

NIHR response to the Intellectual Property Office consultation “Industrial Strategy: Intellectual Property Call for Views”.

1. The National Institute for Health (NIHR)

The National Institute for Health Research (NIHR) is funded by the Department of Health to improve the health and wealth of the nation by research. Since its establishment in April 2006, the NIHR has transformed research in the NHS. It has increased the volume of applied health research for the benefit of patients and the public, driven faster translation of basic science discoveries into tangible benefits for patients and the economy, and developed and supported the people who conduct and contribute to applied health research. The NIHR invests significant funding each year in infrastructure, traineeships, research programmes and systems. Although the majority of research is focused on the UK, the NIHR has recently launched a £122m Global Health ODA funding stream that aims to produce measurable benefits to patients and the public in low and middle-income countries.

2. NIHR’s Perspective on IP

NIHR recognises that intellectual property is one of a number of important tools to deliver patient benefit from the UK taxpayer money it manages. IP is used in a complementary way with other outputs such as publications and presentations to produce diverse impactful outcomes. NIHR expects that the majority of its funding will result in some form of IP that researchers need to recognise, manage and exploit in an appropriate way to improve the health and care system in the UK and overseas (via ODA). NIHR funded IP can take a wide range of forms including know-how, data sets, copyright, trademarks and patents. NIHR also believes that IP assets need to be used by clinical, commercial or charitable bodies with the highest chance of producing patient benefit. Often the organisation using IP is not the research organisation that receives NIHR funding and produces IP. Therefore, effective IP licensing, dissemination and transfer mechanisms are needed for the NIHR to achieve its goals.

NIHR is working to improve how all forms of IP are used in appropriate non-commercial and commercial implementation models to maximise patient benefit from research performed with their involvement and engagement. Based on the NIHR’s experience of funding a wide variety of research, this response to the consultation summarises suggestions of how the IPO and the wider IP community could introduce improved educational and asset exchange opportunities for holders of rights to IP and enable the NIHR to deliver even greater patient benefit from its funding.

3. Undervaluation of Data and Database Rights

The most common form of IP produced by researchers using NIHR funding is data protected by database rights. However, in NIHR’s experience, researchers frequently fail to recognise the intrinsic value in data, or to recognise that databases are an IP asset that should be

managed in an appropriate way depending on whether they are being used for academic or commercial purposes. Moreover, in situations where commercial organisations wish to use the data in a database, it is difficult for research organisations to adequately quantify the value of data. This often delays, and sometimes completely prevents, use of NIHR funded IP in a promising pathway to generate patient benefit. No additional legislative protection is required, as the protections afforded by copyright, database right and confidentiality rights are sufficient in our opinion but there is a significant need for **improved awareness of database rights and intuitive valuation tools** to expedite exploitation of databases. The IPO can promote this by improved provision of education and developing commonly agreed algorithms and processes for valuing database rights in the context of wider licensing negotiations. It is understood that any such processes would be relatively blunt and would be open to the criticism that they fail to take account of specific, unique circumstances, but the NIHR's sense is that this criticism would be outweighed by the positive benefit that a neutral, widely available standard would bring.

4. Maximising Benefit from 'High Impact/Low Profit' IP

NIHR's experience is that, due to their organisational objectives, technology transfer offices in some research institutions prioritise IP that has the highest commercial potential. This creates a situation where NIHR-funded research with the potential to produce significant patient benefit but minimal commercial profit becomes trapped in the system. NIHR wants to improve how high impact/low profit IP is translated in to patient benefit by enabling greater visibility of IP assets that are available to potential exploitation partners which may be other NHS trust, other universities, charities or not-for-profit companies. Often, bundles of low profit IP can have a bigger impact than individual pieces of 'high profit' IP. Therefore, we recommend that the IPO considers **mechanisms to improve the visibility and transfer of IP (including high impact/low profit IP) to interested parties**. In addition to delivering patient benefit, low profit IP also builds capabilities within organisations that lead to future growth. Therefore, there is benefit to all parties and wider society in IP assets being transferred to appropriate partners as efficiently and effectively as possible.

One solution could be a database where potential partners could search for IP that they could use. NIHR also believes that other IT and social media tools being developed may unlock a significant additional amount of underutilised IP. The IP Trading Platforms concept discussed in the consultation document will not directly meet this need, as financially driven platforms will still fail to connect high impact/low profit IP with groups which can use it to produce significant patient benefit. Voluntary IP registers, as discussed in the consultation document, are one way of promoting dissemination of IP but care needs to be taken to ensure that they are user-friendly to promote their use, rather than solely being data repositories without users extracting information. Royalty-free patents may also be a constructive way to promote dissemination of IP with the potential for significant patient benefit.

NIHR recognises that stakeholders will have valid concerns about how such systems would operate and whether there would be costs involved that would not immediately produce identifiable return on investment. This may be an example where governmental body cooperation (e.g. IPO and NIHR) may be appropriate to overcome a failure in the current UK health innovation system. An improved system will deliver benefits for researchers, entrepreneurs, commercial organisations and the wider UK population. Therefore, the NIHR would welcome further discussion on appropriate mechanisms that will promote movement of 'commercially sub-optimal' IP through the innovation process to a point where patient benefit is produced.

5. Educating the Research and Commercialisation Community

In NIHR's experience, universities and NHS Trusts tend to understand IP as only referring to patents, with the value and importance of other forms of IP being underestimated. There is a need to promote an understanding across the IP landscape that IP tools and processes need to be used by innovators at all stages of research and exploitation. Therefore the NIHR suggests that the IPO develops improved **training mechanisms about the wide range of IP tools and processes that are available to researchers and entrepreneurs**. The NIHR IP Unit provides some training to potential applicants, but we would welcome working with the IPO to improve training that is available to all relevant parties to ensure that there is improved awareness of IP in the research and commercialisation community. We recognise that different individuals and roles need different levels of IP literacy. Therefore, there needs to be a range of training available ranging from providing basic awareness at one end of the spectrum and at the other providing on-going professional development for expert users. Emphasising the need to use IP strategies to deliver benefits to society beyond commercial use would be an important way that IPO could demonstrate the wider relevance of IP to the UK.

6. Improving the Speed of Collaboration Set-Up and IP Licensing

The NIHR has recently completed a Push the Pace initiative that aimed to reduce the time taken within the NIHR system for research to produce changes to patient care pathways and patient experience. NIHR would welcome any support that the IPO can provide for **reducing the effect of the IPO's processes on the timeline between research and impact**. A detailed review of business-to-business licensing negotiations and valuation methods may provide ways of reducing common delays that the NIHR experiences when funding research and approving use of the IP that it has funded. The Lambert template agreements between universities and business have provided a useful resource, although users need to be aware that they may need to be modified for a specific collaboration. Therefore, we suggest producing a 'toolkit' that allows B2B licences to be constructed and agreed quickly rather than producing a one-size-fits-all template. Consideration should be given to whether IT technology can be used to produce an initial draft that takes project specific factors in to account before it is submitted for expert legal review.

7. Knowledge Exchange

In NIHR's experience, the importance of capturing know how and transferring to partners who will exploit IP assets is rarely recognised academia or healthcare industries. Particularly for non-commercial health research, transfer of know-how and knowledge can be the most important way of changing clinical practice in an evidence-based way that delivers maximum patient benefit. Therefore, we propose that the IPO works with other parts of the innovation system (e.g. the Knowledge Transfer Network, funders such as NIHR, research institutions and industrial bodies) to **identify creative ways that important commercially profitable and socially valuable know-how can be effectively transferred to deliver maximum impact**. This may take the form of more widely available funding for flexible secondments between different parts of the innovation landscape.

8. Cost of patenting to SMEs

The life sciences industry has a significant SME component which NIHR looks to support across the broad application of funding activities. Many of the smallest companies find the financial burden of filing IP overwhelming, especially if they are too small to defend the patent; with these companies often relying on 'know-how'. A strong IP position, or lack thereof, is often cited as a barrier to securing follow on funding for this SMEs. The IPO may wish to consider an engagement activity, incorporating the smallest companies, to identify if **flexibility in the costs of defending patents could be made proportional to the size of the company and the effect this may have on patenting**.

9. Summary

This response to the "Call for Views" has restated the NIHR's belief in the importance of Intellectual Property as one type of valuable output of the research that it funds. This reinforces the continuing need for the UK to maintain a strong and effective IP legislative regime. As discussed above, the NIHR is very supportive of the IPO's desire to promote collaborations, commercialisation, and knowledge exchange as these are important steps to produce patient benefit. Where the NIHR would like further debate with the IPO and wider community is how to foster a wider understanding of IP as a tool to produce commercial and non-commercial outcomes that benefit wider society and help build capabilities in industry. There is also a need to improve education and tools that enable effective and efficient collaborations, IP management and transfer of IP assets between organisations.