PraxisAuril response to the NIHR on proposed changes to its policy and guidance for determining revenue sharing arrangements.

A. Background and context

The NIHR has consulted on a revised approach to its Policy and Guidance for Determining Revenue Sharing Arrangements which applies to funding recipients that pursue commercialisation opportunities arising from NIHR funded IP and data. The stated aims of the consultation are to:

1) Raise awareness of the new policy and promote transparency among key stakeholders
2) Obtain feedback that may be used to understand concerns and areas where additional guidance is required.

We note that this consultation was introduced at a time when TTOs have been under scrutiny for some time through the Independent Review of University Spinouts[1] (March – November 2023) which aims to transform innovative company creation. Prior to that, some were also involved in the development of the TenU USIT guide[2] (launched June 2023) which proposed a framework for more successful IP exploitation. Key points across both these documents relate to asset valuation, revenue sharing, proportional returns for contribution, speed of process and 'founder friendly' process.

Less specific to commercialisation but relevant to administrative 'burden' and smoothness of process, the Tickell Review of Research Bureaucracy[3] (July 2022, awaiting Government response) is also worth mentioning in this context. Together, these factors make the NIHR's intent to improve its process for seeking consent welcome but may also have influenced how the proposed revisions were received.

Finally, we would like to note strong similarities with the issues raised during a consultation conducted by the Association of Medical Research Charities (AMRC) in 2018. This concerned broader revision to IP guidance for AMRC member charities, but many of the concerns raised about the approach are applicable to the NIHR's current consultation. PrA's response to the AMRC at that time can be read here https://www.praxisauril.org.uk/resource/praxisauril-responds-amrc-consultation-revised-ip-guidance

B. Summary

Our overarching recommendation based on PraxisAuril (PrA) member feedback is that the NIHR does not proceed with this policy but instead takes a genuinely consultative approach to designing a revenue sharing policy that is fit for purpose by taking into account the views and needs of contractors working in TTOs and with professional service partners.

Recommendations

1) Meet with TTO staff and other key dependent roles, to understand specific and sometimes technical concerns in the proposed guidance.

[1] https://www.gov.uk/government/publications/independent-review-of-university-spin-out-companies
[2] https://ten-u.org/news/the-usit-guide
[3] https://www.gov.uk/government/publications/review-of-research-bureaucracy

2) Separate consent processes where consent relates to infrastructure and where it relates to programme grants.

3) Consult with BRC organisations, where there is longstanding experience of NIHR process and approach, separately to smaller and less frequent NIRH contractors. Different approaches to seeking consent may be appropriate. For example, could there be a 'trusted contractor' approach so that universities that submit a large volume of consent forms have standard information pre-captured (for example) rather than starting from scratch each time.

4) Understand end-to-end process and where seeking consent fits in by spending time in a Tech Transfer Office.

5) The Wellcome Trust consent model was referred to as a positive example to follow[4].

We look forward to working with the NIHR to produce a more workable policy that enables our members to support the NIHR in its mission to improve the health and wealth of the nation through research.

C. Addressing the aims of the consultation

1) Raise awareness of the new policy and promote transparency among key stakeholders

The proposed guidance is of direct relevance to PraxisAuril members, who work in research and/or enterprise and technology transfer offices, and so we welcomed our inclusion in the stakeholder consultation phase. Too often we see decisions about commercialisation policy and practice made without the informed opinion of expert practitioners.

PraxisAuril was contacted as one of a number of relevant stakeholder 'umbrella' organisations able to speak for and engage with specific stakeholder groups and to act as a single point of coordination and feedback. We note that PrA was contacted in mid-November 2023 and that feedback was requested by 15th December. We responded promptly to the NIHR's initial email but note that the timeline was short at a very busy time of year.

PrA's Head of Policy & Governance, Tamsin Mann, engaged with the NIHR consultant, James Hudson, to understand more of the background to the policy revisions and provide an initial response to the revised guidance. A virtual meeting was then held for PrA members to discuss the document and to determine feedback to the NIHR. That meeting was not recorded so that attendees could speak freely. Around 25 people attended from a good range of universities, including some of the most research intensive and/or health specialists: Oxford, UCL, Imperial, Manchester, Bristol, Institute of Cancer Research and Southampton.

PrA was subsequently made aware of other stakeholder group discussions, notably the BRC directors, which has helped to put our discussion in context. That dialogue has reinforced the messages that we wish the NIHR to consider in order to agree conditions for successful IP-based research translation in the long-term.

[4] https://wellcome.org/grant-funding/guidance/intellectual-property-guidance/consent-revenue-equity-sharing-policy

2) Obtain feedback that may be used to understand concerns and areas where additional guidance is required.

The following points are presented as a summary of points raised in discussion with PrA members and reported by Head of Policy & Governance[5].

a) Clarity of terms and examples

Some of the terminology and language in the draft guidance was unclear. For example, who is the 'Authority' referenced in a number of definitions and what is 'sufficient information' in clause 2.2.2 (i)?

In PrA's initial feedback we said that better worked examples would help to understand the calculations presented in the Annex. This point was also raised in the meeting.

b) Timescales

The Spinout Review proposes timescales for commercialisation activity of months rather than years. However attainable that aspiration may or may not be, TTOs need clarity of timescales when seeking consent to proceed and confidence that deadlines will be met. If the intention is to provide feedback within 30 days for the light-touch swim lane, that should be clearly stated in the policy. What recourse do TTOs have if that timeframe is not met?

There was some concern relating to process after submission of the consent form i.e. how quickly would a TTO know whether their case had moved into the case-by-case lane? And what would the impact be on timescales in that scenario?

c) Transparency of NIHR process and expectations

These points related to both a) and b) above but also to:

- retrospective consent if a project moves between 'swim lanes' but also if a commercialisation project delivers larger returns than anticipated and/or a project pursues a different route to market to that originally intended.
- the decision making process, post disclosure, still feels opaque.
- Where NIHR-funded infrastructure is factored into a contribution, there was concen

d) Proportionality

Generally, it was felt that the proposed approach presented excessive reach through by the NIHR. A specific point was made where the NIHR is a minor funder, in a multi-funded project or area of work. In these cases, should there be a threshold below which the full consent process is not required?

[5] Any lack of clarity or inaccuracies in reporting are the fault of the author. The NIHR is encouraged to meet directly with PrA members to fully understand issues and reach resolution.

e) Apparent lack of understanding or appreciation of the TTO/Research Office (and potentially wider) process

Identifying, protecting and commercialising IP requires experienced and skilled staff and universities have invested in this resource over a long time. TTO staff have a 'whole picture' point of view of any single research outcome and understand how to treat projects with multiple funders, how to identify background IP, and how to present options for exploitation to researchers, funders and potential investors. Having concern for investment further down the line is an important consideration even at an early stage of commercialisation discussions. Appreciation of this perspective was felt to be absent in the NIHR's proposed approached. Specifically:

- There was lack of trust in TTOs to do a 'good' deal and seek the best possible outcome for the funded research that underpins the commercialisation opportunity.
- The proposal would add time to overall deal process where investors, notably from the USA, won't wait for lengthy consent processes to work through.
- Freedom to operate (FTO) searches are mentioned in the policy but were singled out as not the responsibility of the TTO. This provided of an example of not understanding the parameters of control for the TTO.

f) Impact on TTO sustainability

Comments here related to cost recovery by the TTO, particularly where an office was required to be self-sustaining rather than being funded from HEIF. Where commercial routes are pursued by a university, it is at their cost and risk. A capped and mandate approach to the technology transfer fee proposed by NIHR was not supported by PraxisAuril members.

D. Contact and next steps

For discussion on any of the points raised above, please contact Tamsin Mann, Head of Policy & Governance, PraxisAuril in the first instance Tamsin.mann@praxisauil.org.uk.

PraxisAuril would be happy to convene a further meeting for NIHR representatives with its members.

15 December 2023