

## The Innovator's Guide to Innovation at Plymouth Hospitals NHS Trust

### What is Innovation?

NHS Innovation is the process of developing and applying better solutions that meet existing requirements, new and emerging requirements or even unarticulated needs. These innovations may be in the form of new or improved products, processes or services resulting in improved patient care or saving cost. In some cases, they may also make money for both the innovators and the NHS.

There are three basic types of innovation;

- A new product e.g. a new piece of equipment to be used in a surgical intervention, a software application.
- A new process e.g. patient notes being transferred between clinics to save time.
- A new service e.g. a telephone follow up service.

If you are an NHS employee and you have an idea for a new or improved product, device or software to improve healthcare, PHNT is ready and willing to help turn that idea into reality.

### What if you have an idea?

We are really interested to hear about any idea that you may have, whether it's a new product, process or service. If you have an idea with commercial value the trust may be able to help you develop it which may result in a product which you have a revenue share in. For more details of this please see Annex 1. First of all you can contact the Trust Senior Innovation Lead (TIL), Helen Neilens who will be happy to discuss your idea with you. Alternatively, you can follow this link which will take you to the innovation capture form ([Innovation Capture Form](#)) also in ANNEX 3. If you complete this and submit it to Helen, she will contact you to discuss it. For an overview see the following PHNT General Innovation pathway flow chart.

### Innovation Contacts

Within the Trust, the Senior Innovation Lead is Helen Neilens. In the first instance, please contact Helen on:

Helen Neilens, Senior Trust Innovation Lead Tel: 01752 (4)39991

e-mail: [hneilens@nhs.net](mailto:hneilens@nhs.net)

*Alternatively,*

Victoria Yates or Elinor Pegg, Senior Research Support Facilitators 01752 (4)39992/32197, e-mail: [plh-tr.researchandinnovation@nhs.net](mailto:plh-tr.researchandinnovation@nhs.net)

## **Things you can do**

To ensure we can give you the best advice it will be helpful if you can provide us with as much information about your idea as you can including for example; what it is, what is the problem being addressed and how big is the problem, any evidence that exists or new evidence that it is needed, other Trusts using it/doing it, patient/trust benefits and potential costs/savings involved. Simple online searches such as Google may help with much of this information. Please see the links further in this document for more support and guidance with this.

## **What happens next?**

Once we have all the information we can collate together then we can advise on how best to help you with what you need to take your idea forward. It may be that you can be directed to someone or a department in the Trust who will be able to manage your idea or include it as part of an existing process. Some projects and ideas are more complex and may need more advice and support, for instance resources; financial and time. These will be directed to our Trust Innovation Group (TIG). Please see below for the Trust General Innovation Pathway.

## **Trust General Innovation Pathway**

### **Initial sifting of ideas**

The Trust Innovation Lead will explore your ideas initially, resulting in one of the following outcomes;

1. Inform you that the idea is unfeasible and why.
2. Request more information from you.
3. Discuss the idea with others who have knowledge in that area e.g. service improvement, IT or specialist areas.
4. Direct you to appropriate people who can help develop and implement the idea e.g. in the case of small innovations/service improvements where there are already existing delivery channels.
5. In the case of larger projects which may incur a cost or more complex issues such as Intellectual Property, take idea to second stage.

All ideas whether successful or not will be documented by the Trust Innovation Group. You should receive initial feedback within 10 days of submission.

### **2<sup>ND</sup> Stage review**

For any project that cannot be dealt with in the initial sifting process, they will be taken automatically into the 2<sup>nd</sup> stage which involves a more detailed review. The TIL will assess the feasibility of the innovation in collaboration with individuals with specialist knowledge of the area e.g. service improvement, clinicians, department leads, audit, R&D, SW AHSN. More detailed information will be collected and a formal appraisal conducted. This process will be subject to confidentiality agreements.

Once the formal appraisal is conducted, it will result in one of the following actions;

1. Inform you that the idea/innovation cannot be supported further (with explanation of decision made).
2. Direct you to the appropriate people who can help implement the idea using delivery channels that already exist.
3. The innovation will be discussed at the next Trust Innovation Group (TIG) meeting (please see below). Attendees will be invited dependent on the project and its individual requirements. This will be organised by the Trust Innovation Lead.

### **Taking a project forward**

Before a more complex project can progress, where investment may be required, a business plan will be required. The innovator will develop this with the help of the TIG and any other partners e.g. SW AHSN. Formal agreements from finance and any parties involved will be needed before any project can progress further.

Business plans will have to include a clear set of outcomes, potential costs to the Trust, timelines, review periods, STOP clauses and risk assessment. IP issues and route to commercialisation strategies will be clearly outlined if relevant. The communication plan via which stakeholders and TILs will be kept informed of any progress will be clarified. Advice and support are available for this.

The TIG may de-commission a project at any point where they feel the costs are outweighing the likely benefits.

### **Trust Innovation Group (TIG) meetings**

TIG meetings are held bi-monthly. They consist of a core group of members (detailed below) plus individuals invited to represent departments, Service Lines and specialties as required for specific projects.

### **Purpose of Group**

1. To facilitate the generation of new ideas and the uptake of ideas, practices and processes that have been generated externally or elsewhere in the NHS.
2. To stimulate innovative solutions to key service delivery challenges.
3. To provide a gateway for innovation in the trust
4. To signpost ideas to the appropriate structures e.g. service improvement, AHSN, NISW, CLAHRC, R&D, Estates, IM&T etc.
5. To provide support to PHNT employees who have ideas that they want considered.

### **Decisions**

Following a TIG meeting the Group may decide that a project is not feasible and no further action is required. It is the responsibility of the Senior Trust Innovation Lead to feedback to the innovator. Alternatively the TIG might identify projects that require further support and these will be allocated the appropriate resources.

## **TIG membership**

The following are members of the TIG:

**Non-Executive Director (Chairman)** Richard Crompton

**Executive lead for innovation:** Phil Hughes

**Director of Nursing** Greg Dix

**Senior Trust Innovation Lead** Helen Neilens

**Trust Innovation Lead** Mike Biscombe,

**Associate Director of Finance** Brian Jones

**Clinical Trials Manager** Corinna Mossop

**Director of Therapy Services** Nicky Martin

**Head of Software Development, Integration and Support Services**  
Paul Coplestone

**Service Improvement Lead** Nick Foss

**Business Change Managers** Ashley Davies, Robert Love

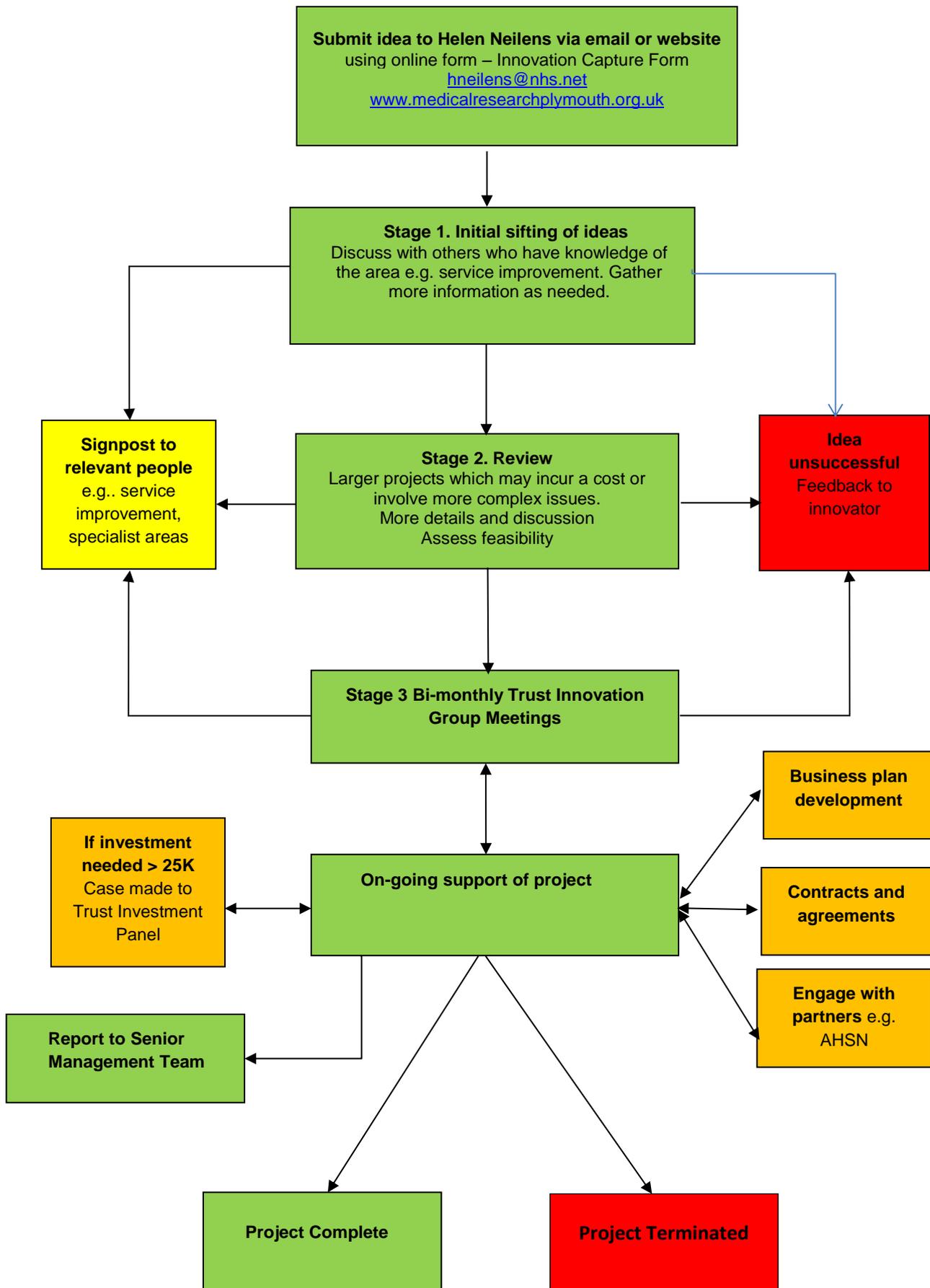
**Head of Clinical Measurement & Innovation, Healthcare Science & Technology** Mike Mayo

**Team Leader Specialist Mechanical Workshop** Andrea Carpenter

**Procurement Lead:** James Leaver

All TIG members are covered by a Non-disclosure Agreement so are able to discuss your ideas in complete confidence.

## PHNT General Innovation pathway



## **PHNT Product Innovation Pathway**

In general terms, process and service innovations will be of significant benefit to your service, the Trust and the wider NHS. These innovations rarely have a commercial value. However product innovations, including software applications, may well have a commercial value both to you and the Trust, in addition to the practical benefits they bring to your service. In cases where commercialisation of the innovation is possible, particular care needs to be taken to protect the value of the idea. Please note the same principles may also apply to process or service innovations where value exists in the Intellectual Property associated with the idea. Advice may be sought in these circumstances.

In order to realise the benefit, you and the Trust will need to work with a Commercial company to develop and ultimately market the product. This is often a long, expensive and speculative process. A company is only likely to invest time and money in bringing a product to market if it can protect its investment with a patent. Patent (Intellectual Property (IP)) protection for your idea is only possible if there has not been a disclosure of the idea before the patent is applied for, except where covered by a Non-Disclosure Agreement (NDA) or other confidentiality agreement. The Trust Innovation Lead will be able to advise you further on this and will be able to work with the Trust's Innovation Group under existing confidentiality agreements to support your innovation. Further details of the pathway for product innovations requiring Patent protection are set out below.

### **IP and Commercialisation**

In cases of invention for innovation or product innovation, appropriate advice will be sought as soon as possible from the Trust's Innovation Lead and possibly the South West Academic Health Science Network. Further details of the role of the SW AHSN are given below. Trust IP policy will be followed (see appendix). Further details, including Revenue Share agreements between the Trust and you as the innovator, are set out in the Innovation Pathway for product innovations requiring Patent protection below.

### **The South West Academic Health Science Network (SW AHSN)**

There is recognition in the Health and Medicines Act 1988 that exploiting ideas and intellectual property is necessary in order to make more income available for improving the health service.

The need for better co-ordination between the NHS and industry was set out in the Department of Health's publication 'Innovation Health and Wealth' in December 2011.

In 2013, fifteen Academic Health Science Networks were set up to facilitate the development and adoption of innovations into the NHS by acting as a link between the NHS, the Universities and the medical and pharma industries.

The SW ASHN covers Somerset, Devon and Cornwall. It has eighteen members comprising the Universities of Exeter and Plymouth and every NHS organisation

in the South West including our four CCGs. Trust Innovation Leads supporting NHS staff with their ideas will have access to the SW AHSN as required by individual projects

## **The Product Innovation Pathway**

### **Initial Concept**

New ideas can be fully formed in a single *eureka* moment or can evolve with time. The best ideas can appear to be so obvious that it can be difficult to believe that no-one has thought of it before. If you have what you think is a great idea, the first thing to remember is the need to preserve confidentially and whom you share your idea with. This is where your innovation leads can help and guide you on a confidential basis.

### **Product Development**

For a product to become a reality, considerable work will be required to develop prototypes, refine designs and commence manufacture. In the majority of cases, the Trust has neither the resources nor the expertise to carry out this process and will need to work in partnership with a commercial company. In order for a commercial company to commit the level of investment required, it will normally require a licence agreement backed up by Intellectual Property ownership (patent protection).

For a medical product to become a reality, there may be the additional requirement and expense for it to be a CE marked medical device. The CE mark is evidence of the fact that the device has been designed, manufactured, tested and placed on the market in accordance with the requirements of the Medical Devices Directive. The Trust does not have the money or infrastructure to CE mark medical devices which means that the only way that your idea will become a reality is if it can be licensed to an established Medical devices company.

### **Confidentiality**

A company will normally only license a product if it can protect its investment of time and resources with a patent, but a patent is only possible if there has not been a disclosure of the idea that was not covered by a Non-Disclosure Agreement (NDA). Within a Trust, employees are covered by confidentiality terms within their employment contract but you must not talk about the idea to anyone outside your Trust, except under the terms of a NDA.

### **Write the Idea Down**

The first step is to write your idea down. Add a drawing or sketch if relevant. Don't worry about the quality of the illustrations but it is important to have some written evidence of what your idea is. Make sure that you sign and date this.

### **Discussions with Colleagues**

The recommendation is that the first person that you disclose your idea to should always be one of the Trust's Innovation Support team (Contact Details as above). With any innovation it is important to get the balance right between

getting feedback on your idea from your colleagues and being able to avoid unnecessary dilution of the innovator's revenue share. Anyone who makes a suggestion that ends up being incorporated in the final version of the innovation will be entitled to a revenue share, so you may wish to be selective about who you talk to. However, bear in mind that a share of something big is always going to be more valuable than 100% of something small or non-existent, so don't completely avoid talking to others who might be able to improve on your initial idea.

### **Internet Search**

Before you go to the Innovation Support Group, it is essential to check to see if someone has already thought of your idea. The most efficient way to do this is with an Internet search. Remember that the name that you have called your idea might not be the only way to describe it. Therefore, make sure that you try as many different search terms as possible and keep a note of the terms that you have used. Innovation Leads and SW AHSN will be able to assist with this.

### **Patent Search**

If possible, do a quick patent search. Espacenet is the free patent search tool provided by the European patent office and is very straightforward to use. The search page can be found at: <http://worldwide.espacenet.com/advancedSearch> A good way to start is to search for key words in the title or abstract. However, do not worry if you find it difficult to do a search, there will be others within your organisation and within the SW AHSN who will be able to help. Your librarian may also be able to help you.

### **Initial Review and Capture of the Innovation**

The Innovation Support Team will review your initial proposal and the results of your Google and Espacenet checks. It may be that they think of alternative search terms. The Innovation Support Team will then work with you to get the details of the innovation entered into the IP-SW system which is the on-line IP management system provided by the SW AHSN for use by its member organisations. You will be given a password to enable you to access your innovation on the IP-SW system so that you can monitor its progress.

### **Innovation Support Group**

The innovation will then be evaluated by the Innovation Support Group comprising the Innovation Leads, and additional staff with relevant expertise as required. The evaluation process will include estimates of the potential benefits to patients, the novelty of the IP and the potential commercial value.

### **Clarity of Concept**

An assessment is made by the Innovation Support Group of what level of concept development is required to ensure that a potential licensee fully understands the concept. This might be a written paper but illustrations are always useful. The cost of a Computer Aided Design (CAD) image is relatively low and has the advantage that the image can be looked at from any point of

view. Once the CAD drawing exists it is also possible to produce a model using 3D printing. This may well not be a working model but it can still be helpful when describing the innovation.

If the cost of achieving Clarity of Concept is low, the Innovation Support Group may be able to provide resources and approval to move the innovation forward.

If the cost of achieving Clarity of Concept is significant, or there is a perceived reputational risk to the Trust, the innovation will be referred, to the Trust's Innovation Group

### **Innovation Group**

All innovations requiring significant financial Support or with a reputational risk to the Trust will be put forward for consideration by the Trust's Innovation Group. Other Trust staff with expertise relevant to the innovations under review may be asked to attend that section of the Group's meeting. A SW AHSN regional NDA is in place, which allows the Innovation Group to include representation from the SW AHSN, the local CCG or the University as well as invited Innovation Leads from other Trusts who are members of the SW AHSN, if this appropriate to your innovation.

A purpose of the Innovation Group is to decide whether or not the Trust should allocate human and financial resources to your innovation. You will be able to present your idea to the panel or you can ask the Innovation Lead to make the presentation on your behalf.

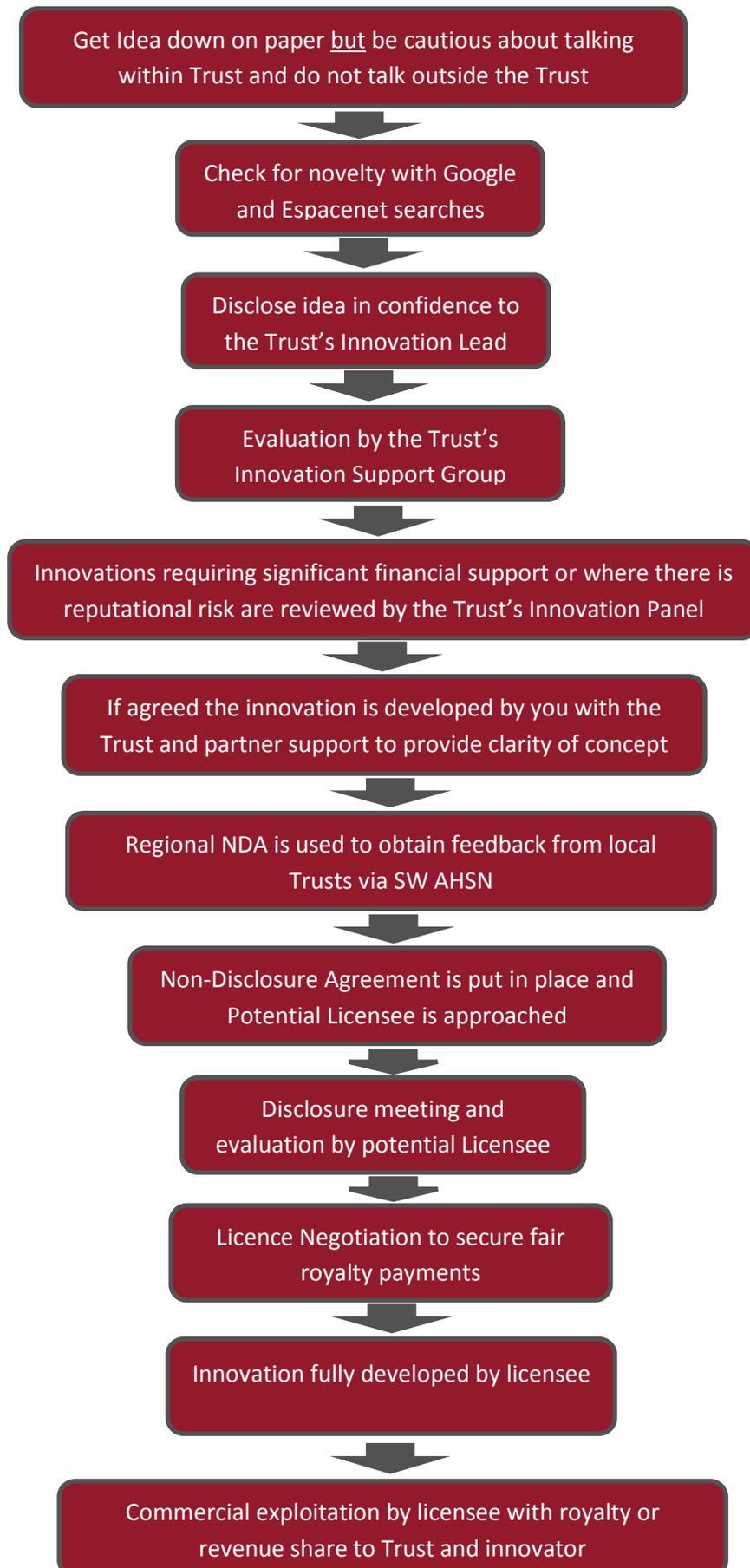
The outcome of the panel meeting is recorded in minutes and you will be entitled to see the minutes relating to your innovation.

If the Innovation Group agrees that your idea should be supported then the Innovation Support Group will be tasked to proceed with the innovation with the full backing of all departments within your organisation and, if appropriate, the SW AHSN.

### **Regional Feedback**

The Trust will make use of a regional NDA that has been signed by all eighteen members of the SW AHSN to obtain feedback on the innovation from appropriate individuals from other Trusts. This feedback is extremely valuable when deciding on how the innovation should be commercialized. This will be discussed with you.

## Summary of the Trust Product Innovation Pathway using the Licensing Route to Market



## **Ownership of Intellectual Property**

The NHS is keen to support the development of innovations that will improve patient care, improve efficiency, reduce costs and generate income for the service.

*'The NHS, like many other health economies, faces a tougher financial climate. Innovation has a vital role to play in fulfilling this purpose by improving the quality of care for patients, releasing savings through productivity, and enabling the NHS to make its contribution as a major investor and wealth creator in the UK'<sup>1</sup>*

The Trust has an Innovation Pathway to support Innovators in developing their ideas and promoting their introduction into the Service as discussed. The Trust can call on its own resources, those of the South West Academic Health Science Network (SW AHSN) and specialist advisors on Intellectual Property, patenting and commercialisation to provide this support. For innovations with a potential commercial value, initial investment will be required to secure patent protection for the idea and to develop the idea into a commercial product. In order to secure this support, the Trust will need clarity on the ownership of the associated Intellectual Property, which is not always immediately obvious. Where the Trust does support these innovations a revenue share agreement will ensure that both the Innovator and the Trust benefit from successful commercial development of the idea.

Clarity on ownership of Intellectual Property (IP) is a critical part of the Innovation Pathway taking innovations from concept through commercialisation to adoption.

As an NHS employee, if you have an idea, your employer has a claim on the ownership of your intellectual property (IP). This is not specific to NHS employees. Clause 39 of the Patent Act 1977 is the legal basis for this. This clause is quoted in full below: –

“Notwithstanding anything in the any rule of law, an invention made by an employee shall, as between him and his employer, be taken to belong to his employer for the purpose of this Act and all other purposes if –

- (a) it was made in the course of the normal duties of the employee or in the course of duties falling outside his normal duties, but specifically assigned to him, and the circumstances in either case were such that an invention might reasonably be expected to result from the carrying out of his duties; or
- (b) the invention was made in the course of the duties of the employee and, at the time of making the invention, because of the nature of his duties and the particular responsibilities arising from the nature of his

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<sup>1</sup> DoH, 2011, *Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS*, DoH, London)

duties he had a special obligation to further the interests of the employer's undertaking"

The first part of section (a) is reasonably clear in that if you have the idea for the innovation because of what you are being paid to do then the invention is owned by your employer i.e. your Trust. The best ideas come from front-line staff being faced with a difficult situation and realizing that it can be done a better way. Therefore, the chances are that your idea will be in your head because of what you have been exposed to in the course of your normal duties. However, because of the uncertainty about the level of expectation that there might be about whether or not "an invention might reasonably be expected to result from the carrying out of your duties", instead of stating that the Trust owns your idea outright, we are stating that your Trust has a claim on the idea. The strength of that claim will vary according to the extent that an invention might reasonably be expected from carrying out those duties. We can discuss this on a case by case basis.

In order to commercially exploit an innovation, it is essential that there is clarity about ownership so that the NHS can invest time and money in your innovation, external investment can be attracted and contracts can be signed. Therefore, a Revenue Share Agreement has been developed in the South West, whereby any IP that is not already owned by your Trust is assigned by you to the Trust in exchange for a package comprising:

- An extremely generous revenue share as indicated below.

| <i>Net revenue</i>     | <i>Inventor/s</i> | <i>Trust</i> |
|------------------------|-------------------|--------------|
| £0 - £50K              | 75%               | 25%          |
| £50,001K-<br>£150,000  | 60%               | 40%          |
| £150,001K-<br>£500,000 | 45%               | 55%          |
| £500,001 and<br>above  | 30%               | 70%          |

- The Trust provides an indemnity against claims for IP infringement or product liability.
- The Trust, possibly supported by the SW AHSN, pays for any prototyping required to provide clarity of concept for your innovation. As an innovator you will not be required to make any financial contribution to the costs of developing your innovation and your work to support the innovation can be in NHS time not your own time.
- The SW AHSN will be able to fully support your innovation making use of the regional network of innovation leads to provide essential, confidential feedback on your innovation.

- The SW AHSN will be able to fully support you and the Trust in identifying a potential licensee, setting up a Non-Disclosure Agreement and then contract negotiation in order to get the best possible financial return to the Trust and therefore to you from the Revenue Share.

Once the Revenue Share Agreement is in place between you and the Trust, you will remain an integral part of the innovation pathway and will remain involved in all decisions relating to your innovation.

If you decide not to agree to the Revenue Share Agreement, it will mean that you are excluding yourself from any support from your Trust, the SW AHSN or the NHS in developing and adopting your innovation. The Trust and indeed the Secretary of State for Health<sup>2</sup>, will also retain the right to challenge your ownership of the IP if the innovation becomes a financial success.

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<sup>2</sup> Clause 7 of the Health and Medicines Act 1988 states that “In order to make more income available for improving the health service ..... the Secretary of State shall have the powers ..... to develop and exploit ideas and exploit intellectual property”.

## **Protection and Commercialisation**

### **Commercialisation Route**

The majority of NHS innovations will need to be CE marked before they can be commercialised. The CE mark process requires accreditation with ISO 13485 and evidence of compliance with the essential requirements of one of the three Medical Devices Directives of which the Directive 93/42/EEC is normally the most relevant. In most cases this means that the Trust is not able to directly place a device on the market irrespective of whether or not the device is being paid for. Therefore, the most likely route to market for NHS innovations will be via a licensing agreement with a commercial company which will have the necessary regulatory structures in place.

Some digital health innovations such as Apps may not require CE marking and can therefore be commercialised directly by the Trust.

It may also be possible for you and the Trust to set up a spin-out, joint venture or Community Interest Company to commercialise your innovation. Examples of these do exist in the South West but they are a very small minority of NHS innovations.

### **Preparation for Disclosure to Potential Licensee**

The best potential licensee is identified and an approach is made. This may be undertaken either by or in conjunction with the SW AHSN which is working to develop and strengthen links with the Medical Industry.

Before a disclosure can be made to the company about your innovation, a Non-Disclosure Agreement (NDA) has to be put in place. This may be a two-way NDA between the trust and the potential licensee or alternatively a three-way NDA including the SW AHSN. You as the innovator do not need to sign because the NDA will be signed on behalf of your organisation. Getting the fully signed NDA in place can be time consuming especially with larger companies where their legal departments may be outside the UK.

### **Licensing**

A typical licence will be based on a company acquiring the world-wide rights to commercialise a patent that remains owned by the Trust. The recommended model is to require the licensing company to pay for the patent protection of the IP and for the cost of the full prototypes. It is possible that the Trust will make a contribution to the prototyping costs in order to demonstrate its commitment to supporting the innovation and this would normally also be supported by the SW AHSN if they are involved using a Match Funding Agreement.

We do not normally seek a cash payment from the licensee as part of the license agreement because we believe that it is better for the licensing company to be putting their money into the prototyping and development of the idea. However, the license agreement will include a royalty as a percentage of the sales

generated by the innovation. This royalty will be paid by the licensee to the Trust from which you will receive a generous revenue share in accordance with the Trust's intellectual Property (IP) Policy. In this way, you will benefit financially if your innovation becomes a commercial success.

### **Patenting**

Patenting is vitally important to protect a product innovation but it is an expensive and risky process which is why we would always seek to transfer the cost and risk to a licensee as soon as possible.

The first step is to check to see that an idea will not infringe an existing patent. If it does not appear to infringe anyone else's patent, then it is possible to file a patent application. In due course, the patent examiner will look to see if the patent infringes any prior art. The examiner will assess if there is novelty, meaning that the idea is completely new. There also has to be an inventive step so for example just combining together a couple of ideas from existing patents is not normally regarded as demonstrating a clear inventive step.

As a general guide, it will cost around £5,000 to engage a patent attorney to draft and submit a UK patent application and pay the initial UK registration and examination fees.

This UK process takes about a year. Twelve months after the UK application has been filed, there is an opportunity to file a Patent Cooperation Treaty (PCT) application that turns the original UK application into an International application; the cost is around £5,000. Eighteen months later the PCT enters the National Phase and it is necessary to choose in which countries the application is to be made. Each country has its own costs but a typical selection covering the major markets would cost upwards of £20,000. The patent is then examined in each selected country and each examiner can make objections. Each response to these objections can cost up to £5,000, with no guarantee that the final result will be a granted patent.

This combination of uncertain outcomes and escalating costs is why we would always prefer to license the innovation before filing the patent application so that it can be the Licensee and not the Trust that pays the patent fees. In the exceptional cases where the Trust files a patent application before a license agreement is in place, great care must be taken to complete the licensing process before the patent costs start to mount up.

**Innovation Capture Form**

**Please complete as much of the form as you are able. This is to enable us to understand the idea as much as possible. We will contact you within the next 10 days.**

|  |                 |
|--|-----------------|
| <b>Name</b>  |                 |
| Contact Details (phone number and email address)                         |                 |
| <b>The Idea</b>  |                 |
| Describe your idea – What is it?   | (100 words max) |
| What problem does it solve?  | (200 words max) |
| Describe the benefits from your idea (patients/staff/organisation)       | (200 words max) |
| <b>Evidence</b>  |                 |
| What is already available/being done?                                    | (200 words max) |
| Is there something similar in another area?<br>Google and patent search? | (200 words max) |
| Is there any evidence that this is useful/effective?                     | (200 words max) |
| Has the idea been tested?<br>What did you learn?                         | (200 words max) |
| <b>Progress</b>  |                 |
| Describe where you are with developing your idea?                        | (100 words max) |
| What level of support is there for this (internal and external)?         | (100 words max) |
| What challenges have you faced so far (if any)?                          | (200 words max) |
| What are your next steps?  | (100 words max) |