

# Welsh Health Circular – WHC/2026/004

## Appendix 1 - Intellectual property (IP) guidance for National Health Service (NHS) Wales organisations

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To ensure that IP management is continuously improved we welcome feedback on this guidance to [hss.innovationtechnologypartnerships@gov.wales](mailto:hss.innovationtechnologypartnerships@gov.wales).

The guidance will be reviewed and updated regularly, in line with the timescales set out in Welsh Health Circular WHC/2026/004.

## Introduction

### **Intellectual property and intellectual property rights**

Intellectual property is a collective term referring to creations of the mind. Intellectual Property (IP) can be defined as the products of intellectual or creative activity in the form of novel ideas, innovation or research & development - that can be given legal recognition of ownership. IP can be assigned or licensed exclusively or non-exclusively and can be generated where R&D, innovation, care delivery or management, or other creative works are being undertaken.

For example:

- acts of research, development and / or innovation
- things you write, make or produce
- the design or look of products
- the names of products or brands
- proprietary knowledge (know-how)

An overview of IP from the Intellectual Property Office (IPO) can be found here: [Intellectual property and your work: What intellectual property is - GOV.UK](#)

NHS Wales organisations and their staff generate, use, and manage IP daily through research, innovation and service delivery. This IP includes, but is not limited to:

- the extensive know-how of NHS staff
- training materials and toolkits
- innovations created with NHS resources (people and infrastructure)
- NHS-generated data, databases and methodologies, including annotated imaging data and outcomes measures
- new medical devices, software, diagnostics, medicines, techniques and information resources.

The legal mechanism that provides protection for acts of innovation and creativity is intellectual property protection, giving rise to intellectual property rights (IPRs). These rights formalise the ownership of IP. While some IPRs—such as patents, trademarks, and

registered designs—are obtained through formal registration, unregistered IP—such as copyright and unregistered designs—receive automatic protection to prevent others from copying them without the owner’s permission. Other examples of unregistered IP—such as know-how, processes, and trade secrets—are protected through appropriate confidentiality and contractual mechanisms rather than registration.

IP can be owned, assigned, licensed, or shared, under different arrangements. Further information on licensing can be found here: [Licensing intellectual property - GOV.UK](#)

## **The importance of effective IP management**

Effective IP management drives innovation by supporting the development of new products, services, and pathways that benefit patients, the public and the organisation's workforce whilst also contributing to economic growth. Active IP management is also critical when adapting or co-creating external innovations that involve the use of NHS Wales resources.

Without clear IP management processes, NHS Wales organisations risk losing valuable opportunities to develop and implement innovation. This new Welsh guidance addresses these challenges by streamlining processes, defining clearer roles and responsibilities, promoting consistent good practices in IP management across NHS Wales organisations and making it simpler for ideas to move from concept to commercialisation. In this way innovation can reach Welsh patients faster and drive growth for both NHS Wales and the economy of Wales.

[Managing Public Money](#), issued by HM Treasury in June 2025, emphasises that effective IP management is essential for safeguarding public assets and maximising value for taxpayers. Public bodies must maintain strategic oversight of IP to protect its value and ensure appropriate licensing or charges to prevent valuable assets from being lost or undervalued (Annex 4.15, Asset Management).

The document also highlights the importance of accountability, transparency, and risk management in preventing IP misuse or infringement. Ultimately, it encourages public bodies to treat IP as a valuable and strategic asset that supports innovation, collaboration and long-term public benefit.

## **Purpose of this guidance**

This IP guidance replaces the February 2005 guidance “*Intellectual Property and Innovation in Health Care in Wales - A Framework and Guidance on the Management of Intellectual Property in the NHS in Wales.*”

This guidance is adapted from the Department for Health and Social Care IP guidance, as issued for NHS England in November 2025 - [Intellectual property \(IP\) guidance for the NHS in England - GOV.UK](#).

The objectives of this updated guidance are to:

- increase awareness of the importance of effective IP management across NHS organisations
- promote consistent good practices in IP management in Wales
- generate, protect and exploit intellectual property (IP) to encourage innovation
- deliver the best possible patient care and explore new sources of income.

This guidance aims to maintain a balance between the legitimate needs to protect the interests of NHS Wales organisations as IP is seen as an asset and the provision of a creative environment for NHS Wales employees in which to work.

This guidance is not legal advice. This is non-statutory guidance offering practical steps and good practice principles for NHS Wales organisations to manage IP strategically, ensuring innovations benefit the NHS and the public, whilst safeguarding valuable public assets.

## **Desired outcomes**

The good practice principles shared in this guidance have been written to help organisations achieve the following outcomes:

### **Strategic outcomes**

- encourage and empower NHS Wales organisations to develop effective IP policies, commercialise innovations on appropriate terms, both independently and with third parties, and reward innovators with meaningful incentives
- develop a culture and ecosystem that encourages individuals, teams and organisations to explore their innovation, improvement, and transformation ideas
- leverage innovation from across NHS Wales to improve healthcare, benefit patients and staff, and contribute to the growth of the UK economy
- gain recognition by creating an environment and culture that promotes NHS Wales as a launch pad for innovation, helping to put NHS Wales on a stable financial footing and positioning the UK as a global leader in healthcare research and innovation

### Operational outcomes

- establish a consistent and effective approach to IP management across NHS Wales, through providing clarity on good practice to help guide operational decisions
- signposting to relevant IP resources and case studies to support organisations
- be ready for IP due diligence and commercial negotiations to accelerate innovation
- empower the workforce by providing clear guidance and reducing procedural barriers to innovation for NHS Wales

### **Scope of this guidance**

This guidance sets out good practice principles covering the assessment of ownership, protection and commercialisation of IP. These principles are relevant for all IP generated by NHS Wales organisations, including when organisations develop IP in collaboration with external parties.

NHS Wales organisations services vary in the maturity of their innovation portfolios, leading to differences in how they manage idea generation, IP ownership, governance, protection, commercialisation, and adoption. This guidance provides forward-looking support to help organisations at all maturity levels strengthen their IP management practices.

### **Strategic alignment and key legal considerations**

These good practice principles align with wider UK Government guidance on IP, knowledge asset management, and commercialisation, including:

- [The Rose Book: Knowledge asset management in government](#)
- The IPO's [Intellectual Property Rights Guidance Note](#) which features collaborative information from the IPO and others on options to consider when approaching IPR in contracts
- The Government Office for Technology Transfer's (GOTT) [Guide to Managing Intellectual Property and Confidentiality](#). This guidance on IP is in alignment with legislation such as:
  - [Patents Act 1977](#)
  - [Trademarks Act 1994](#)
  - [Copyright, Designs and Patents Act 1988](#)

- [Copyright and Rights in Databases Regulations 1997](#)
- [Registered Designs Act 1949](#)
- [Subsidy Control Act 2022](#)
- [Competition Act 1998](#)
- [National Security Act 2023](#)
- [HMG Security Policy Framework](#)

#### IP considerations internationally

It is important to note that IP rights are territorial, with different legislation and terminology applying overseas. NHS Wales organisations engaging in international partnerships, research or collaborations should ensure they have appropriate IP protection, that any agreements align with existing guidance, international standards and legislation, and are adapted for overseas contexts. These arrangements are likely to require additional legal support from an early stage in order to navigate compliance, ethical considerations and negotiation requirements. Additional information on IP considerations when operating internationally can be found here in the IPO document: [International IP service - GOV.UK](#).

### **Audience**

This guidance has been written to empower all NHS Wales organisations providing and supporting healthcare services to establish an SRO, effective IP oversight teams and management processes, which support IP and innovation to become business as usual. Therefore, this guidance is directed at those responsible for management of IP within or on behalf of an NHS Wales organisation.

Typically, this responsibility sits with Innovation and/or Research & Development teams. In cases where there the ownership of IP is unclear, this guidance is directed at executive teams within organisations and the assigned SRO, as set out in the covering Welsh Health Circular.

## IP decision-making in NHS Wales organisations – step by step guide.

This section sets out step-by-step the IP decision-making process for NHS Wales organisations, utilising good practice principles.

Effective IP management is a critical enabler to ensure innovations are identified, protected, and translated into real-world benefit efficiently – thereby maximising public benefit, driving economic growth, and supporting healthcare advancements.

The step-by-step process and the good practice principles outlined here aim to:

- establish effective and proportionate governance by appointing responsible leaders and implementing clear governance structures
- promote transparency and efficiency in IP decision-making and processes
- encourage early, confidential internal identification of new ideas and innovations to the appropriate IP or innovation lead for timely IP assessment and protection
- support innovation and commercialisation through transparent IP pathways
- protect valuable IP assets whilst avoiding unnecessary costs
- enable a timely pathway for IP management, balancing innovator incentives with NHS Wales contributions
- position NHS IP as a key contributor to improving health and patient care
- enable the Welsh Government's economic growth objectives, as set out in *Wales Innovates: the 2023 [Innovation strategy for Wales](#)* and the UK [Life Sciences Sector Plan](#).

By following these steps and good practice principles, organisations providing and supporting NHS services can create a structured, fair and innovation-friendly approach to managing IP whilst ensuring that both the NHS and the wider public benefit from new healthcare innovations.

It is also important to remember that IP can overlap with other issues, such as the proper management of personal data, and organisations will still need to comply with GDPR.

## **Step 1: Establish IP governance and decision-making framework**

### Good practice principles

- Appoint a senior responsible officer (SRO) and supporting team from Research and Development and Innovation, to oversee IP management across the organisation.
- Apply the Template IP policy at Appendix 2 to your organisation.
- Utilise the support services offered by NHS Wales Shared Services Legal and Risk Services team.
- Review and update IP policies annually
- Make the organisation's IP policy publicly available (for example, publish on website)
- Develop clear governance structures for IP decision-making. Local IP policies should indicate the ultimate decision maker.
- Establish decision-making processes with clearly defined stage gates, metrics and feedback mechanisms
- Define innovation pathways to stimulate and support innovation, and clearly explain how IP will be treated within these processes
- Communicate IP governance and the decision-making frameworks to ensure transparency with staff and external collaborators

### Resources

- Welsh Health Circular WHC/2026/004 Appendix 2 - Template IP policy.
- [case study 1](#) – NHS IP senior responsible officer (SRO) personas
- [case study 2](#) - The innovation pathway
- [case study 3](#) – IP governance and decision-making
- resource 1 - For further guidance on appointing an SRO, please see GOTT's [Knowledge Asset Senior Responsible Owner: guide to appointing and the role](#)

## **Step 2: Clarify IP ownership**

### Understanding IP ownership, assignment, and commercial return

A persistent barrier to enable and develop innovation across NHS Wales is a lack of clarity around IP - particularly the assumption that retaining legal ownership of IP is the only way to benefit from it. This misunderstanding often leads to delays, disputes, wasted time and abandoned projects.

To support innovation and ensure that ideas can move from concept to impact, it is essential to clarify the following concepts:

### Legal ownership of IP

This refers to who legally holds the rights to IP. Clarity of ownership of IP through a clearly defined, documented and available process is important. The owner may be the NHS Wales organisation, a staff member or a third-party. Owning IP does not automatically deliver commercial benefit and nor does it necessarily ensure successful development of the idea. The legal position on ownership of IP is decided on a case-by-case basis, taking into account any relevant contractual arrangements and legislation, as appropriate, depending upon the type of IP created and the parties involved.

Where a number of parties are collaborating to produce innovations, joint IP ownership is extremely complicated (particularly where Crown copyright is also involved) and is unlikely to be the preferred option. Best practice would be for NHS Wales organisations to own any IP generated through public money (whether through employment or the direct funding of projects), subject to pre-existing contractual arrangements. Joint IP ownership should not be regarded as fair compromise without legal advice.

### Assignment of IP rights

Assigning IP means transferring its ownership to another party. This is often necessary when an external innovator, a spinout company, or another commercial partner is better placed to develop and scale the innovation than the NHS Wales organisation. Where commercial partners are spin out companies which have yet to establish sufficient financial resources fully to deliver the innovation, organisations should consider granting a licence with the option to obtain an assignment once financial milestones are met. There are a number of ways organisations can benefit financially, by including terms that provide commercial return, even after assignment. It is important to obtain fair market value for the IP and seek legal advice on competition law and subsidy law.

### Licensing of IP rights

Licensing IP means giving permission to a third party to use, share or commercialise IP under agreed conditions, such as for a specific purpose, usually in return for fees or royalties. It does not transfer ownership of the IP and the costs and responsibility for managing the IP

stays with the owner. For further guidance on licensing please see the IPO's guidance on [Licensing intellectual property](#). Retaining ownership of IP and granting a licence to use it is often preferable when the IP will remain valuable to NHS Wales organisations or it can be made available to a number of different parties for a commercial return. Licences can be:

- Exclusive (only the licensee can use it in a particular field and the licensor cannot use it); or
- Sole (only one licensee and the licensor can use it); or
- Non-exclusive (many licensees and the licensor can use it).

Government policy and laws such as the Reuse of Public Sector Information Regulations 2015, may also mean that some IP should be made available, for instance using the Open Government Licence. In addition, organisations should generally avoid granting exclusive licences other than in exceptional circumstances (see, for example, Principle 3 of [the 5 Principles for Data Partnerships](#)) and organisations should seek legal advice on this point.

Where an NHS Wales organisation grant licences to selected groups or on different terms depending on the identity of the licensee or where only a specific company will benefit, rather than many, it is important to obtain fair market value for the IP and seek legal advice on competition law and subsidy law.

#### Commercial return

This is the financial or strategic benefit gained from the commercialisation of the IP. Consideration should be given to commercial return in the public interest at fair market value as set out in [Managing Public Money](#). Crucially, commercial return does not necessarily require ownership. Through licensing or assignment agreements, the organisation providing and supporting NHS services can secure a share of future revenues, royalties, or equity in spinouts- without necessarily bearing the risk or cost of development.

#### Good practice principles

- Include clear statements in your IP policy regarding the determination of ownership of IP generated by all staff, collaborations and contracts. These include:
- Employees - including but not limited to those employed for clinical services, clinical academics as well as those employed for non-clinical services such as research, innovation, transformation or change.
- Non-employees - including but not limited to individuals on secondments or placements, non-clinical consultants, contractors and students.

- Collaborators - including but not limited to university or commercial partners, research partners, funders and relevant bodies such as Health and Care Research Wales.
- Contractual relationships - including but not limited to contracts with large pharmaceutical, medical device companies, service providers and startups.
- clarify the position regarding the determination of ownership of IP and ensure all parties understand the difference between an assignment of IP rights and a licence of IP rights, as well as understanding the potential for commercial returns generated from IP, such as by means of licensing.

### Step 2 resources

- [exemplar 1](#) - example template for an organisation's IP policy

## **Step 3: Raise awareness and provide IP training**

### Step 3 good practice principles

- IP policies are available to all staff (including procedures and decision-making frameworks) and are communicated to relevant staff (for example: commercial, innovation, research and legal teams). All staff should familiarise themselves with IP terms in NHS standard contracts and frequently used terms and conditions to ensure that:
  - Staff understand the actions they must take when they generate or contribute to innovations that may result in IP
  - Staff engaging with external collaborators or contracting with third parties initiate discussions about IP at the earliest opportunity
- Facilitate access to regular and up-to-date IP training opportunities to make sure staff understand the importance of IP, the identification of IP, their roles in IP management, and to ensure that staff are aware of the types of operational and R&D outputs that may be protected by IP.

### Step 3 resources

- [case study 4](#) – Communicating IP policy and processes
- [case study 5](#) – IP training
- resource 2 - for IP tools and training see the IPO's [Online support tools](#)

## **Step 4: IP disclosure, collaborations and record keeping**

### Step 4 good practice principles

- Clarify and communicate the requirement for all staff to:
  - Disclose early-stage innovations or potentially valuable creations at the earliest possible opportunity but only to the appropriate IP or innovation lead/team within the organisation
  - Ensure there is no external disclosure (for example, publication, presentation, or non-confidential discussion with third parties) until an internal IP review has taken place
  - Ensure the internal disclosure is appropriately confidential and the process is clearly signposted and accessible to all staff
  - Build in IP by design. Think about what IP will be created at the earliest possible opportunity, ideally before work begins. Also think about how it should be protected and managed (see Step 6: understanding IP rights and protection strategies) and keep the IP confidential until any decisions about other protection have been made.
- Clarify and communicate the requirement for all new collaborations and contracts to:
  - Report new collaborations or contracts that have the potential to generate IP to the designated team within their organisation (for example, IP, innovation, research, commercial, legal teams), as early as possible.
  - Make the internal disclosure process accessible to teams involved in setting up or managing collaborations and contracts.
- Create an efficient and secure system to record internal IP disclosures, track decision-making, and actively manage IP assets on an ongoing basis
- Provide clear guidance to the workforce on maintaining IP confidentiality, including:
  - Avoiding any informal sharing of IP with external parties
  - Using confidentiality agreements (also known as non-disclosure agreements (NDAs) whenever confidential information is likely to be shared with an external party
  - Maintaining confidentiality until the initial IP review is completed. Once the initial IP review is completed, the decision may be to keep the innovation confidential, protect

it with patents, registered designs or trade marks as applicable, or make it publicly available.

#### Step 4 resources

- [case study 6](#) - IP disclosure, decision-making and tracking systems
- [case study 7](#) - IP awareness in contracts and early identification
- [exemplar 2](#) - Exemplar NDA templates for collaborative projects involving potential IP development

### **Step 5: IP initial evaluation and feedback**

#### Step 5 good practice principles

- Review all internally identified IP and assess its potential for adoption, scaling and commercialisation
  - Conduct market assessments and horizon scanning to inform next steps
  - Seek early advice from relevant legal, innovation and commercial teams to support IP protection and facilitate appropriate returns from the outset
- Where appropriate, propose options for a development and adoption or commercialisation pathway, ensuring it is regularly reviewed and adapted as the project progresses, and new insights emerge
  - This should include consideration of the end point for real-world use, the route to impact, and the IP protection strategy
- Where relevant, consider opportunities to align with university partners, enabling collaboration routes to jointly develop IP
- Provide timely feedback to innovators, collaborators and third parties

#### Step 5 resources

- [case study 8](#) - IP triage and evaluation frameworks
- [case study 9](#) - jointly developed IP through university/academic partner collaboration
- [exemplar 3](#) - collaboration agreements, NHS Wales and university/academic/ industry partner on IP matters

## **Step 6: understanding IP rights and protection strategies**

Not all IP needs to be formally protected by registration in order to be valuable or useful. In some cases, the costs of obtaining and maintaining registered protection may outweigh the potential benefits, particularly where the IP has limited commercial potential or a short lifecycle. Additionally, some IP may be better safeguarded through confidentiality and good information management. The decision to apply for registered protection of IP should always be strategic - guided by its potential value, relevance to the innovation's development path and the organisation's broader goals.

### **Step 6 good practice principles**

- Understand that different types of IP require different protection processes and strategies. Protection should be aligned with the intended development and commercialisation pathways:
  - AI-generated innovations present unique challenges, such as authorship, data ownership, and the protection of AI-driven innovations. Information on using AI safely, effectively and securely can be found at the Government Digital Service's [AI Playbook for the UK Government](#). This a rapidly developing area, which should be checked regularly for updates
- Seek advice from legal, innovation, and commercial experts to assess whether and how to protect IP in line with the chosen strategy, including consideration of whether protection is needed in international markets
- Take a balanced approach to IP protection, weighing the potential value of IPRs against the cost of protection
- Conduct regular reviews of NHS-registered IP assets to maintain value for money and actively manage IP portfolios in line with these good practice principles:
  - Avoid spending money and resources on protection unless a development plan exists and unless there is an intention that the IP will be actively supported and developed towards adoption and/or commercialisation
  - Use standardised templates for evaluating the cost-effectiveness of maintaining IP rights, ensuring resources are directed toward assets with the highest potential impact
- Managing IP in collaborations:

- Establish clear agreements on the ownership, use, and management of jointly developed IP, as well as background IP, ensuring alignment between partners, and alignment with funders' terms
- Define who is responsible for assessing and documenting background IP at the outset of collaborations to prevent disputes and to clarify ownership
- Implement structured methods to track and measure foreground IP within collaborations, ensuring fair attribution and appropriate commercialisation strategies

#### Step 6 resources

- [case study 10](#) - IP protection vs open source-open licensing for wider benefit
- [case study 11](#) - using expert legal advice to shape IP protection strategy
- resource 3 - the [IPO's online support tools](#) for people learning how to manage or use IP
- resource 4 - for further information on IP Rights, please see GOTT's [Guide to Managing Intellectual Property and Confidentiality](#).

### **Step 7: IP development and commercialisation**

Not all innovations should, or need to, lead to commercial returns. Some innovations are essential for improving NHS Wales services or patient care without a commercial pathway, whilst others may offer opportunities for licensing, spinouts, or other commercial models. Both types, however, create value - by improving care, enabling adoption, or generating returns - and NHS Wales organisations should foster environments where innovation thrives to meet healthcare challenges.

In order to maximise impact of innovations, NHS Wales organisations should adopt a clear framework to assess which route is the most appropriate on a case-by-case basis and take appropriate legal advice.

#### Step 7 good practice principles

To determine the most appropriate route, organisations should consider the following factors:

- The intended use and impact - what is the end goal for this output or innovation; what is its intended use and where will it have impact?
- NHS Wales contributions to date and planned support - including access to data, staff time, infrastructure or funding.

- Internal capacity – does the NHS Wales organisation have the skills, resources or mandate to lead development?
- Partner capability - is the innovator or an external party better positioned to deliver?
- Contractual context - are there pre-existing obligations to partners, funders or regulators?
- Fair return - what level and form of return is proportionate (for example, royalties or equity) Consideration should be given to understanding or applying fair market value.
- Feasibility and market potential - have feasibility assessments, market analysis and IP due diligence been conducted to evaluate the innovation's commercial viability and strategic alignment?

An assessment against these principles will support organisations in selecting the most suitable IP development and commercialisation route.

#### IP development and commercialisation routes

Below are three primary routes, supported by good practice principles. Whilst these are unlikely to cover every scenario, they provide a useful framework for decision-making.

#### Route 1: development, adoption, and spread with no commercialisation

Some innovations designed to improve services within NHS Wales may have no clear commercial opportunity, however benefit may still accrue to organisations through development and scaling within an NHS setting or through open dissemination to enhance the body of knowledge. In these cases:

- Focus should be on effective dissemination of non-commercial NHS outputs or innovation through publication under appropriate licences including [Creative Commons Licenses](#) that provide clarity on how permissions are being granted for use and reuse. Registered IP protection may still be needed to ensure quality control and consistency, or to safeguard future development options.
- Organisations should:
  - Support adoption, sharing through collaboration, education, or digital infrastructure
  - Consider open access or permissive licensing where appropriate
  - Track and evaluate the impact on patient outcomes and service quality
  - Avoid unnecessary costs of seeking registered IP protection if it does not serve a practical purpose

- Encourage innovators by recognising their contribution, even when no commercialisation occurs
- Consider whether IP which is no longer being used in an organisation could be sold to a third party for fair market value or, where appropriate, made available

#### Route 2: innovator or third-party development with NHS exit

Where the NHS Wales organisation decides it is not best placed to develop the IP due to limited internal capability or strategic alignment it should act decisively to transfer the innovation for development elsewhere taking into consideration the views of individual staff members involved. However, even where IP is to be assigned, any agreement should contain a licence back to the organisation for the purposes of patient care, teaching and research.

- Organisations should:
  - License or assign the IP to the innovators or third party in a timely and transparent way
  - Secure a fair commercial return (consideration should be given to fair market value) that reflects the organisation's contribution to date and the potential of the IP
  - Establish a fair, transparent and benchmarked reward structure that incentivises innovators or third parties to develop the IP
  - Clearly define the terms under which innovators or third parties may continue to access NHS resources (for example, clinical input, data) after licensing or assignment of the IP to them
  - Where IP is to be assigned to a third party, include a licence back to the NHS for continued use
  - Ensure obligations to funders, investors, and collaborators are upheld
  - Provide timely feedback to all parties to maintain momentum and organisation.

#### Route 3: strategic co-development for commercialisation

Where NHS Wales brings significant added value, such as access to data, infrastructure, expertise, or resources, it may be appropriate to co-develop the innovation and share future returns. This approach should be underpinned by clear and early agreements (particularly where the parties need to comply with applicable legislation, such as GDPR) and strong collaboration.

Organisations should:

- Clearly define their support offer, including:
  - Access to data, software, technology, infrastructure, expertise or patients.
  - Clinical validation or research capabilities.
  - Support for regulatory or real-world testing.
- Establish and record upfront agreements on:
  - Contributions from all parties to-date.
  - Planned roles and inputs going forwards.
  - The planned ownership of IP outputs, noting that joint ownership is rarely an appropriate or effective option.
  - Responsibility for registering IP outputs (if applicable).
  - What should happen to the IPR on termination and whether anyone can continue to use it.
  - Commercial model options based on each parties' contributions (for example, licensing, equity, or joint ventures).
- Ensure no development proceeds without a clear, shared understanding of expectations and upfront agreements in writing.
- Use flexible commercial models that:
  - Incentivise innovation from the NHS workforce.
  - Fairly reflect the contribution of the NHS Wales organisation.
  - Balance financial returns with the speed of development.
  - Enable clear, transparent, and efficient negotiations.
- Ensure funder, investor, and collaborator needs are reflected in agreements, where appropriate.

### Characteristics of effective IP commercialisation models

- Clarify the nature and value of NHS Wales contributions to an innovation, such as clinical insight, infrastructure, data access, or funding, and how these are recognised in any future IP or commercial discussions
- Shift the focus from retaining IP ownership to fair value realisation, emphasising that ownership is not the only route to securing returns. NHS Wales contributions can be protected and recognised through licensing, equity or revenue-sharing agreements.
- Any proposed assignment of IP should entail full consideration of the maturity and stability of entity taking control of publicly funded innovations to ensure it is appropriately placed to commercialise publicly funded innovations.
- Outline expected commercial returns early in the process, ensuring fairness, transparency, and organisation between partners.
- Reward all parties appropriately, negotiation should focus on long-term innovation partnerships rather than maximising short-term income or control.
- In cases of international collaboration, to ensure IP is addressed in a way which supports international adoption, sharing whilst providing returns to NHS Wales.

### Step 7 resources

- [exemplar 3](#) - collaboration agreements, NHS Wales and university/academic/ industry partner on IP matters.

## **Step 8: IP asset management and tracking returns**

### Step 8 good practice principles

- Implement a system to actively manage IP assets, ensuring that:
  - IP agreements are properly entered into and managed for the life of the agreement.
  - Revenue, licensing fees, or other returns are accurately recorded.
- Ensure financial returns to staff are handled in accordance with IP policies of the NHS Wales organisation.
- Direct NHS-generated returns toward supporting future innovation and continuous improvement in IP management within organisations.
- Implement structured frameworks for reviewing IP portfolios, ensuring that NHS-registered IP assets are actively managed and aligned with strategic priorities.

- Consider the ongoing utility of any registered IP assets, and where these are no longer in use and it is appropriate to do so, sell to a third party for fair market value or allow the registered rights to lapse.

#### Step 8 resources

- [case study 14](#) - Managing and Reinvesting NHS IP Returns for Future Innovation

### **Step 9: access IP expertise and technology transfer offices or capabilities**

To implement an efficient and effective IP management system, all NHS Wales organisations require access to IP expertise and Technology Transfer Offices (TTOs – also referred to as Technology Transfer Capabilities). TTOs provide the skills, support, and ability to execute the commercialisation of IP. See page 84 for further information.

Currently, NHS Wales organisations access TTOs through the following models:

- Collaboration with Welsh University TTOs and business accelerators such as the Life Sciences Hub Wales.
- Building in-house TTOs through R&D or Innovation teams.
- Working with private sector providers of TTO services.

#### Step 9 good practice principles

If not already in place, NHS Wales organisations should:

- Evaluate the necessity of accessing TTOs and explore available TTO support
- Make sure their TTO partnerships reflect good practice principles
- Ensure that any fees are proportionate to the work undertaken by the TTO
- Make IP policies and TTO arrangements publicly available (e.g. publish on website)
- Provide appropriate training in IP and commercialisation for SROs and NHS Wales staff involved in technology transfer activities:
  - Training should align with good practice principles and equip innovators and supporting teams (for example: commercial, legal, innovation) with the necessary skills to manage and commercialise NHS-generated IP effectively.

## Case Studies

These case studies accompany the intellectual property (IP) guidance for NHS Wales.

Case studies are organised according to the relevant steps in the guidance above, providing practical examples to support implementation.

### Case study 1 – IP Senior Responsible Owner (SRO) personas

These personas showcase examples of two NHS Wales organisations' Senior Responsible Owners (SRO) for IP, highlighting the key responsibilities, decision making authority, and the commercial and IP expertise essential for the role.

#### **Persona 1 - Director of Research & Development / Innovation / Commercial Strategy / Medical Director**

##### **About**

- Member of the Executive Leadership Team.
- Senior Responsible Owner (SRO) for knowledge assets.
- Focuses on clinical innovations and service improvement tools.

##### **Key Responsibilities Related to IP and Commercialisation**

- Leads integration of IP into clinical research, digital health, innovation and pathway redesign.
- Aligns IP strategy with organisational priorities and patient benefits.

##### **Day-to-Day Involvement**

- Oversees early-stage IP identification and triage with clinical and non-clinical teams and R&D office
- Supports evaluation of IP potential in digital tools, AI models, and technologies designed to aid clinical decision-making processes
- Participates in commercial discussions with industry and academic partners

## **Commercial and IP Expertise**

- Experience and/or academic expertise in health innovation, R&D and commercial frameworks
- Experienced in NHS procurement, data governance, innovation and collaborative research and development agreements.
- Skilled in identifying clinical value and commercial potential of frontline innovations.

## **Persona 2 – Research & Development / Innovation Manager or Lead**

### **About**

- Member of the Innovation Team responsible for overseeing innovation at an NHS Wales, regional or other network-based structure, which brings together organisations and leads as part of delivery of health care across the region.
- Senior Responsible Owner (SRO) for IP policy, management, and training. This is part of their wider innovation role and undertaken alongside their day-to-day responsibilities.
- focuses on supporting commercialisation of IP, including through developing partnerships and collaborations across acute, primary care, and community care settings.

### **Key Responsibilities Related to IP and Commercialisation**

- Develops and maintains IP policy at the collaborative and its partners, including NHS Wales organisations, GP practices and community hubs.
- advises wider collaborative and partner organisations on arising IP issues.
- Ensures staff across partner organisations have knowledge of IP policies and procedures.

### **Day-to-Day Involvement**

- Oversees early-stage IP identification and triage with innovation teams and business managers.
- Supports evaluation of IP potential in innovations across the collaborative.
- Facilitates conversations with inventors about IP and commercialisation.

## **Commercial and IP Expertise**

- Experience working in health innovation in NHS Wales organisations, including community care.
- Expertise in IP management in relation to clinical research and innovation across multiple care settings.
- Experience in developing and maintaining IP disclosures and agreements
- Experience in discussions and negotiations around IP and commercial models.
- Skilled in conducting market research to understand innovation potential.

### Case study 2 - The innovation framework

#### **Example 1: General overview of the NHS Wales innovation framework.**

The [Innovation Framework - Health and Social Care Innovation Wales](#) as set out on page 25 of the [NHS Wales Technical Planning Guidance](#) sets out the six stage innovation process that guides the development and adoption of innovations. The six stages, in order, are:

- Describe, understand and define
- Explore and Identify solutions
- Develop solutions
- Create evidence and prove value
- Adapt, adopt and deploy
- Spread and Scale

Each stage has clear decision points, with defined routes for progression and non-progression. Support mechanisms and actions at every step can help move innovations from concept to national scale. The innovation framework helps innovators, teams, and organisations to:

- Understand the end-to-end innovation process.
- Set out what support from which organisation is available at each Framework stage.

- Navigate decisions, funding, and regulatory requirements.
- Accelerate adoption of high potential innovations across the health system.

### **Stage 1: Describe, understand and define the idea**

#### **Purpose:**

Generate and identify promising new ideas, describing and defining their scope.

#### **Activities and Support:**

- demand signalling – capturing unmet clinical needs, issues and problems (e.g., from clinicians/practitioners, patients, NHS Wales staff)
- entrepreneurship training – building innovation and commercial skills
- initial tech transfer support – e.g., protecting ideas and applying for first patents
- applying standard IP and commercial frameworks across organisations

#### **Decision Point:**

Does the idea have potential – is the idea aligned with identified NHS Wales needs, can potentially benefit patients and is worthy of initial development?

- yes – proceed to the next stage.
- no – provide feedback, capture idea in an innovation register for future review, and/or redirect to training or demand signalling. Option to archive if the idea no longer meets current needs, with the possibility of re-entry if conditions change.

### **Stages 2 and 3: Explore, Identify and Develop solutions**

#### **Purpose:**

Explore feasibility of the idea and identify potential solutions to the unmet clinical needs or problems.

#### **Activities and Support:**

- product and regulatory advice
- Work with expert partners - [Life Sciences Hub Wales Partner Directory](#)
- access to development environments and datasets to test concepts
- explore external funding guidance (venture capital, grants, research funding) - [Life Sciences Hub Wales Funding Directory](#)
- managing IP, royalties, and equity on behalf of members

### **Decision Point:**

Does the idea have technical, clinical, and commercial potential to justify validation?

- yes – proceed to Validation stage
- no – provide feedback to the innovator and either:
  - refine and re-test (loop back within Development)
  - return to Idea stage for re-scoping
  - record in the innovation register, archive if appropriate, with option for re-entry
  - allow the innovator to take forward idea, making clear that no further support from the organisation will be provided

### **Stage 4: Validate, create evidence and prove value**

#### **Purpose:**

Prove the concept and gather evidence of effectiveness, safety, and potential economic value

#### **Activities and Support:**

- continued access to test environments, data, and regulatory support
- evidence generation – e.g., clinical trials, health economics, real-world data
- Continued support for grant and funding applications [Life Sciences Hub Wales Funding Directory](#)

**Decision Point:**

Does the evidence confirm that the innovation is safe, effective, and viable for adoption?

- yes – proceed to Adoption stage
- no – identify gaps, provide targeted feedback, and either:
  - return to Development for improvement
  - record in the innovation register and archive until conditions change
  - allow the innovator to take forward idea, making clear that no further support from the organisation will be provided.

**Stage 5: Adoption, adaptation and deployment****Purpose:**

Prepare the innovation for uptake within the NHS Wales organisation and wider healthcare system

**Activities and Support:**

- use patient, clinical, and operational panels to identify innovations that support adoption and recommend them for procurement
- negotiate commercial agreements
- evidence impact through pilots, health economics, and compliance with relevant regulations (e.g., MHRA medical device approval, data protection, clinical safety standards) in appropriate testing environments
- Explore partnerships across NHS Wales pilot sites or environments that enable safe integration, workflow testing, and staff training before full rollout
- access external expertise in areas such as health economics and regulatory compliance (e.g., legal from NHS Wales Shared Services, data protection, procurement rules)

**Decision Point:**

Is the innovation ready and approved for operational use and/or procurement?

- yes – proceed to Scaling stage
- no – provide feedback and either:
  - redirect to Validation for further evidence generation and testing
  - redirect to Development for redesign
  - record in the innovation register and archive with the option to revisit later if no further work is supported
  - allow the innovator to take forward idea, making clear that no further support from the organisation will be provided.

## **Stage 6: Spread and Scale**

### **Purpose:**

Support wider implementation across NHS Wales.

### **Activities and Support:**

- standardise commercial and contractual terms (e.g., scaling discounts)
- confirm information governance, cyber security, and regulatory compliance (e.g., legal, safety, quality, and procurement requirements) at scale
- facilitate regional and national adoption campaigns

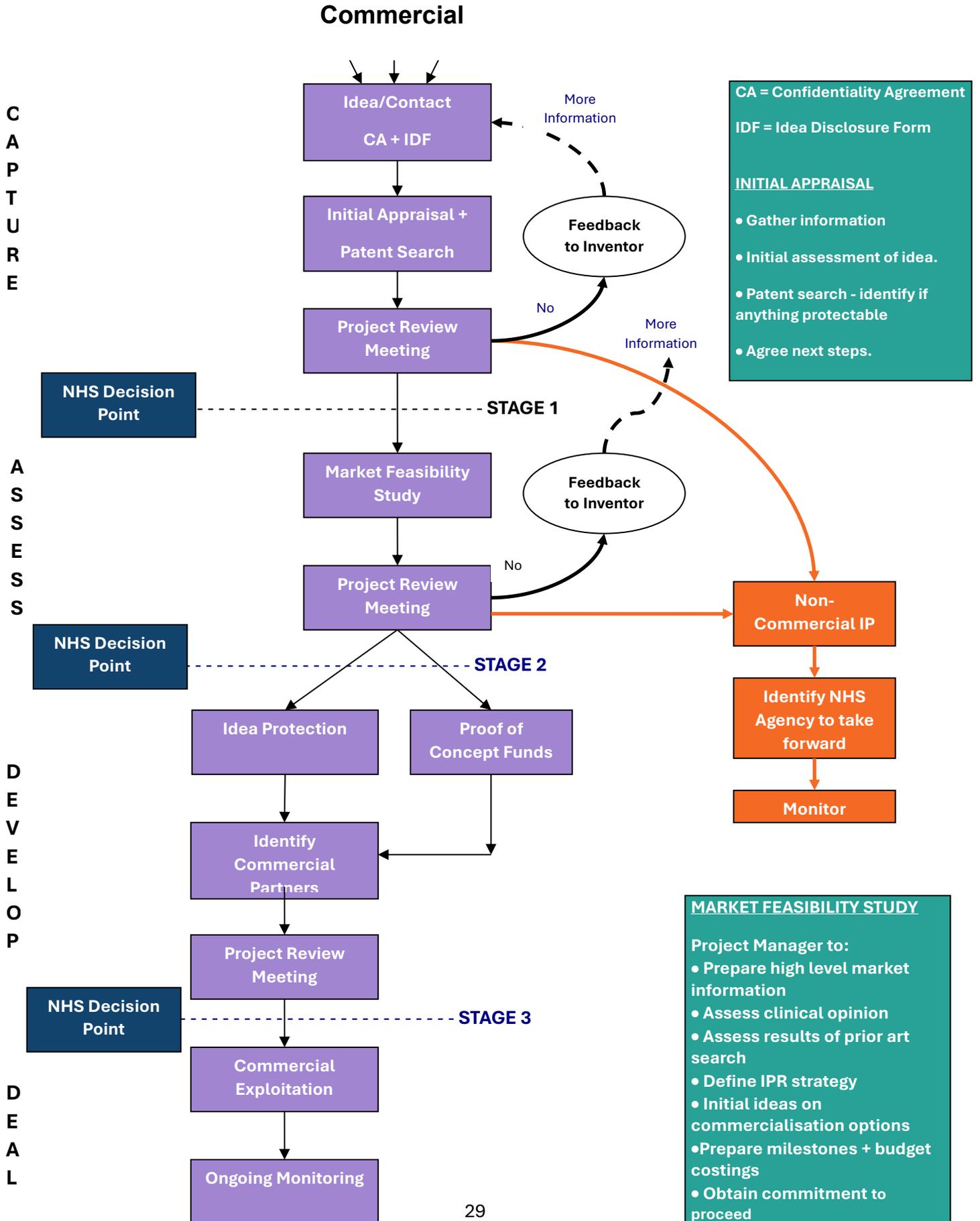
### **Decision Point:**

Can the innovation be sustainably scaled across the system?

- yes – implement nationally and explore international adoption, including national clinical or non-clinical groups
- no – either:

- identify scaling barriers and return to Adoption or Validation as appropriate
- if scaling, adoption, and/or validation is no longer viable, record in the innovation register, provide feedback, and archive, with option to revisit in the future
- allow the innovator to take forward idea, making clear that no further support from the organisation will be provided.

**Example 3: commercialisation pathway for NHS innovations**

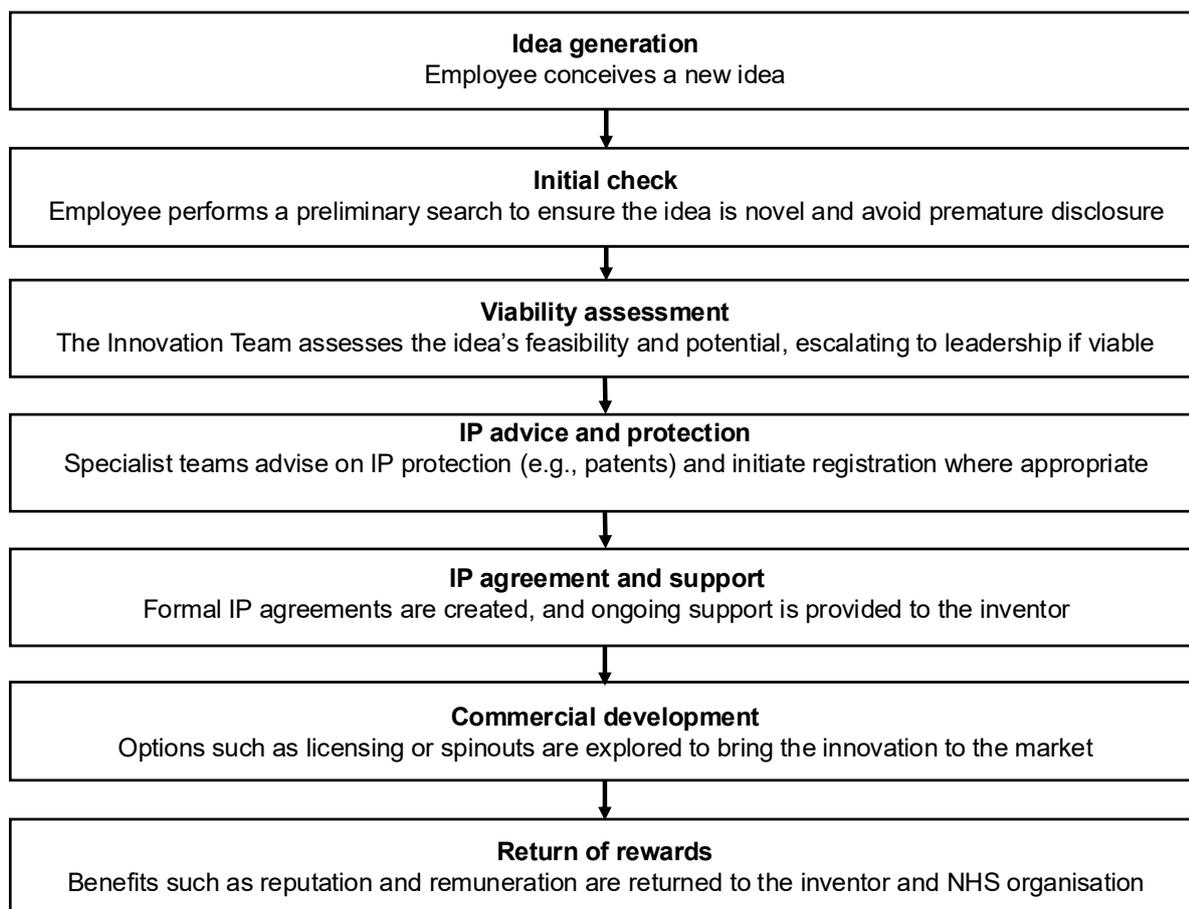


The example above is a flowchart describing a commercialisation pathway for NHS innovations, moving from idea capture to commercial exploitation. It is structured around 4 phases: Capture, Assess, Develop, and Deal. This structured pathway ensures:

- Clear IP capture
- Support for both commercial and non-commercial routes
- Ongoing monitoring post-commercialisation
- Clear decision points throughout the process

### Case study 3 - IP governance and decision-making

#### NHS Wales IP Governance Best Practice Flow Diagram



## **Example 1 - Clear IP governance and decision-making process**

Several organisations use a structured process outlined in the flow diagram below for IP governance and decision making.

### **1. Idea Generation**

Employee conceives a new idea.

### **2. Initial Check**

Employee performs a preliminary search to ensure the idea is novel and avoid premature disclosure.

### **3. Contact Innovation Team**

Employee contacts the Innovation Team (or relevant team, sometimes Research & Innovation team) to discuss the idea and initiate the IP process.

### **4. Viability Assessment**

The Innovation Team assesses the idea's feasibility and potential, escalating to leadership if viable. Following the viability assessment, the following stages should take 3 months to complete.

### **5. IP Advice & Protection**

Specialist teams advise on IP protection (e.g., patents) and initiate registration where appropriate.

### **6. IP Agreement & Support**

Formal IP agreements are created, and ongoing support is provided to the inventor.

### **7. Commercial Development**

Options such as licensing or spinouts are explored to bring the innovation to market.

### **8. Return of Rewards**

Benefits such as reputation and remuneration are returned to the inventor and organisation.

In establishing a clear IP governance process, from idea generation to commercialisation, defining clear roles, decision points, and sign-off routes, the NHS Wales organisation

ensures timely, accountable IP management. This enables innovations to progress efficiently and strategically

### **Step 3: Raise awareness & provide IP training**

#### **Case study 4- Communicating IP policy and processes**

##### **Example 1 - Easily accessible IP and innovation processes**

This case study highlights how an NHS Wales organisation can take a proactive, inclusive approach to communicating its IP policy, ensuring all staff can engage with innovation processes.

##### **Key actions taken:**

##### **Accessible policy and tools:**

- the IP policy is hosted on the staff intranet alongside a digital IP disclosure form.
- this encourages early and accurate reporting of innovations.
- the IP Senior Responsible Officer (SRO) uses this data to monitor activity and identify support needs.

##### **Inclusive access:**

- an Equality Impact Assessment led to the introduction of paper-based disclosure forms alongside digital versions
- this ensures staff without regular computer access can still participate in the IP process.

##### **Staff engagement and feedback:**

- the organisation tracks the number and quality of disclosures.
- feedback from training sessions is used to refine communication and improve understanding.

##### **Impact:**

- improves early IP identification across all staff groups
- ensures equitable access to innovation processes

- supports a culture of innovation and continuous improvement
- helps protect ideas that could lead to patient benefit

By embedding IP processes into daily workflows and aligning communication with staff needs, the organisation is building a more innovation-ready workforce.

### Case study 5 - IP training

#### **Example 1 - Structured, role-specific training**

This case study highlights how an NHS Wales organisation can strengthen IP awareness and capability through a structured, role-specific training approach.

By tailoring content to different staff groups, the organisation ensures that learning is relevant, practical, and supports innovation that benefits patients.

Key features of the approach:

#### **Business Managers**

- receive bespoke training on the organisation's IP policy
- sessions include informal discussion to explore real-world application
- supports consistent understanding and encourages innovation within teams

#### **Clinical Academic Staff**

- receive targeted training on foreground vs background IP
- this builds confidence in identifying and protecting IP from research and clinical work

#### **Testing an All-Staff Approach**

- digital learning hosted on an Electronic Staff Record (ESR) training module is under evaluation, which once approved, will offer scalable, accessible IP training across the organisation

#### **Specialist Training**

- with support from local partners, the organisation commissioned the Intellectual Property Office to deliver a two-day in-person course

- attendees included innovation leads, research managers, technology transfer, commercial, procurement and contract management staff

**Impact:**

- improves staff confidence and consistency in handling IP
- supports safe, effective innovation and commercialisation
- enables faster translation of ideas into patient benefit

This blended learning model helps embed a culture of innovation and ensures staff at all levels can engage meaningfully with IP in their roles.

**Example 2 - IP training as a core part of an innovation training programme**

A group of organisations can partner with training providers to deliver a structured innovation training programme for staff. A core module of the programme focuses on IP, helping staff understand how to protect and manage ideas that could improve care.

**Who it is for:**

- open to all staff across participating organisations
- supports those interested in innovation, entrepreneurship, or adopting new technologies
- helps staff with service improvement ideas understand where to begin

**What the programme offers:**

- introduction to key innovation concepts, including how to develop, protect, and commercialise ideas
- peer support from a regional community of healthcare innovators
- access to expert trainers and ongoing support from business development and innovation teams

**The IP module covers:**

- what IP is and why it matters in NHS Wales
- IP ownership and NHS Wales policy
- different types of IP protection and when to use them

- practical steps to protect IP in day-to-day work

**Impact:**

- builds staff confidence to take ideas forward
- ensures valuable innovations are protected and used effectively
- supports faster, safer adoption of new ideas that benefit patients

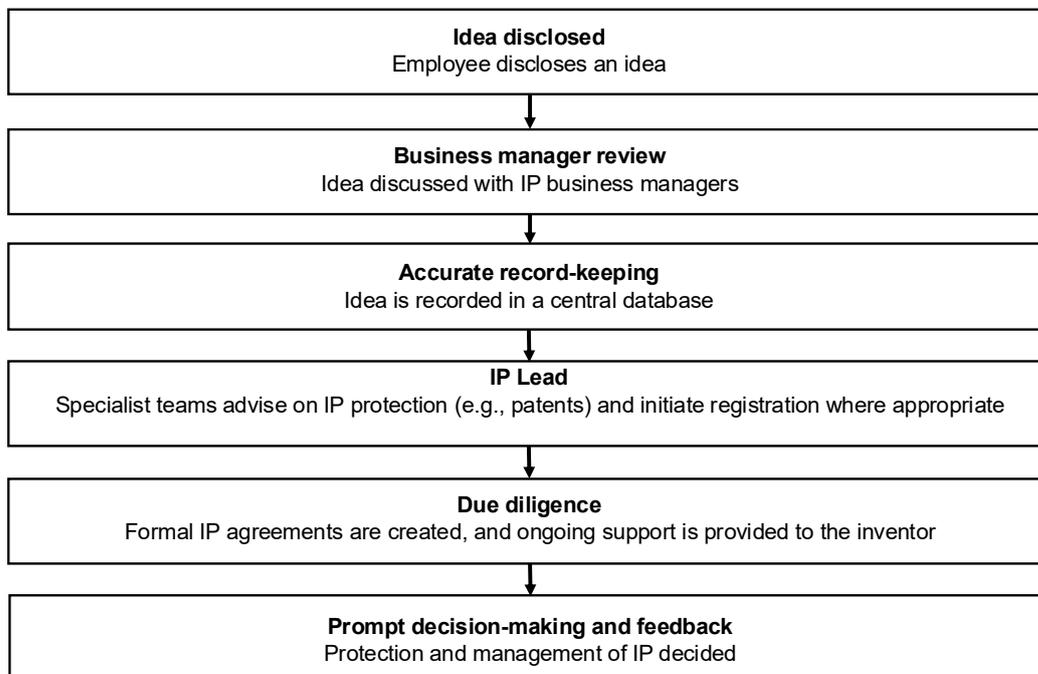
By embedding IP into core innovation training, this programme helps create a more confident, capable NHS Wales workforce ready to turn ideas into impact.

**Step 4: early identification, collaborations & record keeping**

Case study 6 - IP disclosure, decision-making and tracking systems

**Example 1 - Providing clear and timely feedback to IP disclosures**

An organisation could use the following step-by-step process to track IP disclosure and decision-making:



## **1. Idea Disclosed**

- a staff member discloses an idea that may have IP involved or commercial potential using the staff disclosure form. This is the first step in identifying possible intellectual property.

## **2. Business Manager Review**

- all IP disclosures are discussed. A meeting is held with Business Managers to assess the idea. Key questions include:
  - does this idea have IP potential?
  - who should support its development (e.g. research, innovation, or commercial teams)?
- this early triage ensures the right expertise is involved from the start.

## **3. Accurate Record keeping**

- the idea is recorded in a central database. While not yet integrated into a formal IP management system, this log helps track:
  - what was submitted
  - when it was submitted
  - what decisions were made
  - who is responsible for next steps
- clear documentation is essential from the outset. The organisation has developed a simple, visible process that staff can follow to submit ideas confidently.

## **4. IP Lead Review**

- the IP Lead reviews each submission to determine the appropriate innovation pathway for the idea:
  - research-related ideas go to the Joint Research Office
  - innovation-focused ideas are handled by the Innovation Manager
- this ensures ideas are assessed by the right people with the right expertise.

## 5. Due Diligence

- initial market research is carried out by the Innovation Manager to assess whether the idea is novel, protectable, and commercially viable, with external advice sought if required.

## 6. Prompt decision-making and feedback

- once due diligence research is completed, the Innovation Manager decides whether to protect and manage the IP. Any IP that is not protected and managed by the organisation is assigned back to the staff member and/or innovator.
- all IP disclosures are discussed in a one-to-one meeting with the staff member who has completed the disclosure, to ensure clear communication and feedback.

A focus on early disclosure, a structured review process, and strong record-keeping means that this organisation significantly improves the chances of protecting IP and supporting timely commercialisation where relevant.

### Case Study 7 - IP awareness in contracts and early identification

#### **Example 1 - A practical checklist to support early identification of IP**

This case study highlights how an organisation could embed IP awareness into its wider commercial and innovation partnership processes.

To support early identification of IP and strengthen governance, the organisation developed a partnership checklist. This tool helps teams assess and document key considerations when forming formal or informal collaborations.

Key features of the checklist, developed with input from executives and non-executive directors.

- The checklist covers areas such as:
  - clinical involvement
  - commercial opportunity
  - strategic alignment
  - governance and legal risks

- IP ownership and management
- cost-benefit analysis
- workforce and estates impact
- sustainability and subsidy control
- provides guidance on capturing these considerations in business cases, non-disclosure agreements, and data-sharing agreements

#### **How it works:**

- the checklist is administered by the innovation team, with input from all project stakeholders
- the checklist is applied in stages, with sign-off at each point to ensure robust decision-making
- ensures early, informed discussions about IP with external partners

#### **Impact:**

- improves early identification of IP opportunities and risks
- supports better-informed, legally sound partnerships
- enhances patient benefit by accelerating safe and sustainable innovation adoption

This approach demonstrates how IP considerations can be hard-wired into partnership planning, ensuring NHS Wales organisations protect and maximise the value of innovation from the outset.

### **Example 2 - Embedding early identification and notification in organisational policies and procedures**

This case study highlights how a research intensive NHS Wales organisation can embed early IP identification and notification into its core research policies and procedures.

The organisation uses two key documents to ensure IP is considered before contracts are signed:

- **The organisation's IP Policy**

- management of Contracts (Research) Standard Operating Procedure (SOP), which applies to the research and development (R&D) Department, the Clinical Trials Unit, departments of other NHS Wales organisations involved in research, and Investigators conducting or participating in studies sponsored by the NHS or other organisations.

#### **How it works:**

- staff are directed to the R&D Manager or the organisation's partner health technology consultancy (HTC) for IP queries.
- an HTC IP notification form is completed to trigger early review.
- the HTC works closely with:
  - the R&D legal team
  - an in-house IP and commercialisation expert
- this ensures early identification of IP risks and opportunities.

#### **Grant applications:**

- all grant applications involving incoming funding must be reviewed and signed off by the R&D Manager.
- this ensures the R&D team is aware of any potential IP issues, even if not identified earlier.

#### **Contract management:**

- the R&D governance team supports researchers in setting up funded studies.
- all research-related contracts must be reviewed and approved by R&D before signing, as required by the SOP.

#### **Impact:**

- ensures early, expert review of IP in research projects
- prevents delays and legal risks by embedding IP checks upfront
- supports smoother, safer research delivery that benefits patients through faster access to innovation

This approach shows how clear policies and procedures can hard-wire IP awareness into NHS research governance.

## **Step 5: IP initial evaluation & feedback**

### **Case Study 8 - IP triage and evaluation frameworks**

#### **Example 1 - Initial evaluation framework**

An organisation can develop a clear, staged framework to evaluate new ideas and IP disclosures from staff and collaborators. This makes sure that only viable innovations progress and helps to focus resources and reduce risk.

The framework can include:

- initial disclosure, capturing the details about idea
- feasibility assessment, including early market research to assess need, competition and IP implications
- market validation, which involves deeper market analysis to confirm potential
- development of the idea, which looks at sourcing funding, identifying partners, and managing the project

Each stage includes a go/no-go decision. Inventors receive a report after the feasibility stage, and further support is provided as the idea progresses. Throughout the process, searches are done to check if similar ideas or inventions already exist, to assess protection options.

This structured approach ensures that promising ideas are identified early, developed with the right support, and commercialised through the most appropriate route, maximising impact and value for the organisation.

#### **Example 2 - Collaborative IP evaluation model to accelerate innovation decision-making**

An organisation can work closely with its university's technology transfer company and a health technology consultancy to evaluate and commercialise IP. This partnership, via the

Research Centre IP Manager, supports the organisation's National Institute for Health and care Research Centre and wider innovation activity.

Inventors can disclose IP to the organisation, the university's technology transfer company, or the health technology consultancy. The receiver of the disclosure conducts an initial evaluation to assess the idea's potential, including ownership, patentability, and relevance. This may involve a prior art search and patent review.

Key evaluation criteria include:

- legal strength of the IP (for example, novelty of the idea, potential for exclusivity)
- commercial potential (for example, the cost of protection, market value)
- maturity of the idea (more developed IP is easier to assess)

The evaluator also considers:

- what problem the idea solves
- who might benefit commercially
- how the inventor wants to proceed

The organisation's R&D Head of Legal is involved where needed. Inventors receive feedback and suggestions for next steps from the receiver of the disclosure, which may include:

- funding opportunities
- patent filing
- commercialisation planning
- partner engagement

This collaborative model, seeking early advice and expertise from partners increases capacity and speeds up decision-making, helping the organisation's innovations move forward efficiently and effectively.

## Case Study 9 - jointly developed IP through university/academic partner collaboration

### **Example 1 - Successful partnership with university and sub-licencing model**

An organisation taking part in a UK research project, led by a university and another NHS Wales organisation, may develop new knowledge, e.g. biomarker for cancer. The project may be funded by a major research charity, who holds the patents through its technology transfer arm.

The organisation secured a research licence to scale up and validate the test, using public innovation funding and working with genomic labs across the UK. The licence agreement required the ability to sublicense to other partners through collaboration agreements.

After successful validation, the organisation secured a worldwide exclusive licence to commercialise the test both in NHS Wales and internationally. Under this agreement, the NHS Wales organisation will receive a share of any future sales revenue from the product.

To support ongoing collaboration, the organisation has a Memorandum of Understanding with its university partner. This sets out an equal 50/50 split of revenue between them.

This case study shows how NHS Wales organisations can lead complex licensing negotiations and work with a range of partners to bring new healthcare innovations to patients.

### **Example 2 - IP management, collaboration and revenue sharing agreement with partner research institute**

An organisation may work with a Health and Care Research Wales Research Centre and manage IP under a shared IP Policy. This policy overrides individual organisational policies for all work funded by their research funder. The policy covers various types of IP, including research data and software.

Under the policy, foreground IP is owned by the organisation unless a joint decision is made at an 'Opportunities Meeting.' Staff must report any IP with commercial potential to their employer's IP lead. The funder oversees this process by requiring consent for commercial licensing and receiving reports on IP with commercial potential, ensuring outcomes benefit patients and the public.

Financial returns are shared after deducting direct IP costs such as legal and patent fees, the funder's share, and any co-owners' entitlements. Each partner then applies its own internal revenue-sharing policy to the remaining income.

This overarching IP policy ensures clear ownership, fair revenue distribution, and consistent governance. It supports innovation while aligning commercial outcomes with each party's contribution.

### **Example 3 - 50:50 revenue sharing agreement with university partner**

Two NHS Wales organisations, each with HCRW Research Centres, have signed identical commercialisation agreements with their university partner and its technology transfer company.

The agreements will:

- make it easier to commercialise joint research and innovation
- allow new technologies and treatments to reach patients faster
- ensure that any commercial income is shared fairly between the organisations and the university

The agreement includes a broad definition of projects in scope. Where there have been relevant contributions to projects that have commercial returns, proceeds from commercial returns will be shared 50:50 between the university and respective NHS Wales organisation, after deducting payments to inventors, other agreed distributions, and the direct costs of commercialisation.

By removing the need for separate negotiations for each project, the agreement will:

- reduce delays in the commercialisation process
- speed up investment of revenues
- attract more investors through increased efficiencies

Revenue generated will be ringfenced to support further research and innovation in health and care, in line with HCRW policy.

This agreement lays the foundation for closer collaboration between the partners, supporting the development of new technologies that benefit both patients and the wider economy.

## **Step 6: understanding IP rights & protection strategies**

### Case study 10 - IP protection vs open source-open licensing for wider benefit

One NHS Wales organisation regularly develops and licenses educational and knowledge-based resources, such as training videos and toolkits. An example includes an educational video shared with an international charity.

The organisation uses a value-based, case-by-case approach to decide whether to protect or openly share IP. They use the following assessment criteria to guide decision-making:

- will open sharing increase reach and impact?
- do we have the resources to protect and manage the IP?
- is there a clear commercial or strategic benefit to IP protection?

If protection isn't viable or necessary, they opt for open licensing. In the above example, a Creative Commons (CC) licence was created to allow free use while retaining attribution and usage rights. The CC-licensed video was successfully shared internationally, extending its impact.

Not all IP needs protection, and structured, early conversations help clarify the best route. Open sharing can be a useful tool for public benefit when a commercialisation approach isn't a preferred option.

### Case study 11 - using expert legal advice to shape IP protection strategy

#### **Example 1 - Supporting in-house expertise with external patent lawyers**

One organisation uses external patent lawyers for expert advice on the patentability of ideas, and to handle the preparation, submission, and renewal of patent applications.

They appoint external lawyers to advise on IP queries that are complex and require specialist input.

Their patent law firms offer a bi-monthly 'IP surgery', when a lawyer will visit the organisation to answer staff questions about their ideas or inventions. This IP surgery aims to help inventors refine and structure their ideas with patentability considerations in mind.

The organisation has also developed in-house IP expertise, managing the following areas internally:

- IP project structuring and governance
- IP project contracting and negotiation
- IP project record-keeping and follow-up

This internal capability makes sure that:

- only viable inventions are submitted for patenting, avoiding unnecessary costs
- commercialisation is supported by robust contractual structures, which are compliant with applicable laws, regulations and internal policies and processes
- developing in house expertise alongside using external legal advice has fills knowledge gaps and maintains a robust IP strategy.

## **Step 7: IP development & commercialisation**

### Case Study 12 - IP agreement involving NHS data

#### **Example 1 - A scorecard to assess the value of data shared in commercial partnerships**

An organisation can develop a structured way to assess the value of data it shares in commercial partnerships.

Most of the organisation's data sharing is for non-commercial research. In these cases, it includes clear terms: if the data or any findings from it are later used for commercial purposes, the organisation must give permission and agree a new contract. This contract would ensure the organisation receives a fair share of the resulting commercial value.

When entering data sharing arrangements for commercial purposes, the organisation uses a scorecard to help decide the value of the dataset. It considers:

- how common the data is
- how much of it exists
- its quality and depth

Below is an example of this data valuation process. The data requested is common, with high volumes of such data generated each year, and of good quality and depth (value score = 85 out of a maximum 100)

### Example - Scorecard with score of 85/100

Guideline	Weighting	Assessment criteria	Score	Adjusted weighting
Availability of data	5%	Relevant Directorate Patient numbers per year for that condition Available Quantity Requested Quantity (HIGH = full availability, MEDIUM = Less than 80% availability, LOW = Less than 50% availability)	HIGH	5
Volume of data	5%	High volume of data indicates low rarity, therefore score: - (LOW for high volume, MEDIUM for average volume (ie. neither rare nor common), HIGH for low volume).	LOW	0
Data quality and depth	15%	Data fields Longitudinal data Diversity of the patient population	HIGH	15
Rarity / uniqueness	10%	Prevalence of the disease / condition in the UK or globally Can include rarity within a common disease (subset of a cohort) Rare disease: less than 1 in 2000 (0.05%) - EU definition (HIGH = less than 0.05% for rare disease, or less than 5% within common disease cohort, MEDIUM = less than 1% of population for rare disease or 10% within a common cohort, LOW = more than 5% for rare disease or more than 10% for common cohort)	LOW	0
Data value chain (Non-ownership)	10%	Raw data Processed data Organisation/administrative data (LOW = only raw data/organisational data involved, MEDIUM = Mix of Raw data and some basic level of processed data, HIGH = Raw data and highly developed processed data)	HIGH	10
Data value chain (Ownership/Arising IP)	10%	Processed data (LOW = No Arising IP ownership, HIGH = some processed data within Arising IP applies)	HIGH	10
Purpose/application of the data	45%	Commercial/non-commercial use (LOW = No commercial purpose for data, MEDIUM = a mix of commercial use with material social value, HIGH = main purpose is commercial in nature, with some social value)	HIGH	45
100%			<b>TOTAL SCORE</b>	<b>85</b>

The scorecard gives a standardised and logical way to measure the additional value of the data, beyond the production costs of the data such as extraction and/or curation. This extra value can be reflected in different ways, such as:

- a data fee (on top of costs)
- a royalty on future revenues
- a proxy towards an equity value
- It is important that the assessment criteria are constantly monitored to ensure they remain valid, current and effective.

This approach helps ensure the organisation is securing fair value from its data, in line with national guidelines on realising value from NHS datasets.

## **Example 2 - Data sharing partnership with a software company**

To address the challenge of missed or cancelled outpatient appointments, an NHS Wales organisation partners with a software company to develop an AI system combining predictive scheduling with behavioural nudging. The goal was to reduce missed appointments, improve patient access, and make better use of existing NHS Wales capacity.

The AI system was trained using anonymised NHS data including appointment schedules, past attendance patterns, clinic codes, and patient behaviour indicators. No sensitive clinical information was used, following ethical AI principles. The organisation acted as clinical lead and data provider, while the company built the AI tools with support from digital communications and consulting partners.

The project followed comprehensive NHS Wales governance processes with joint programme boards overseeing delivery. Data sharing was governed by a formal processing agreement, with the NHS Wales organisation as Data Controller and the company as the Data Processor. Local ethical approval was secured and the system met NHS Wales technology code requirements.

Under a fair commercial model, the company retained AI tool ownership but shared all learning with NHS Wales. NHS data was never monetised - value was returned through patient benefits.

In six months, missed appointments fell by 23% beyond standard text reminders, enabling 1,910 additional patient attendances and releasing £1.3 million of clinical capacity. Among the most deprived patients, missed appointments dropped by 30%, improving health equity.

The company received a three-year contract with 10% of first-year revenue returning to the organisation when used as a reference site, ensuring fair NHS value.

### Case Study 13 - fair NHS Wales commercial returns- licensing and spin-out models

#### **Example 1 - Fair returns for co-developed software through royalties**

One organisation commissioned a technology company to develop an operational management software. The organisation acted as both a development and testing partner.

The technology company owned the IP and could resell the software in the UK and internationally. However, the software could not have been developed without the organisation's direct involvement. Its clinical and operational staff shaped the software's design and functionality through ongoing feedback.

Initially, the organisation was fully funding the software's development. It had no recognition of its contribution to creating the software or claim to the foreground IP. There was also no incentive for staff to ensure the product would meet the needs of other NHS users or broader markets.

To correct this imbalance, the parties renegotiated the contract. The new agreement allowed the technology company to continue owning the foreground IP and to sell the software to other customers. In return, the organisation secured:

- a significantly reduced development cost- paying only a proportion of the original funding, on the basis that the company could now resell the software elsewhere
- a royalty arrangement, giving the organisation a share of revenue from future sales across the NHS and in other market

This approach ensured the organisation's input- including funding, staff expertise, and real-world testing- was properly recognised and rewarded. While the tech company retained IP ownership, the organisation paid a proportionate share of the development costs and secured a share of future returns. This helped align incentives, supported staff engagement, and contributed to the creation of a high-quality, scalable product.

## **Example 2 - Various fair revenue sharing models in collaborating with a Digital Health Company to Commercialise NHS IP**

A digital health company has partnered with several NHS Wales organisations to commercialise their IP. By spinning out innovations or allowing the company to commercialise them, these organisations have brought their solutions to market faster and with greater financial sustainability.

### **Model 1 - Spin-out with shared equity**

The company worked with an NHS organisation to co-develop a digital health product. A new spin-out company was set up under a collaborative agreement, with shareholdings held by the organisation, the digital health company, and the clinical inventor. All foreground IP was transferred to the spin-out, enabling external investment and acquisition opportunities. The board includes all parties to ensure balanced and efficient decision-making.

### **Model 2 - Licencing, with IP retained in NHS Wales**

In another case, the company developed a product for an NHS Wales organisation, but the organisation retained IP ownership. The company licenses the product back from the

organisation, and the organisation receives a fixed return per license sold. While this model allows the organisation to retain IP, it can limit external investment potential.

### **Model 3 - Revenue share based on contribution to development costs**

In another case, the company partnered with a community care provider to co-develop a digital health product. The company contributed a portion of the development cost and receives a multiple of that investment back through a revenue share agreement. For example, if the project costs £10, the company would pay £2 towards this and earn a multiple of this £2 through the revenue sharing agreement. This model balances upfront affordability with long-term returns for both parties.

Across these models, NHS Wales involvement ranges from passive governance to active input. The company typically leads on product development and technical delivery. Clear upfront agreements- including equity splits, termination clauses, and revenue mechanisms are essential to avoid future disputes and ensure fair value distribution.

### **Example 3 - Securing a mix of returns without NHS Wales IP ownership**

An NHS Wales organisation partners with a small or medium-sized enterprise (SME) to develop an AI-based clinical tool. The organisation is supporting with access to data, research infrastructure and, in future, a test-bed environment.

The organisation and the SME have agreed that the SME will retain all IP rights for the project. However, the NHS Wales organisation benefits from the product's success through several arrangements:

- an equity stake in the SME, including some profit-sharing
- royalties from future product sales
- guaranteed ongoing use of the product by the NHS Wales organisation at a discounted price
- charges for services provided by the organisation, which include NHS Wales staff time paid according to Agenda for Change pay bands and HCRW guidance for investigator-initiated trials
- market-rate fees for access to data, with milestone payments built in

By agreeing to this mix of returns instead of negotiating IP ownership, the organisation has enabled faster commercialisation while still retaining value if the product succeeds.

#### **Example 4 - Revenue share agreement with charity funder**

Eye conditions like macular degeneration and amblyopia (lazy eye) need regular monitoring to prevent permanent vision loss. In one NHS Wales eye clinic, over 2,000 patients are seen each month. Due to COVID-19, more than 80% of consultations moved to telephone, limiting clinical information for decision-making. Even when routine clinics resume, long delays were expected, risking preventable vision loss for some patients.

An employee of the clinic develops a web-based vision-testing app for patients to test their vision at home. The app gained CE (Class 1) marking. The NHS Wales organisation running the clinic supported formal validation and sponsored a clinical investigation, funded by a charity.

A revenue share agreement was made between the organisation and the charity. The organisation owns the IP, while the charity receives a share of any revenues from commercial use of the app

Decisions about commercialisation are led by the inventor and the organisation's research and development legal team.

This innovation has helped maintain eye care during the pandemic and could improve patient access to vision monitoring in the future.

#### **Example 5 - Licensing IP to industry supplier with Royalties Shared Between NHS Collaborators**

After heart surgery, patients can face serious wound complications and pain due to the strain on the chest. While chest support can help, existing products were not meeting patient needs effectively.

To address this, one NHS Wales organisation collaborated with patients and experts from two other organisations to co-design an improved chest support vest for people recovering from heart surgery. The new vest helps protect wounds, supports healing, reduces pain, and offers more comfort than similar products. It can be adjusted by the patient for a better fit.

The lead organisation filed a patent application for the underlying IP and registered design rights for the vest. Patent applications are ongoing in both Europe and the US – two important markets for the product.

To make the vest available to patients, the organisation licensed the rights to a trusted industry supplier with an existing supply chain. Licensing was chosen because the product complements the supplier's current work.

Since 2021, the supplier has been making and marketing the vest worldwide. The lead organisation receives a royalty from each sale, which are shared with the partner organisations, staff inventors, and their departments in line with the lead organisation's IP policy.

This case study shows how collaborating across the NHS and using IP licensing in a strategic way can lead to better products for patients, while also generating fair commercial returns for NHS Wales.

## **Step 8: IP asset management & tracking returns**

### **Case study 14 - Managing and Reinvesting NHS Wales IP Returns for Future Innovation**

#### **Example 1 – NHS Wales managed IP fund**

An NHS Wales organisation sets up an IP fund, managed by their commercial legal services team. The fund makes sure that income received from IP licensing or assignment, income from spin-out shares, or income from data partnerships can be reinvested to support:

- patent attorney advice and patent applications
- IP lawyers' advice for large complex IP transactions and spinouts
- contracting with third parties, such as a university, for development of prototypes
- contracting with third parties for tech transfer support

The main aims of the IP fund are to:

- provide an IP commercialisation function with minimal financial burden to the NHS Wales organisation
- encourage uptake and scaling up of innovation across NHS Wales

- advance the strategic goal of building innovation and enhancing outcomes and efficiencies

The organisation has developed a sustainable innovation programme by reinvesting commercial returns from IP into future innovation.

## **Step 9: access IP expertise & technology transfer capabilities**

### **Case study 15 - In-house Technology Transfer Office or Capability (TTO or) models**

#### **Example 1 - Using a mix of In-house and university TTOs**

An NHS Wales organisation develops a blended model for managing and commercialising intellectual property, combining in-house expertise with external partnerships.

The organisation works closely with a partner university's technology transfer office under a formal framework agreement. This sets out how joint research and resulting IP are managed.

To support IP developed outside they also partner with a health technology consultancy.

Their responsibilities include:

- encouraging and managing new IP disclosures
- assessing commercial potential and market fit
- supporting funding applications and identifying background IP

The organisation also develops tools to help clinicians and researchers navigate available support and plans to expand outreach sessions delivered by the consultancy.

This model ensures IP is identified early, managed effectively, and supported by the right expertise, helping the organisation progress ideas through to commercialisation.

### **Case study 16 - Support with IP expertise from an Innovation Network or Partnership**

#### **Example 1 - An Innovation Network or Partnership (e.g. NHS Wales Innovation Leads or R&D Directors group)**

A group of NHS Wales organisations are members of a regional Innovation Network or Partnership that brings together Leads to share ideas, collaborate, and support each

other's innovation efforts. Full details of the NHS Wales Innovation leads group are available at [www.hsciw.wales](http://www.hsciw.wales).

The forum meets bi-monthly, with hosting duties rotating between members. Hosts often partner with local organisations, helping members expand their networks and build regional connections.

The forum provides:

- a space for peer support and knowledge exchange
- opportunities for upskilling and learning
- updates on funding and innovation opportunities

The Partnership is then expanded to include primary care, social care and Community-based initiatives.

By developing collaboration and organisation, the forum helps teams strengthen their innovation capacity, improve IP management, and accelerate the development of ideas that can benefit patients and the wider health system.

#### Case study 17 – Using university Technology Transfer Office or Capability (TTO or TTC)

##### **Example 1 - Using a university's technology transfer office or capability**

To support innovation and build an entrepreneurial culture, an NHS Wales organisation has established a long-term partnership with a university's TTO. This partnership is underpinned by a formal IP policy and protocol, ensuring that innovations are identified, protected, and commercialised effectively.

The organisation commissions the TTO to manage IP, as it lacks the internal capacity to do so independently. The TTO handles IP developed solely or jointly with the organisation, seeking protection and commercial opportunities where appropriate. IP is assigned to the TTO under a service-level agreement, ensuring the NHS benefits from any commercial returns even when IP resides with the academic partner.

This relationship has delivered:

- a strong innovation pipeline
- increased visibility of innovation activity

- a rise in invention disclosures since the IP policy was introduced

The TTO also provides ad hoc commercial advice, saving consultancy costs. Internal marketing and collaboration with the organisation's charity have further boosted staff engagement.

The partnership is managed by the Head of Commercial and Innovation and supports the organisation's wider ambition to grow through innovation and reward staff involvement.

### **Example 2 - Revenue sharing agreement with university technology transfer office or capability (TTO)**

An NHS Wales organisation works with a university's TTO, drawing on its research and expertise to manage its IP effectively. Their partnership is governed by a Framework Intellectual Property Agreement (FIPA). This agreement names the university TTO as the main body responsible for exploiting IP created at the organisation.

Under the FIPA, research teams identify new IP and record it using standard forms. The university TTO carries out due diligence to confirm IP ownership and check for any third-party rights. The organisation's IP lead oversees this process and reviews the TTO's exploitation plans to make sure they fit the organisation's interests. This approach centralises commercialisation expertise while keeping organisation oversight.

Under the FIPA, in most circumstances 50% of the income from IP goes to the organisation for research reinvestment and 50% goes to the inventors. The FIPA also accounts for overheads, allowing for up to a certain percentage of gross receipts for the TTO or the organisation to cover operational costs.

This model ensures:

- a fair return to the NHS Wales organisation
- direct reinvestment into patient-benefiting research
- proportional revenue sharing with distribution based on each party's financial, inventive, and technical contributions
- maximise overall commercial value of IP through the university's TTO expertise, benefiting all partners

### **Example 3 - Revenue sharing agreement with 2 advisory technology transfer office or capability (TTO) advisors**

One organisation works with two advisory organisations to manage its IP. TTO Adviser 1, which is a TTO of its partner university, supports IP where employees of the university partner have been involved. TTO Adviser 2 manages all other IP generated by the organisation's staff.

A senior IP manager within the organisation oversees IP from identification through to commercialisation. All collaborative research is supported by written agreements that clearly set out IP ownership from the start. This structure allows the organisation to access expert support whilst maintaining strong governance.

Once commercial income is received, direct costs like patent fees are deducted. The advisory organisation then receives a 20% commission on the remaining income. The remaining 80% is typically split in three equal parts:

- one-third goes to the inventor(s)
- one-third to the inventor's department
- one-third to the organisation.

The fixed 20% commission ensures a clear and predictable fee for advisory services. The standard three-way revenue split provides fair and consistent returns across all parties. For the organisation, this helps fund research, legal costs and operational overheads.

This model supports innovation by rewarding inventors and ensuring the NHS benefits from IP created with public funding.

### **Example 4 - Tiered fee structure for university TTO**

An NHS Wales organisation partners with a university and its technology transfer office or capability (TTO), which leads on commercialisation of IP developed within the organisation.

The organisation's staff must report potentially valuable IP to Legal services, keep detailed records, and declare any conflicts of interest. All IP must be disclosed alongside assigned confidentiality agreement and all IP agreements must follow the approval process. These steps help protect and manage IP effectively.

The model uses a tiered revenue-sharing system based on net cumulative income. When the university TTO leads, a 'commercialisation fee' is applied - 10% for income up to

£100,000, increasing to 40% for income over £1 million. The remaining income is split between the inventors, the clinical department, and the organisation's central funds.

This tiered fee structure is a mechanism to incentivise the TTO for their commercialisation efforts, particularly for high-value IP which carries significant risk and requires substantial investment. This policy is designed to balance the reward for commercialisation expertise with the goal of ensuring higher value returns are reinvested into the NHS and its research activities.

## Model Agreements and Templates

### Template NHS Wales Intellectual Property policy

See Appendix 2 of WHC/2026/004.

### NDA template for collaborative projects involving potential IP development

This **CONFIDENTIALITY AGREEMENT** is dated [insert date] (the “**Agreement**”)

#### **BETWEEN:**

(1) [ORGANISATION NAME], whose principal place of business is [insert the address] (the “**Organisation**”); and

(2) [NAME AND ADDRESS] (“**Party 2**”)

together the “**Parties**” and each a “**Party**”.

#### **BACKGROUND**

A. each Party wishes to share Confidential Information with the other for the purpose of [insert background; note link with clause 3.2.5] (the “**Permitted Purpose**”)

B. the Parties have agreed to comply with this Agreement in connection with the disclosure and use of Confidential Information

#### **IT IS AGREED:**

##### **1. INTERPRETATION**

##### **1.1 In this Agreement, unless the context otherwise requires:**

- “**Affiliate**” - means in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;
- “**Confidential Information**” - means, irrespective of whether it is marked as being confidential or not:

(a) information provided or made accessible by one Party to another in connection with the Permitted Purpose (whether before or after the date of this Agreement) that relates to:

(i) the Disclosing Party;

(ii) the Disclosing Party's Group; and/or

(iii) the operations, management, business, affairs, developments, intellectual property rights including data, algorithms and code, trade secrets, know-how, techniques, financial, commercial, technical, tactical or strategic information and/or personnel of the Disclosing Party or the Disclosing Party's Group;

(b) other Information: (i) provided or made accessible by the Disclosing Party or the Disclosing Party's Group to the Receiving Party in connection with the Permitted Purpose (whether before or after the date of this Agreement) or (ii) that ought reasonably to be considered to be confidential which comes (or has come) to the Receiving Party's attention or into the Receiving Party's possession in connection with the Permitted Purpose;

(c) discussions, negotiations, and correspondence between the Disclosing Party or the Disclosing Party's Group and/or any of their directors, officers, employees, consultants or professional advisers and the Receiving Party and/or any of their employees, consultants and/or professional advisers in connection with the Permitted Purpose and all matters arising therefrom; and

(d) information or analysis derived from any of the above. But not including any Information that:

(i) was in the possession of the Receiving Party without obligation of confidentiality prior to its disclosure by the Disclosing Party or the Disclosing Party's Group;

(ii) the Receiving Party obtained on a non-confidential basis from a third party who is not, to the Receiving Party's knowledge or reasonable belief, bound by a confidentiality agreement with the Disclosing Party or any member of the Disclosing Party's Group or otherwise prohibited from disclosing the information to the Receiving Party;

(iii) was already generally available and in the public domain at the time of disclosure otherwise than by a breach of this Agreement or breach of a duty of confidentiality;  
or

(iv) the Receiving Party's evidence to the reasonable satisfaction of the Disclosing Party was independently developed without access to the Confidential Information;  
or

(v) the Disclosing Party agrees in writing does not constitute Confidential Information

- "Control" - means the possession by a person, directly or indirectly, of the power to direct or cause the direction of the management and policies of the other person (whether through the ownership of voting shares, by contract or otherwise) and "Controls" and "Controlled" shall be interpreted accordingly;
- "Copies" - means copies, reproductions, summaries, extracts, analyses, memoranda, notes or compilations (in any form or medium, including electronic or digital files of any kind) of Confidential Information, or any other documents, electronic files or records containing, reflecting or derived from the Confidential Information;
- "Disclosing Party" - means a Party that directly or indirectly discloses or makes available Confidential Information;
- "Disclosing Party's Group" - means, the Disclosing Party and its Affiliates;
- "Effective Date" - means the date of this Agreement as set out above;
- "Freedom of Information Act or FOIA" - means the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time;
- "Information" - means all information of whatever nature, however conveyed or accessed and in whatever form, including without limitation, in writing, orally, by demonstration, electronically and in a tangible, visual or machine-readable medium, whether stored on computer systems or sites (including and not limited to in cloud computing models that enable storage on the internet and access either through the public internet or a dedicated private network connection or both (and whether accessed or used through a web portal, website, a mobile app or by other means));
- "Permitted Purpose" - has the meaning given to it in the recital to this Agreement;
- "Receiving Party" - means a Party that directly or indirectly receives Confidential Information from a Disclosing Party;
- "Representatives" - means members, directors, employees, officers, agents and/or advisers of the Organisation or Party 2;
- "Working Day" - means a day other than Saturday, Sunday or public holiday in England and Wales when banks are open for business

## 2. CONFIDENTIALITY OBLIGATIONS

2.1 in consideration of the benefits to the Parties of the disclosure of the Confidential Information, each Party wishes to disclose Confidential Information to the other solely for the Permitted Purpose on the terms set out in this Agreement

2.2 a Receiving Party shall:

**2.2.1** treat all Confidential Information as confidential;

**2.2.2** have in place and maintain proper security measures and procedures which shall be at least as stringent as the measures and procedures it applies to its own confidential information to protect the confidentiality of the Confidential Information (having regard to its form and nature);

**2.2.3** not disclose or permit the disclosure of, nor otherwise make available, any of the Confidential Information in whole or in part to any other person without obtaining prior written consent from the Disclosing Party (which the Disclosing Party shall have the express right to grant or deny) or except as expressly set out in this Agreement;

**2.2.4** not use or exploit any of the Confidential Information for any purpose whatsoever other than the Permitted Purpose;

**2.2.5** not copy, reduce to writing or otherwise record the Confidential Information except as strictly necessary for the Permitted Purpose;

**2.2.6** keep a written record of any document containing Confidential Information or other Confidential Information received from the other in tangible form, and of any Copies made of the Confidential Information, and make the same available to the Disclosing Party promptly upon request; and

**2.2.7** immediately notify the Disclosing Party in writing if it suspects or becomes aware of any unauthorised access, copying, use or disclosure in any form of any of the Confidential Information

## 3. PERMITTED DISCLOSURES

3.1 the Receiving Party may only disclose the Disclosing Party's Confidential Information to those of its Representatives who need to know the Confidential Information for the Permitted Purpose, provided that:

3.1.1 it informs these Representatives of the confidential nature of the Confidential Information before disclosure and obtains from its Representatives enforceable undertakings to keep the Confidential Information confidential in terms at least as

extensive and binding upon the Representatives as the terms of this Agreement are upon the parties; and

3.1.2 at all times, it is responsible for these Representatives' compliance with the obligations set out in this Agreement

3.2 the Receiving Party shall be entitled to disclose Confidential Information only to the minimum extent that it is required to do so by applicable law or by order of a court or as required by the rules and regulations of any regulatory body or any enquiry or investigation by any governmental, parliamentary or official body which has the power to compel disclosure

3.3 Before making a disclosure pursuant to Clause 3.2, the Receiving Party shall at the earliest opportunity and, to the extent that is legally permitted to do so:

3.3.1 notify the Disclosing Party in writing of the proposed disclosure; and

3.3.2 ask the court or other official body, if applicable, to treat the Confidential Information as confidential

3.4 where notice of disclosure under Clause 3.2:

3.4.1 is legally permitted, the Receiving Party shall take into account the reasonable requests of the Disclosing Party in relation to the proposed disclosure; or

3.4.2 is prohibited, the Receiving Party shall notify the Disclosing Party of the disclosure as soon as possible following the disclosure when it is legally able to do so

#### 4. FREEDOM OF INFORMATION ACT 2000 (FOIA)

4.1 Party 2 acknowledges and agrees that:

4.1.1 the Organisation may be subject to the requirements of the FOIA and shall assist and cooperate with the Organisation to enable the Organisation to comply with any Information disclosure obligations;

4.1.2 the Organisation shall be responsible for determining in its absolute discretion, and notwithstanding any other provision in this Agreement or any other agreement whether any Confidential Information or any other information, is exempt from disclosure in accordance with the provisions of the FOIA;

4.1.3 in no event shall Party 2 respond directly to a Request for Information unless expressly authorised to do so by the Organisation

## 5. TERM

5.1 each party's obligations under this Agreement shall continue in full force and effect for a period of [5] years from the Effective Date

5.2 nothing in this Agreement shall oblige either Party to continue discussions or negotiations in connection with the Permitted Purpose or to disclose any information (whether Confidential Information or otherwise) to the other Party

5.3 if either Party decides not to continue to be involved in the Permitted Purpose with the other Party, it shall notify that other Party in writing immediately. The end of discussions relating to the Permitted Purpose shall not affect each Party's obligations under this agreement or any accrued rights or remedies to which either Party is entitled

## 6. RETURN OF INFORMATION

6.1 the Disclosing Party may serve a notice (an "**Information Return Notice**") on the Receiving Party at any time under this Clause 50. An Information Return Notice must specify whether it relates to (i) all Confidential Information provided or made accessible by the Disclosing Party which is protected by this Agreement or (ii) only specified Information or categories of Confidential Information so protected (in either case, the "**Specified Scope**"). On receipt of an Information Return Notice, the Receiving Party shall:

6.1.1 at the Receiving Party's option, securely destroy or return and provide to the Disclosing Party documents and other tangible materials that contain any of the Confidential Information within the Specified Scope, including in any case all Copies of the relevant documents and other materials made by the Receiving Party;

6.1.2 ensure, so far as reasonably practicable, that all Confidential Information within the Specified Scope that is held in electronic, digital or other machine-readable form (including any systems and/or data storage services provided by third parties) is permanently and securely erased; and

6.1.3 make no further use of any Confidential Information which falls within the Specified Scope

6.2 following any secure destruction or return of Confidential Information to the Disclosing Party pursuant to Clause 6.1, the Receiving Party's obligations under this Agreement (including in relation to any Confidential Information which falls outside the Specified Scope) shall otherwise continue in force until this Agreement has expired

6.3 the Receiving Party's obligation to comply with an Information Return Notice in respect of any Confidential Information which falls within the Specified Scope shall not apply in respect of Confidential Information:

6.3.1 that is stored as part of an electronic back-up system that is rendered inaccessible in the normal course of business; or

6.3.2 whose retention is required by any applicable law, rule, regulation or requirement of any competent judicial, governmental, supervisory or regulatory body, or for the purposes of any audit

6.4 the Receiving Party's obligations under this Agreement in respect of the Confidential Information referred to in Clause 6.3 shall continue to be in force until this Agreement expires

## 7. ASSIGNMENT

7.1 this Agreement is personal to the Parties and shall not be assigned or otherwise transferred in whole or in part by either Party without the prior written consent of the other Party, provided that the Organisation may assign its rights under this Agreement to another Organisation assuming responsibility for the role of the Organisation relevant to the Permitted Purpose as part of an NHS reorganisation

## 8. GENERAL

8.1 save as expressly set out in this Agreement, all rights in Confidential Information shall remain the property of the Disclosing Party. Each Party reserves all rights in its Confidential Information

8.2 this Agreement does not include, expressly or by implication, any representations, warranties or other obligations

8.2.1 to grant the Receiving Party any licence or rights other than as may be expressly stated in this Agreement

8.2.2 to require the Disclosing Party to disclose, continue disclosing or update any Confidential Information; or

8.2.3 as to the accuracy, efficacy, completeness, capabilities, safety or any other qualities whatsoever of any Information or materials provided in connection with the Permitted Purpose

8.3 each Disclosing Party warrants that it has the right to disclose its Confidential Information to the Receiving Party and to authorise the Receiving Party to use such Confidential Information for the Permitted Purpose

8.4 the rights, powers and remedies provided in this Agreement are cumulative and not exclusive of any rights, powers or remedies provided by law. No failure or delay by either Party to exercise any right, power or remedy will operate as a waiver of it nor will any partial exercise preclude any further exercise of the same, or of some other right, power or remedy

8.5 each Party will be responsible for all costs incurred by it or on its behalf in connection with this Agreement

8.6 this Agreement may be executed in any number of counterparts and by the Parties on separate counterparts, but shall not be effective until each Party has executed at least one counterpart. Each counterpart shall constitute an original of this Agreement, but all the counterparts shall together constitute but one and the same instrument

## 9. SEVERANCE

9.1 if any provision of this Agreement (or part of any provision) is or becomes illegal, invalid or unenforceable, the legality, validity and enforceability of any other provision of this Agreement shall not be affected

9.2 if any provision of this Agreement (or part of any provision) is or becomes illegal, invalid or unenforceable but would be legal, valid and enforceable if some part of it was deleted or modified, the provision or part-provision in question shall apply with such deletions or modifications as may be necessary to make the provision legal, valid and enforceable. In the event of such deletion or modification, the Parties shall negotiate in good faith in order to agree the terms of a mutually acceptable alternative provision

## 10. ENTIRE AGREEMENT

10.1 this Agreement constitutes the entire agreement between the Parties in respect of its subject matter and supersedes and extinguishes all prior negotiations, arrangements, understanding, course of dealings or agreements made between the Parties in relation to its subject matter, whether written or oral

10.2 Neither Party has been given, nor entered into this Agreement in reliance on, any warranty, statement, promise or representation other than those expressly set out in this Agreement

10.3 Nothing in this Clause 10 shall exclude any liability in respect of misrepresentations made fraudulently

## 11. THIRD PARTY RIGHTS

11.1 a person who is not a Party to this Agreement has no right under the Contract (Rights of Third Parties) Act 1999 (as amended, updated or replaced from time to time) to enforce any term of this Agreement but this does not affect any right or remedy of any person which exists or is available otherwise than pursuant to that Act

## 12. NOTICES

12.1 any notices sent under this Agreement must be in writing

12.2 the following table sets out the method by which notices may be served under this Agreement and the respective deemed time and proof of service

<b>Manner of delivery</b>	<b>Deemed time of service</b>	<b>Proof of service</b>
Email	9.00am on the first Working Day after sending	Dispatched as a pdf attachment to an e-mail to the correct e-mail address without any error message
Personal delivery	On delivery, provided delivery is between 9.00am and 5.00pm on a Working Day. Otherwise, delivery will occur at 9.00am on the next Working Day	Properly addressed and delivered as evidenced by signature of a delivery receipt
Prepaid, Royal Mail Signed For 1st Class or other prepaid, next working day service providing proof of delivery	At the time recorded by the delivery service, provided that delivery is between 9.00am and 5.00pm on a Working Day. Otherwise, delivery will occur at 9.00am on the same Working Day (if delivery before 9.00am) or on the next Working Day (if after 5.00pm)	Properly addressed prepaid and delivered as evidenced by signature of a delivery receipt

12.3 notices shall be sent to the addresses set out below or at such other address as the relevant Party may give notice to the other Party for the purpose of service of notices under this Agreement

	<b>Party 2</b>	<b>Organisation</b>
<b>Contact</b>		
<b>Address</b>		
<b>Email</b>		

12.4 this Clause 12 does not apply to the service of any proceedings or other documents in any legal action or other method of dispute resolution

13. GOVERNING LAW AND JURISDICTION

13.1 this Agreement and any issues, disputes or claims (whether contractual or non-contractual) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of England and Wales

13.2 the Parties agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (whether contractual or non-contractual) that arises out of or in connection with this Agreement or its subject matter or formation

This agreement has been entered into on the date stated at the beginning of it

Signed by the Organisation	Name:  Signature:  Position in Organisation:
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Signed by the Party 2	Name:  Signature:
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# Commercial Collaboration agreement between NHS Wales and university/academic/ industry partner on IP matters

THIS COLLABORATION AGREEMENT is dated [DATE]

## **BETWEEN**

(1) [ORGANISATION NAME], whose principal place of business is [insert address] (the "Organisation"); and

(2) [**COLLABORATOR NAME**] a company registered in England and Wales under registered number [insert registered number] whose registered office is at [insert registered address] OR [PERSON NAME] of [address] (the "**Collaborator**")

together the "**Parties**" and each a "**Party**"

## BACKGROUND

A. the Parties wish to establish to collaborate on the project set out in Schedule 1 (Project Plan).

B. this Agreement sets out the terms and conditions on which the collaboration will take place.

## 1. DEFINITIONS AND INTERPRETATION

1.1 in this Agreement the following expressions have the meaning set opposite

- "**Agreement**" - this document, including its Schedules, as amended from time to time;
- "**Background**" - Intellectual Property Rights provided by one Party (whether belonging to that Party or to a third party) to the other Party for use in the Project, whether before, on, or after the date of this Agreement, except any Result;
- "**Business Day**" - Monday to Friday (inclusive) except bank or public holidays in England and Wales;
- "**Commencement Date**" - [insert the date on which the Project is to start/started];
- "**Confidential Information**" - any confidential or secret information in any form directly or indirectly belonging or relating to a Party disclosed by the one and received by the other pursuant to or in the course of the Project, including any Background and Results.
- "**Data Protection Legislation**" - all applicable data protection and privacy legislation in force from time to time in the UK including the UK GDPR; the Data Protection Act 2018 (DPA 2018) (and regulations made thereunder); the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426) as amended and all other legislation

and regulatory requirements in force from time to time which apply to a Party relating to the use of personal data (including, without limitation, the privacy of electronic communications); and the guidance and codes of practice issued by the Information Commissioner or other relevant regulatory authority and applicable to a Party;

- **"Field"** - [describe technical area where Collaborator is permitted to exploit the Results]
- **"Financial Contribution"** - the financial contribution to be provided by a Party set out in Schedule 1;
- **"Group Company"** - in relation to a company, that company, any subsidiary or holding company from time to time of that company, and any subsidiary from time to time of a holding company of that company;
- **"Intellectual Property Rights"** - patents, utility models, rights to inventions, copyright and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off or unfair competition, rights in designs, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets), semiconductor topography rights, image rights, rights in personality and similar rights, plant variety rights, and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;
- **"Key Personnel"** - the key personnel identified as such in the Project Plan;
- **"Non-Commercial Purposes"** - research, teaching, education and clinical patient care (diagnosing, treating and managing the health of a person);
- **"Project"** - the programme of work described in the Project Plan;
- **"Project Period"** - the duration of the Project described in the Project Plan;
- **"Project Plan"** - the project plan set out in Schedule 1, as varied from time to time under the terms of this Agreement
- **"Results"** - all information, data, techniques, and Intellectual Property Rights that arise or is obtained or developed by, or by Party in the course of the Project ;
- **"VAT"** - value added tax chargeable under the Value Added Tax Act 1994, or any tax replacing that tax.

1.2 the headings in this Agreement are for ease of reference only; they do not affect its construction or interpretation

1.3 references in this Agreement to **a person** include a natural person, corporate or unincorporated body (whether or not it has a separate legal personality)

1.4 a reference in this Agreement to a statute or statutory provision is a reference to it as amended, extended or re-enacted from time to time and includes all subordinate legislation made from time to time under that statute or statutory provision

1.5 a reference in this Agreement to **writing** or **written** includes email

1.6 a reference in this Agreement to any other agreement or document is a reference to that other agreement or document as varied or novated (in each case, unless in breach of this Agreement) from time to time

1.7 references in this Agreement to clauses and Schedules are to the clauses and Schedules of this Agreement and references to paragraphs are to paragraphs of the relevant Schedule

1.8 any words in this Agreement following the expression including, include or in particular, or any similar expression, are to be construed as illustrative and do not limit the sense of the words preceding that expression

1.9 the acts and omissions of a Group Company are deemed to be within the relevant Party's control, and the acts and omissions of any contractor are deemed to be within the control of the Party engaging that contractor

## 2. THE PROJECT

2.1 the Project starts on the Commencement Date and will continue until the completion of the Project as set out in the Project Plan or any later date agreed in writing between the Parties, or until this Agreement is terminated in accordance with clause 7 or 8. If this Agreement is entered into after the Commencement Date, it will apply retrospectively to work carried out in relation to the Project from the Commencement Date

2.2 each of the Parties will use reasonable endeavours to carry out the tasks allotted to it in the Project Plan, and will provide the resources, Background, materials, facilities and equipment which are designated as its responsibility in the Project Plan

2.3 the Parties shall each appoint the Key Personnel to assume overall responsibility for their respective roles and obligations in connection with the Project

2.4 each of the Parties will obtain and maintain all governance, regulatory and ethical approvals, consents and licences ("**Approvals**") necessary to allow it to carry out the tasks

allotted to it in the Project Plan and will carry out the Project in accordance with all laws and regulations which apply to its activities under or pursuant to this Agreement

2.5 each of the Parties will ensure that its employees and contractors involved in the Project: observe the conditions attaching to any Approvals; and keep complete and accurate records of all research, development and other work carried out in connection with the Project and of all Results

2.6 each of the Parties will ensure that its staff involved in the Project, when working on or visiting the other Party's premises, comply with the other Party's health and safety and security policies and procedures and, when accessing or using the other Party's information systems, comply with the other Party's information security policies and procedures

2.7 the Key Personnel will meet regularly and will provide the Party with reports summarising the progress of the Project and a copy of all of the Results in accordance with the Project Plan

2.8 each of the Parties will notify the other promptly if at any time any of the Key Personnel appointed by that Party is unable or unwilling to continue to be involved in the Project. Within [1] month after the date of that notice, the Party who originally appointed that member of the Key Personnel will nominate a successor

2.9 each of the Parties will notify the other promptly after identifying any Result which it believes is patentable and will supply the other with copies of that Result. Each of the Parties will notify other Results to the other in the reports provided under clause 2.7

2.10 each of the Parties warrants to the other that it has full power and authority under its constitution and has taken all necessary actions and obtained all Approvals, to allow it to enter into and perform this Agreement

2.11 each party will comply with the provisions of Data Protection Legislation and, where the Parties need to exchange personal data, the Parties will enter a data sharing agreement

2.12 if a Party agrees to transfer any biological or chemical material to the other Party in connection with the Project, that transfer will be subject to the terms of a separate Materials Transfer Agreement entered into between the Parties in relation to that material

### 3. FINANCIAL ARRANGEMENTS

3.1 each Party will keep complete and accurate accounts of its expenditure on the Project. The Parties will pay the Financial Contribution in accordance with the Project Plan. Where the Financial Contribution is being claimed against costs and expenses incurred by a Party, each invoice must be accompanied by a statement itemising expenditure

3.2 all amounts payable under this Agreement are exclusive of VAT (if applicable)

3.3 if a Party fails to make any payment due to the other under this Agreement, without prejudice to any other right or remedy available, the receiving Party may charge interest (both before and after any judgement) on the amount outstanding, on a daily basis at the rate of four per cent per annum above the Bank of England's base rate (Bank Rate) from time to time. That interest will be calculated from the date or last date for payment to the actual date of payment, both dates inclusive, and will be compounded quarterly

3.4 [where Results are being exploited by the Collaborator the Organisation should ensure it is obtaining fair market value for its contribution, for instance through a revenue sharing mechanism. This will also need to include revenue reporting revenue so that the revenue share/royalty can be verified]

#### 4. USE AND EXPLOITATION OF INTELLECTUAL PROPERTY RIGHTS

4.1 this Agreement does not affect the ownership of any Intellectual Property Rights in any Background. The Intellectual Property Rights in Background will remain the property of the Party which contributed them to the Project (or its licensors). No licence to use any Intellectual Property Rights is granted or implied by this Agreement except the rights expressly set out in this Agreement

4.2 each Party grants the other a royalty-free, fully paid-up, non-exclusive licence to use its Background and its Results for the purpose of carrying out the Project. Neither Party may grant any sub-licence to use the other's Background or Results except as set out in the Project Plan to enable the use by Party's Group Company or sub-contractor to carry out the Project

4.3 all Intellectual Property Rights in the Results shall vest in and be owned absolutely by [the Organisation/the Collaborator/ the Party creating or developing the Result]. To the extent that either Party sub-contracts performance of the Project, that Party shall ensure that any Intellectual Property Rights in Results arising from the work of its sub-contractor shall be assigned to that Party absolutely

4.4 [where the Organisation owns Results which will be exploited by the Collaborator] The Organisation grants to the Collaborator a non-exclusive, licence (with the right to grant sub-licenses) for x years to [manufacture and sell products/provide services] falling within the scope of its Intellectual Property Rights in the Results in the Field (including a non-exclusive licence to the Organisation's Background solely to the extent required for the Collaborator to enjoy the licence to the Results granted in this clause)

4.5 [where the Collaborator owns Results which will be exploited by the Organisation] The Collaborator grants to the Organisation a non-exclusive, licence (with the right to grant sub-licenses) for x years to [manufacture and sell products/provide services] falling within the scope of its Intellectual Property Rights in the Results for [describe scope of commercial

use] (including a non-exclusive licence to the Collaborator's Background solely to the extent required for the Organisation to enjoy the licence to the Results granted in this clause)

4.6 the Collaborator grants to the Organisation a non-exclusive, worldwide, irrevocable, royalty-free licence to the Collaborator's Intellectual Property Rights in the Results for Non-Commercial Purposes for the full term of those Intellectual Property Rights

## 5. CONFIDENTIALITY

5.1 Subject to clause 4, a Party receiving Confidential Information (the **Receiving Party**) from the other (the **Disclosing Party**) shall:

5.1.1 treat all Confidential Information as confidential;

5.1.2 have in place and maintain proper security measures and procedures which shall be at least as stringent as the measures and procedures it applies to its own confidential information to protect the confidentiality of the Confidential Information (having regard to its form and nature);

5.1.3 not disclose or permit the disclosure of, nor otherwise make available, any of the Confidential Information in whole or in part to any other person without obtaining prior written consent from the Disclosing Party (which the Disclosing Party shall have the express right to grant or deny) or except as expressly set out in this Agreement;

5.1.4 not use or exploit any of the Confidential Information for any purpose whatsoever other than the Project;

5.1.5 not copy, reduce to writing or otherwise record the Confidential Information except as strictly necessary for the Project;

5.1.6 keep a written record of any document containing Confidential Information or other Confidential Information received from the other in tangible form, and of any copies made of the Confidential Information, and make the same available to the Disclosing Party promptly upon request;

5.1.7 immediately notify the Disclosing Party in writing if it suspects or becomes aware of any unauthorised access, copying, use or disclosure in any form of any of the Confidential Information

5.2 the Receiving Party may only disclose the Disclosing Party's Confidential Information to those of its employees and contractors (Representatives) who need to know the Confidential Information for the Project, provided that

5.2.1 it informs these Representatives of the confidential nature of the Confidential Information before disclosure and obtains from its Representatives enforceable

undertakings to keep the Confidential Information confidential in terms at least as extensive and binding upon the Representatives as the terms of this Agreement are upon the parties; and

5.2.2 at all times, it is responsible for these Representatives' compliance with the obligations set out in this Agreement

5.3 the Receiving Party shall be entitled to disclose Confidential Information only to the minimum extent that it is required to do so by applicable law or by order of a court or as required by the rules and regulations of any regulatory body or any enquiry or investigation by any governmental, parliamentary or official body which has the power to compel disclosure

5.4 before making a disclosure pursuant to clause 5.3, the Receiving Party shall at the earliest opportunity and, to the extent that is legally permitted to do so

5.4.1 notify the Disclosing Party in writing of the proposed disclosure; and

5.4.2 ask the court or other official body, if applicable, to treat the Confidential Information as confidential

5.5 where notice of disclosure under clause 5.4:

5.5.1 is legally permitted, the Receiving Party shall take into account the reasonable requests of the Disclosing Party in relation to the proposed disclosure; or

5.5.2 is prohibited, the Receiving Party shall notify the Disclosing Party of the disclosure as soon as possible following the disclosure when it is legally able to do so

5.6 The Collaborator acknowledges and agrees that:

5.6.1 the Organisation may be subject to the requirements of the Freedom of Information Act 2000 (FOIA) and shall assist and cooperate with the Organisation to enable the Organisation to comply with any Information disclosure obligations;

5.6.2 the Organisation shall be responsible for determining in its absolute discretion, and notwithstanding any other provision in this Agreement or any other agreement whether any Confidential Information or any other information, is exempt from disclosure in accordance with the provisions of the FOIA;

5.6.3 in no event shall the Company respond directly to a Request for Information unless expressly authorised to do so by the Organisation

5.7 neither Party will use the other's name or the name of any of the Key Personnel provided by the other Party or the other Party's logo in any press release or product advertising, or for any other promotional purpose, without first obtaining the other Party's written consent

5.8 each party's obligations under this clause shall continue in full force and effect for a period of [5] years from the end of the Project

## 6. WARRANTIES AND LIABILITY

6.1 each of the Parties warrants to the other that, to the best of its knowledge and belief (having made reasonable enquiry of those of its employees involved in the Project or likely to have relevant knowledge, but not having made any search of any public register), any advice or information given by it or any of its employees who work on the Project, or the content or use of any Results, Background or materials, works or information provided in connection with the Project, will not constitute or result in any infringement of third party rights

OR

6.1 other than expressly stated in writing, neither of the Parties makes any representation or gives any warranty to the other that any advice or information given by it or any of its employees who work or have worked on the Project, or the content or use of any Results, Background or materials, works or information provided in connection with the Project, will not constitute or result in any infringement of third-party rights

6.2 subject to clause 6.4, the liability of either Party to the other for any breach of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement, the Project and the Results, will not extend to

6.2.1 any indirect damages or losses; or

6.2.2 any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity, whether direct or indirect, even if the party bringing the claim has advised the other of the possibility of those losses, or if they were within the other Party's contemplation

6.3 subject to clause 6.4, the maximum liability of each Party to the other in aggregate for all and any breaches of this Agreement, any negligence or arising in any other way out of the subject matter of this Agreement, the Project and the Results, will not exceed in total £ [insert figure]

6.4 nothing in this Agreement limits or excludes either Party's liability for

6.4.1 death or personal injury caused by negligence; or

6.4.2 any fraud or for any sort of liability that, by law, cannot be limited or excluded

6.5 the express undertakings and warranties given by the Parties in this Agreement are in lieu of all other warranties, conditions, terms, undertakings and obligations, whether express or implied by statute, common law, custom, trade usage, course of dealing or in any other way. All of these are excluded to the fullest extent permitted by law

## 7. FORCE MAJEURE

7.1 if the performance by a Party of any of its obligations under this Agreement (except a payment obligation) is delayed or prevented by from acts, events, omissions, happenings or non-happenings beyond its reasonable control, including acts of God, riots, war or armed conflict, acts of terrorism, acts of government, local government or regulatory bodies, fire, flood, storm or earthquake, or disaster but excluding any industrial dispute relating to any Party, the Party's personnel or any other failure of a sub-contractor, that Party will not be in breach of this Agreement because of that delay in performance. However, if the delay in performance lasts more than [3] **OR** [6] months, the other Party may terminate this Agreement with immediate effect by giving written notice to the Party whose performance is delayed or prevented

## 8. TERMINATION

8.1 [either Party may terminate this Agreement without cause by giving the other [3] months' notice.]

8.2 either Party may terminate this Agreement with immediate effect by giving notice to the other Party if the other Party

8.2.1 is in breach of any provision of this Agreement and (if it is capable of remedy) the breach has not been remedied within [30] days after receipt of written notice specifying the breach and requiring its remedy; or

8.2.2 becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other party's assets, or if the other party makes any arrangement with its creditors

8.3 clauses 1, 3, 4 (subject to clause 8.4), 5, 6 and 8-20 will survive the completion of the Project or the termination of this Agreement for any reason and will continue in full force and effect indefinitely or, in the case of clause 5, in accordance with clause 5.8

8.4 on the termination of this Agreement under clause 7 or 8 all rights and licences granted by one Party to the other Party under or pursuant to this Agreement will automatically terminate except any rights to use any Results for Non-Commercial Purposes

8.5 on the termination of this Agreement, each Party will pay the other all sums due to the other at the date of termination. In addition, where a Party has already incurred costs or has unavoidable future expenditure in accordance with the Project Plan and the other Party is obliged to pay for that work in the Project Plan, those sums shall also be payable (up to the sums stated for that work) provided that this sentence shall not apply where the paying Party has terminated the Agreement in accordance with clause 8.2.1

## 9. NOTICES

9.1 any notices sent under this Agreement must be in writing

9.2 the following table sets out the method by which notices may be served under this Agreement and the respective deemed time and proof of service

Manner of Delivery	Deemed time of service	Proof of service
Email	9.00am on the first Working Day after sending	Dispatched as a pdf attachment to an e-mail to the correct e-mail address without any error message
Personal delivery	On delivery, provided delivery is between 9.00am and 5.00pm on a Working Day. Otherwise, delivery will occur at 9.00am on the next Working Day	Properly addressed and delivered as evidenced by signature of a delivery receipt
Prepaid, Royal Mail Signed For 1st Class or other prepaid, next working day service providing proof of delivery	At the time recorded by the delivery service, provided that delivery is between 9.00am and 5.00pm on a Working Day. Otherwise, delivery will occur at 9.00am on the same Working Day (if delivery before 9.00am) or on the next Working Day (if after 5.00pm)	Properly addressed prepaid and delivered as evidenced by signature of a delivery receipt

9.3 notices shall be sent to the addresses set out below or at such other address as the relevant Party may give notice to the other Party for the purpose of service of notices under this Agreement

	<b>Assignee</b>	<b>NHS Organisation</b>
<b>Contact</b>		
<b>Email</b>		

9.4 This Clause does not apply to the service of any proceedings or other documents in any legal action or other method of dispute resolution

**10. ASSIGNMENT**

this Agreement is personal to the Parties and shall not be assigned or otherwise transferred in whole or in part by either Party without the prior written consent of the other Party, provided that the Organisation may assign its rights under this Agreement to another organisation assuming responsibility for the role of the Organisation relevant to the Project as part of a NHS reorganisation

**11. ILLEGAL/UNENFORCEABLE PROVISIONS**

if any provision of this Agreement (or part of any provision) is or becomes illegal, invalid or unenforceable, the legality, validity and enforceability of any other provision of this Agreement shall not be affected

**12. WAIVER OF RIGHTS**

if a Party fails to enforce, or delays in enforcing, an obligation of the other party, or fails to exercise, or delays in exercising, a right under this Agreement, that failure or delay will not affect its right to enforce that obligation or constitute a waiver of that right. Any waiver of any provision of this Agreement will not, unless expressly stated to the contrary, constitute a waiver of that provision on a future occasion

**14. ENTIRE AGREEMENT**

this Agreement constitutes the entire agreement between the Parties in respect of its subject matter and supersedes and extinguishes all prior negotiations, arrangements, understanding, course of dealings or agreements made between the Parties in relation to its subject matter, whether written or oral

**15. AMENDMENTS**

no variation or amendment of this Agreement will be effective unless it is made in writing and signed by each Party's representative

**16. THIRD PARTIES**

a person who is not a Party to this Agreement has no right under the Contract (Rights of Third Parties) Act 1999 (as amended, updated or replaced from time to time) to enforce any term of this Agreement

**17. GOVERNING LAW AND JURISDICTION**

17.1 this Agreement and any issues, disputes or claims (whether contractual or non-contractual) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of England and Wales.

17.2 subject to clause 18, the Parties agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (whether contractual or non-contractual) that arises out of or in connection with this Agreement or its subject matter or formation

**18. ESCALATION**

if the Parties are unable to reach agreement on any issue concerning this Agreement or the Project within 14 days after one Party has notified the other of that issue, they will refer the matter to [insert officer] in the case of the Organisation, and to [insert officer] in the case of the Collaborator in an attempt to resolve the issue within [14] days after the referral. Either Party may bring proceedings in accordance with clause 17.2 if the matter has not been resolved within that [14] day period, and either Party may bring proceedings to protect its Intellectual Property Rights or Confidential Information in any jurisdiction, whether or not any issue has been escalated under this clause

**19. ANTI-BRIBERY**

each Party will comply with all laws, statutes and regulations which apply to it or its activities and which relate to anti-bribery or anti-corruption (or both), including the Bribery Act 2010

**20. COUNTERPARTS**

this Agreement may be executed in any number of counterparts and by the Parties on separate counterparts, but shall not be effective until each Party has executed at least one counterpart. Each counterpart shall constitute an original of this Agreement, but all the counterparts shall together constitute but one and the same instrument.

<b>SIGNED</b> for and on behalf of the Organisation:	<b>SIGNED</b> for and on behalf of the Collaborator
Name:	Name:
Position:	Position:
Signature:	Signature:

## **Hand back / opt-out agreement - NHS Wales allowing innovator or third party to develop IP**

NOTE: Organisations must assess and document fair market value for the Innovation being assigned considering potential purchasers, cost of development and IP protection, exploitation potential, costs and risks of future development and costs savings in relation to any ongoing IP prosecution and maintenance fees.

This ASSIGNMENT Agreement is dated [insert date] (the "Agreement")

BETWEEN:

(1) [ORGANISATION NAME], whose principal place of business is [insert the address](the "Organisation"); and

(2) [ASSIGNEE NAME AND ADDRESS] ( the "Assignee")

together the "Parties" and each a "Party".

### **BACKGROUND**

A The Assignee has developed the Innovation which is owned by the organisation providing and supporting NHS services because of an agreement or the operation of law.

B The Organisation has determined that the Assignee is best placed to ensure the Innovation is used for the benefit of the public and patients within the NHS and the Parties have agreed that the Organisation will assign the Intellectual Property Rights in the Innovation to the Assignee on the terms set out in this Agreement.

### **IT IS AGREED:**

#### **1. INTERPRETATION**

1.1 In this Agreement, unless the context otherwise requires:

- "Assigned Rights" - has the meaning given to it in clause 2.1
- "Documents" - the documents relating to the Innovation which are in the Organisation's possession identified in Part 2 of the Annex
- "Innovation" - the product, process, work, data or information described in Part 1 of the Annex

- "Intellectual Property Rights" - means patents, rights to inventions, copyright and neighbouring and related rights, trade marks, rights in designs, database rights, confidential information (including know-how and trade secrets) and all other intellectual property rights, whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection in any part of the world
- "Working Day" - means a day other than Saturday, Sunday or public holiday in England and Wales when banks are open for business
- 1.2 In this Agreement:
  - 1.2.1 a reference to any gender includes a reference to other genders;
  - 1.2.2 the singular includes the plural and vice versa;
  - 1.2.3 the word "include" and cognate expressions shall be construed as if they were immediately followed by the words "without limitation";
  - 1.2.4 references to any statutory provision include a reference to that provision as modified, replaced, amended and/or re-enacted from time to time (before or after the date of this Agreement) and any prior or subsequent subordinate legislation made under it;
  - 1.2.5 the expressions "subsidiary", "holding Assignee" and "subsidiary undertaking" shall have the meanings given to them in the Companies Act 2006;
  - 1.2.6 headings are included for ease of reference only and shall not affect the interpretation or construction of this Agreement; and
  - 1.2.7 references to Clauses are to clauses of this Agreement

## 2 ASSIGNMENT AND HANDOVER

2.1 the Organisation assigns to the Assignee all the right, title and interest that it owns in the Intellectual Property Rights in the Innovation (the Assigned Rights) including the right to claim damages and other relief in respect of any infringement occurring before or after the date of this Agreement.

2.2 the Organisation shall deliver the Documents to the Assignee within 10 Working Days of the date of this Agreement by electronic means or by such other method as the parties shall agree.

2.3 at the Assignee's expense the Organisation shall use reasonable endeavours to execute such documents and perform such acts as may reasonably be required for the purpose of giving full effect to this Agreement, including:

2.3.1 registration of the Assignee as applicant or (as applicable) proprietor of any of the Assigned Rights which are registered; and

2.3.2 providing information or additional documents which are in the possession of the Organisation to assist the Assignee in obtaining the Assigned Rights which are applications

### 3. FINANCIAL

3.1 [the Assignee shall pay to the Organisation the sum of [£] + VAT on signing this Agreement.]

3.2 [consider whether an ongoing revenue sharing mechanism may be applicable. If so, the Assignee should also report revenue so that revenue share/royalty can be verified]

3.3 the Assignee shall be responsible for any fees (including registry or attorney fees) in relation to the Assignment Rights unpaid, due or arising on or after the date of this Agreement

### 4. NO WARRANTY

4.1 The Parties acknowledge that the Assignee, having first-hand knowledge of the Innovation, is in the best position to assess and understand the risks associated with the Assigned Rights, the Organisation assigns the Assigned Rights as is and all conditions, warranties, representations or other terms that might otherwise be implied into this Agreement by statute, common law or otherwise are excluded from this Agreement to the fullest extent permitted by law

### 5. GENERAL

5.1 each Party will be responsible for all costs incurred by it or on its behalf in connection with this Agreement

5.2 this Agreement may be executed in any number of counterparts and by the Parties on separate counterparts, but shall not be effective until each Party has executed at least one counterpart. Each counterpart shall constitute an original of this Agreement, but all the counterparts shall together constitute but one and the same instrument

5.3 if any provision of this Agreement (or part of any provision) is or becomes illegal, invalid or unenforceable, the legality, validity and enforceability of any other provision of this Agreement shall not be affected

5.4 this Agreement constitutes the entire Agreement between the Parties in respect of its subject matter and supersedes and extinguishes all prior negotiations, arrangements, understanding, course of dealings or Agreements made between the Parties in relation to its subject matter, whether written or oral.

5.5 a person who is not a Party to this Agreement has no right under the Contract (Rights of Third Parties) Act 1999 (as amended, updated or replaced from time to time) to enforce any term of this Agreement

## 6. NOTICES

6.1 any notices sent under this Agreement must be in writing

6.2 the following table sets out the method by which notices may be served under this Agreement and the respective deemed time and proof of service

<b>Manner of delivery</b>	<b>Deemed time of service</b>	<b>Proof of service</b>
Email	9.00am on the first Working Day after sending	Dispatched as a pdf attachment to an e-mail to the correct e-mail address without any error message
Personal delivery	On delivery, provided delivery is between 9.00am and 5.00pm on a Working Day. Otherwise, delivery will occur at 9.00am on the next Working Day	Properly addressed and delivered as evidenced by signature of a delivery receipt
Prepaid, Royal Mail Signed For 1st Class or other prepaid, next working day service providing proof of delivery	At the time recorded by the delivery service, provided that delivery is between 9.00am and 5.00pm on a Working Day. Otherwise, delivery will occur at 9.00am on the same Working Day (if delivery before 9.00am) or on the next Working Day (if after 5.00pm	Properly addressed prepaid and delivered as evidenced by signature of a delivery receipt

6.3 notices shall be sent to the addresses set out below or at such other address as the relevant Party may give notice to the other Party for the purpose of service of notices under this Agreement

	<b>Assignee</b>	<b>Organisation</b>
<b>Contact</b>		
<b>Address</b>		
<b>Email</b>		

6.4 this Clause does not apply to the service of any proceedings or other documents in any legal action or other method of dispute resolution

**7. GOVERNING LAW AND JURISDICTION**

7.1 this Agreement and any issues, disputes or claims (whether contractual or non-contractual) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of England and Wales

7.2 the Parties agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (whether contractual or non-contractual) that arises out of or in connection with this Agreement or its subject matter or formation

Signed by the Organisation	Name:
	Signature:
	Position in Organisation:

Signed by the Assignee	Name:
	Signature:

## **Considerations for NHS Wales organisations when entering into agreements with Technology Transfer Organisations.**

Technology Transfer Organisations (TTOs) can provide a useful service to NHS Wales organisations by providing development and exploitation support. TTOs can provide IP evaluation, protection, market analysis, licensing, and spin-out support.

This note outlines key considerations, governance principles, and operational steps to ensure alignment with NHS values, legal compliance, and commercial success. It provides guidance on good practice to assist NHS Wales organisations to understand the opportunities provided by collaborating with a TTO and how to negotiate reasonable terms.

### Understanding the role of the TTO

TTOs act as intermediaries between organisations and external parties (e.g., industry, academia) to commercialise innovations developed within the organisations. From a legal perspective, they will usually be agents for the organisation so that the organisation is responsible for managing its IP and concluding contracts, but the TTO manages the opportunities, financial elements and helps facilitate the relationship with the other parties.

TTOs' responsibilities typically include:

- IP assessment and protection (e.g., patents, trademarks)
- market analysis and partner identification
- negotiation and execution of licensing agreements
- revenue management and royalty collection
- It is important for the contract with a TTO to clearly define the scope of the TTO's role and the boundaries of their authority. Organisations will need to consider how IP is identified and selected to be included in a contract with a TTO – most important, promising and highest value IP first. Organisations will need to define clearly that a TTO cannot commit the organisation to a contract with a third party without final review and approval by the organisation.

Occasionally, TTOs play a direct role in IP commercialisation. In these cases, the IP is licensed to the TTO which then is responsible for developing it into a commercial product and further licensing it to commercial parties. In these cases the NHS organisation will need much clearer reporting and controls on the TTO's activities to ensure it maintains an appropriate degree of oversight.

## Key contractual elements to manage

### **Appointment**

TTOs are often appointed as agents to provide services (such as marketing and managing innovations) to the organisation. This may be on an exclusive basis so it is important to consider the best TTO for the organisation in a procurement process.

Set clear strategic objectives in the contract with the TTO, including the following:

- align with NHS values: public benefit, affordability, and accessibility
- define success metrics: e.g. licences executed, revenue, time-to-market, health impact

### **IP ownership and rights**

The organisation needs to ensure that the innovations included in the TTO agreement are actually owned by the organisation. This means these arrangements are less suitable for IP developed through multi-party collaborations unless all the parties agree or the organisation engaging the TTO has clear rights to exploit the IP.

It is important to verify the organisation's ownership of IP before the TTO starts work as withdrawing innovations from the process at a later stage could result in the organisation having to pay the TTO additional costs.

The organisation and the TTO need to agree the type of IP licences the TTO can negotiate. Typically licence the TTO can negotiate will:

- define the type of licence (exclusive, non-exclusive, field-limited – note that non-exclusive licences will be the normal approach and exclusive licenses will need to be justified and only agreed after legal advice).
- ensure terms reflect DHSC IP guidance
- include performance milestones and termination clauses for underperformance by the licensee

### **Fees and revenue sharing**

The TTO business model is likely to include some inclusive services (which are paid for under an annual fee and revenue share for IP which is later licensed) and service charges for additional services.

NHS Wales Organisations should:

- establish a transparent revenue-sharing model (e.g., net revenue split between the organisation (and any other parties, inventors etc) and TTO
- the level of fees and revenue sharing needs to be assessed and negotiated by the NHS Wales organisation. This should be carefully considered in the context of the IP being developed and commercialised to assess proportionality. In addition, the ability for the TTO to receive payment before another (top slicing) needs to be considered by reference to the commercial risk taken by each party and negotiated against a balanced model where each party receives the agreed share of the revenue at the same time
- consider other benefits such as discounts, priority access and provision of devices, facilities and other equipment
- clearly define how revenue is calculated and exactly which costs can be deducted prior to calculating the share of net revenue
- include audit rights to verify financial reporting

### **Exit and renewal strategy**

- include clear exit provisions (e.g., breach, insolvency, conflict of interest)
- plan for contract renewal, transition, or re-tendering based on performance and market conditions. Understand that obligations to continue to pay the TTO a revenue share are likely to continue after contract termination (consider whether this is appropriate if the contract has been terminated for breach by the TTO)

### Governance and reporting - managing TTOs

Agreements with TTOs are most likely to be successful where there is active engagement by all interested parties:

- involve clinical and operational leads, R&D, commercial, legal and innovation teams early in the process
- ensure inventors understand their rights and obligations
- set up a joint steering committee or review board for oversight
- require regular reporting on licensing activities, deal pipeline, and financials
- carefully review due diligence on potential licensees (financial stability, ethical alignment)

- use KPIs such as time to agree licence, revenue generated, and number of active licences
- review TTO performance quarterly with a more formal review annually
- require detailed financial reporting and conduct cost benefit reviews
- encourage knowledge sharing from the TTO to the organisation