

FAQs on intellectual property

Q. Why is the NIHR interested in Intellectual Property?

A. The NIHR's mission is to improve the health and wealth of the country through funding excellent research. Like all research funding organisations, the NIHR needs to be confident that the outcomes of that research will make it through to delivering benefit. The NIHR recognises the key role of Intellectual Property (IP) assets in driving innovation, and the importance of a range of associated activities such as fostering a culture of invention through to collaborating with industry.

Q. Why change the standard contract?

A. The new standard research contract has been adapted to ensure that the NIHR, NHS and broader public sector have the best chance of realising benefits and achieving impact. The **amendments** are intended to ensure that Intellectual Property generated from NIHR funding is secured within an appropriate legal, contractual environment to facilitate benefit realisation for patients. The new contract maintains the **existing** position on ownership of foreground IP and the ability of the Authority (the Department of Health) to ensure a return is secured where appropriate. The amendments are also there to ensure as far as is reasonably possible, that the IP on which a Contractor wishes to base its NIHR funded research is also free for use by such research.

Q. Has the NIHR changed its policy around the ownership of Intellectual Property?

A. Although some of the clauses in the research contract concerning Intellectual Property have been amended, the position on ownership of Intellectual Property remains the same as it was in previous versions of the contract. The Department of Health still expects that where possible and appropriate, the Contractor owns IP arising from research. However, this is not always the case in research with collaborators.

Q. What if my research involves a collaborator, who should own intellectual property?

A. The NIHR recognises the complex nature of research and the many partners needed for success. The standard research contract now contains provisions that recognise collaborations and the need to accommodate flexible IP ownership.

Q. Why does the NIHR want to see a copy of collaboration agreements?

A. The NIHR is interested in ensuring that the research it supports is undertaken in an environment that promotes maximum dissemination and if appropriate, exploitation of any results. It is essential therefore, that the NIHR is aware of who is involved in the research and how that relationship is governed.

Q. Doesn't that mean NIHR can block collaborations?

A. No. The standard research contract places obligations on organisations to disclose arrangements made with third parties, and to ensure that no agreements are entered into which prevent organisations from complying with the terms of the contract. Whilst the NIHR wishes to be able to review such agreements and advise on their compatibility with the contract, the responsibility is ultimately with the recipient organisation.

Q. Why has the NIHR introduced provisions in the contract concerning Background IP?

A. The aim of NIHR is to derive patient benefit from funded research, and see this benefit captured in the NHS and wider healthcare communities. Background IP can be crucial in unlocking Foreground IP. The amended provisions on Background IP are therefore intended to supply the Department of Health (the Authority) with confidence that research outcomes funded by NIHR will be eventually be translated for patient benefit.

Q. Why would NIHR seek assignment of Contractor Background IP?

A. This right is one we expect to be rarely exercised, and under limited circumstances. Inclusion of these provisions, which would enable the Department of Health to have a Contractor's Background IP assigned to it, are necessary and consistent with the desire to ensure that IP arising from NIHR funded research can be exploited or disseminated without any hindrance. Any assignment would be subject to agreement with the Contractor and only as a result of the Contractor electing to abandon Intellectual Property that the Department of Health considers relevant or critical for realising benefit from the research being supported. Any assignment would also take into account pre-existing rights to Background IP.

Q. Does the contract give similar rights over Third Party IP?

A. No. The rights to take assignment of Contractor Background IP extend only to the contracting organisation.

Q. Why does the contract allow the NIHR to take ownership of Foreground IP?

A. As with the provisions concerning Background IP, this right is one we expect to be rarely exercised. The NIHR seeks to ensure that arising Foreground IP is exploited where possible and appropriate to achieve public and patient benefit.

Therefore there are two conditions for possible transfer of ownership to the Department. First, if the Contractor elects **not** to protect the Foreground IP, **then** the Department reserves the right (but not the obligation) to take ownership, but this would be a very unlikely occurrence. Second, if reasonable steps are not being taken to exploit or manage Foreground IP then, subject to any third party rights the same right for the Department applies.

Q. What if new collaborators or IP assets are brought into the Research after signature.

A. NIHR understands that new *ad hoc* interactions will occur during the lifetime of the Research and that not all of these are foreseen at the outset. Therefore the contract is written such that we expect the Contractor to warrant it has the necessary rights and powers to conduct the research and comply with the contract **at the point of signature**.

Q. What does NIHR mean by 'benefit realisation'?

A. The NIHR is interested in ensuring the benefits of funded research are captured by the effective and timely translation into usage of the research outcomes. Typically, these benefits will be in the form of improved patient outcome or experience, and sometimes there will be an associated cost saving within the NHS setting. Revenues are currently an uncommon outcome of research funded by the NIHR, and revenue generation is not the overriding objective behind our improving the intellectual property position within contracts.

The NIHR also believes that in many circumstances benefit realisation and effective translation is not only achieved by the publication of the final report – although this is recognised as important. The NIHR also believes that in each case the Contractor should consider carefully the mechanisms available to them: to develop and follow the plans initially set out in the application form and revised during the project lifetime; and to drive widespread dissemination and adoption of outcomes.

Q. What does the NIHR expect from the institutions to which it has provided funds?

A. The NIHR recognises that those institutions that it funds share its vision and goal of maximising the benefit of the research they undertake. For that reason, the NIHR expects both the NHS and Universities to have appropriate procedures and policies in place to protect and manage arising intellectual property assets as well as the assets they introduce to the research that NIHR funds. Moreover, it expects that these arrangements should not prevent realisation of benefit through exploitation or dissemination of these assets by the most appropriate party.

Q. How do the new provisions on Intellectual Property apply in the case of Biomedical Research Centres, Units and other infrastructure, which involve relationships that are both complex and extensive?

A. The NIHR acknowledges that in the case of infrastructure funding, such as NIHR BRCs and BRUs, and some other awards, complex interactions with a partner university are the norm. This therefore often results in arising IP being owned by either the Contractor or the partner university,

or subject to further collaboration agreements with a third party collaborator not within the partnership. The Department of Health is likely to accept Contractors' proposals for management of IP, provided that clear and auditable relationships exist between the NHS and university partners, with regard to realising the benefits of Intellectual Property.

Q. Why has the NIHR introduced a consent right for exploitation?

A. Consent to exploit provides a mechanism for all parties to be made aware of exploitation, to input to the process and to agree what return (if any) is being shared. This is a commonly used mechanism by major research funders in the UK, and introduction of this provision by the Department of Health provides parity with partner funders.

Q. What return is the Department of Health seeking from the exploitation of Intellectual Property supported by its funding?

A. It is not the overriding intention of the Department to seek a direct financial return from exploitation of Intellectual Property generated through research. Clearly, revenue sharing is one possible way to achieve benefit but it is not the only way: we are seeking to be as flexible as possible on the issue of return. Where consent is sought by the Contractor for exploitation of IP, the Contractor may be required to sign a commercialisation contract. The commercialisation contract (rather than the research contract) provides options for sharing income generated by exploitation, and the exact terms will be subject to negotiation. Where a simple revenue or equity sharing arrangements is not appropriate, return will be negotiated on a case-by-case basis. In deciding whether to require a commercialisation agreement, the Department of Health will take into consideration the relative contribution of the Department, the Contractor, and other third parties to the Foreground IP.

January 2013