.

#### 1. Know-how

Know-how (also known as a 'trade secret') is any information that is not in the public domain which has an assumed value. Know-how is often the most valuable of all IP assets. For example, it can be the knowledge about how to perform a procedure or to create a product or process.

Know-how can be identified and protected by a Non-Disclosure Agreement (NDA) (also known as a Confidential Disclosure Agreement (CDA)). When working with other parties NDAs can be reciprocal agreements whereby the boundaries of confidential information that is disclosed and received is identified and any obligations on both receiving and disclosing parties are detailed.

Know-how and confidential information can be bought, sold, licensed or traded like any other forms of IP and persists indefinitely, as long as it remains covered by the terms of an NDA.

#### 2. Licenses

The negotiations to license or assign Public Health Wales owned IPR will be conducted by the Board Secretary and Deputy Chief Executive/Executive Director of Finance and Operations. Any legal documents to implement agreements will, in appropriate cases, be drafted and or scrutinised by NWSSP Legal and Risk Services who advise Public Health Wales on intellectual property matters. The authorisation of documents/agreements should be made in accordance with the Public Health Wales Scheme of Delegation.

In the case of the licence of Public Health Wales owned IPR, any such licences would contain restrictions to preserve Public Health Wales' IPR, for example, by limiting the scope of the licensee's right to such IPR, any right to sub-licence being on prescriptive terms. When a

licence agreement has been entered into, the respective Executive Lead for Innovation (see table 1) and the Executive Director for Finance and Operations shall be responsible for ensuring that its terms are complied with, that the proper royalties are received by the organisation, and that all income arising is properly distributed in accordance with the revenue-sharing arrangement.

## 3. Copyright

Copyright is likely to be the most common area of IPR. Copyright is an automatic right in the UK. However, it is necessary to be able to establish the date on which it was created. Where documented material produced within Public Health Wales is being distributed externally a copyright statement should be included. The usual format and 'rights' statement would be:

© Public Health Wales <insert date>.

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

A statement on permitted use of the material may also be included. It may be agreed that for certain areas of activity permission does not have to be obtained eg "non-for-profit organisations such as NHS Health Boards and Trusts, may reproduce this work solely for the purposes of teaching or further non-commercial research. In all other circumstances the permission of Public Health Wales must be obtained".

#### 4. Patents

A patent is a monopoly granted by the Crown, usually for 20 years. It provides absolute protection for an idea, however the technology must be made public. Conditions that must be met to register a patent are: there is an invention; it is new; it is inventive (not just the next step); it is capable of industrial application; it must not be an excluded category (discovery, scientific theory or mathematical method).

It can be difficult to establish the novelty of an invention, and if international patent rights are likely to be required, rigorous laboratory record keeping is essential in order to prove 'date of invention'.

If an invention is sufficiently novel and significant to a Patent application, such application will normally be made in the name of Public Health Wales, and will include the name(s) of the inventor(s).

If Public Health Wales decides not to progress with the commercial development of the invention it may assign its rights to the inventor(s).

## 5. Design Rights

Design Rights protect against the copying of the shape or configuration of an article. Design Rights may exist in addition to other forms of protection offered by patents or copyright.

## 5.1. The "Design Right"

The "unregistered" Design Right as it is known, similar to copyright, is an automatic right and can last up to fifteen years. It can protect the 3D features of an article, internal and external features, but there are a number of exclusions for example where the article is dependent on another article the so-called "must-fit, must match" exclusion. A surgical instrument could be protected by this right. However, unregistered design rights are generally considered to be weak IP rights and often stronger rights such as patents are sought, at least to improve levels of protection. Given the particular requirement of this "niche" aspect of IP law it is best in the first instance not to assume that the design right will protect a given article.

## **5.2.** Registered Design Rights

Both UK and European law provide for registered design rights which last up to 25 years. Registered design rights protect the appearance of a product, for example its shape, colour or texture of materials. For example, a new design of surgical gown or a patient's pillow could be the subject of a registered design right.

#### 6. Trade marks

A trademark is a sign or symbol that is used to distinguish a product or service of one undertaking (e.g. a company or organisation, such as an NHS organisation) from another undertaking. Trademarks can protect words, logos, shapes, colours and even smells (e.g. the name "Coca Cola" and also the shape of the Coca Cola bottle are registered trademarks). Trademarks are the IP right that protect brands. They can last forever, providing renewal fees are paid.

## **Appendix 2 Template Heads of Terms (HoT)**

It is important for researchers and their managers to create the optimum conditions for a collaboration and to understand what it aims to achieve and the process for achieving it. HoT enable research decision makers to identify the key issues surrounding a collaborative project in plain language. The very process of creating a HoT can be a very constructive and useful way for all parties to understand the needs and expectations of the other parties at the outset and may minimise disagreements and disputes later. In this way a research project is more likely to be productive. It is important to consult lawyers after you have created your draft HoT but the process itself of creating the HoT should not be confined to lawyers. A template HoT is provided below.

- The Parties
- Purpose of project
- Scope of project
- Start date and main time points.
- Resources provided by each party (e.g. financial, personnel, data, existing IP etc)
- Role of each of the Parties
- Ownership of IP in results
- Access rights to IP arising in the project
- Access rights to other parties existing IP necessary for performing the project
- Confidentiality
- IP exploitation plan
  - Management of project IP
  - Decision making relating to IP exploitation
  - Revenue/equity
- Dispute resolution
- Termination conditions

## **Appendix 3 Revenue Sharing**

Example of revenue sharing schemes adopted by some NHS organisations are shown below. It is emphasised that these are only examples. Each HB/Trust should decide on its own revenue-sharing scheme. University Health Boards should pay particular attention to their corresponding universities revenue sharing policy.

Cumulative	Inventor(s)	Department	R&D	HB/
net income				Trust
First £2K	100%	0%	0%	0%
£2K-£20K	60%	20%	10%	10%
£20K-£100K	50%	20%	15%	15%
£100K-	40%	20%	20%	20%
£250K				
Over £250K	35%	20%	15%	30%

Net Revenues	Inventor(s) %	Directorate (s) %	UHB %
First £2,000	100	0	0
Next £40,000	60	20	20
£42,000 - 200,000	50	25	25
Over £200,000	30	35	35

% Net revenue paid	to	Net revenue to HB/Trust
employee inventors		
75		£0-50,000
50		Subsequent £50-250,000
25		Subsequent >250,000

Below is an example of income distribution arising from the exploitation of IP arising from work funded by a sponsor using the previous example's revenue sharing scale.

	£000s
Total income	150
Less Costs	30
Income remaining	120
Sponsors share (e.g. 40%)	48
Net income to HB/Trust	72
Employee inventor share 75% of	37.5
£50,000	
+ 50% of £22,000	11
Total employee share	48.5
HB/Trust remaining share	23.5

## **Appendix 4**

#### References

Cardiff and Vale University Health Board, 2016. *Intellectual Property Rights Policy*, UHB 148.

Health and Care Research Wales, 2013. NISCHR Template Policy.

Wales Office of Research and Development for Health and Social Care (WORD). Research Governance Framework for Health and Social Care in Wales (second edition).

Welsh Government, 2005. A Framework and Guidance on the Management of Intellectual Property in the NHS in Wales.

Cwm Taf University Health Board, 2017. *Intellectual Property Management Policy, OP51.* 

Devon Partnership NHS Trust, 2018. *Innovation and Intellectual Property Policy, G22.* 

## Appendix 5 Case studies Employee ownership and invention

#### 1. Introduction

Under UK law, inventions made by employees who are employed to invent are owned by their employer. This is provided by statute (Patents Act 1977) which overrides contract law and specifically any terms in contracts of employment. In the UK, contract law is therefore generally only relevant in determining ownership of inventions made by inventors who are not employed in an inventive/creative capacity or outside of employment.

### 2. UK Law Relating to Employee Inventions - Section 39 UKPA77

In summary, an invention by default belongs to the inventor. However, in the case of employment, an invention made by an employee belongs to his employer (1), if:

- (1a) it was made in the course of his/her normal duties, or in the course of additional specifically assigned duties, and an invention might be reasonably expected to arise from them, or
- (1b) it was made in the course of the employee's duties and implicit in these duties is a special obligation to further the interests of the employer.

Any other invention belongs to the employee (2).

Notably, duties is not specifically defined and is often regarded as a role of employment rather than specific tasks that he or she may undertake as part of that employment. As a result, typically duties are stipulated in contracts of employment, and unless careful consideration of same is given, these are often by default quite vague and broadly defined.

To exemplify how this statutory provision may be applied, please consider the following theoretical case scenarios and how ownership may be determined in such cases.

#### 3. Case Study 1: Dr X, Clinical Oncologist and Researcher

Dr X is a medical oncologist involved in assessment and treatment of certain types of cancer in the oncology department.

**Normal Duties:** Dr X is primarily employed to clinically assess and directly treat certain cancer subtypes in the oncology department. He also undertakes research including cancer clinical trials, the development of new drugs and studies about the fundamental mechanisms of specific cancer subgroups.

**Assigned Duties:** No specific contracted duties.

**Invention:** Through undertaking a clinical trial, in collaboration with other health and academic institutes, Dr X has elucidated certain markers in urine samples that can be used as early diagnostic markers indicative of certain forms of renal cancers. Many of the clinical samples utilised in the trial were provided by Dr X with clinical records pertaining to same (including patient outcome, treatment path and survival).

**Ownership:** Dr X as part of his employment undertakes research into the clinical treatment of cancer and is regularly involved in, and undertakes, clinical trials into new treatments and therapeutics. As part of a collaboration an improved diagnostic test for the determination of cancer has been devised, a significant part of which has arisen from data generated from patient records forming part of his day to day tasks. Although his contract of employment is not specifically drawn towards this particular aspect of research, the invention has arisen as a consequence of same.

The invention thus resides with Dr X's employer and possibly the other health and academic institutes.

# 4. Case Study 2: Mr Y, Consultant Wound Care Specialist and Surgeon

Mr Y is a wound care specialist and surgeon with extensive experience in the sector.

**Normal Duties**: Mr Y has experience in reconstructive foot and ankle surgery, orthopaedic/general trauma, paediatric orthopaedics, diabetic limb salvage, and wound care. He is primarily employed to clinically assess all cases of wound care and treatment thereof including use of advanced treatment techniques such as wound vacs, skin substitutes and use of new ultrasonic debridement techniques as part of conventional treatment plans. His contract does not stipulate limits upon techniques to be employed or the development of alternative methods, but he is also employed to contribute to treatment pathways in this clinical area at the hospital.

**Assigned Duties:** No specific contracted duties.

**Invention:** Mr Y has determined that during the course of treating certain chronic wounds a particular dose of a specific and already known wound therapeutic has unexpected and preferential wound healing effects, far superior to that already experienced during conventional clinical treatment. Further, it has been determined that treatment is most effective during a certain clinical wound 'time-window'. The proposed invention is therefore use of a specific dosage regimen when using a known therapeutic for treating of wounds.

**Ownership:** Mr Y is not employed to invent or research, although he does so as part of his personal career progression. However, he is employed as a wound care specialist with a view to undertaking and devising treatment plans for patients, including performing treatment using existing or new treatment options.

Although not employed to innovate *per se*, the invention has arisen as a consequence of his regular day to day tasks, inherent problems faced when undertaking same and devising a solution that can be used as an alternative.

The invention thus resides with the employer.

## Case Study 3: Mrs Z, Clinical Nurse Specialist

Mrs Z is a nurse currently employed in the department of Geriatric Medicine.

**Normal Duties**: Mrs Z provides clinical leadership and education for the Staff Nurses working in her department, and has specialist skills and knowledge upon which ward nurses can. Her role is to act with other nurses to advance nursing practices, improve outcomes, and provide clinical expertise to effect system-wide changes to improve programs of care. She has a role in directing clinical practice including expertise in advanced assessment, implementing nursing care, and evaluating outcomes. Her research involves interpreting and using research, evaluating practice, and collaborating in research.

**Assigned Duties:** No specific contracted duties.

**Invention:** Mrs Z, a keen gardener in her spare time, has devised a new and improved water butt that can be implemented into existing household water drainage systems. The system comprises a unique setup that allows retention of water flow from downpipes for use in the garden but importantly does not lead to reduced flow during heavy rainfall that can lead to overflow and flooding as with existing systems.

**Ownership:** Mrs Z is employed in the clinical sector. The proposed invention clearly is separate from her employment and normal course of duties and has no relevance or significance thereto. Devising the invention has arisen as a consequence of personal interest in a sector outside and separate from her employment.

The invention resides with the individual.

#### Summary

An employee who has developed an invention during the execution of duties pertaining to his/her employment contract i.e. usually, but not exclusively, during his/her working time within the institution/work environment using knowledge employed during his/her working day will belong to the employer.

To avoid confusion and possible disputes, employers often specify ownership of intellectual property in employment contracts. However, in many circumstances, the employee's duties can be referred to quite vaguely, and so it is prudent to consider carefully an employee's duties when reviewing and agreeing contracts of employment.

Regardless, depending on the merits of each case, the employee may have a right to equitable remuneration in accordance with legislative provisions or the employment contract. The Patents Act 1977 provides a statutory regime whereby an employee may become entitled to financial reward, or compensation, where the employer has obtained outstanding benefit from a patented invention made by an employee. The relative amount of remuneration will vary from case by case, and will ultimately depend upon the success of the invention (having regard to the size and nature of the employer's undertaking) and the extent of the contribution made by the employee to the patent.

In any case, the employee will always retain the right to be mentioned as the inventor, unless he/she expressly renounces this right.