NIHR Newcastle Biomedical Research Centre 2017-2022

Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University

Intellectual Property (IP) Policy

1. Introduction

The Newcastle upon Tyne Hospitals NHS Foundation Trust (‘the Trust’) has formally entered into a contract with the Secretary of State for Health for the new NIHR Newcastle Biomedical Research Centre (BRC) over the period 1st April 2017- 31st March 2022 (“BRC Contract”) This contract is subject to NIHR review and approval in year two. The partnership between Newcastle University (‘the University’) and the Trust is critical to the effective fulfilment of the BRC contract. The Trust and the University have a history of working together and have well-established mechanisms for doing so, including those described in the current Memorandum of Understanding between the two organisations. However, as the legal obligations surrounding the management and exploitation of IP are significantly more stringent than for previous NIHR Newcastle BRC awards, this Policy outlines the measures that both the Trust and the University have mutually agreed will be put in place to ensure that BRC IP is managed in line with these contractual obligations. One such obligation is the introduction of this BRC IP Policy.

The Trust and University both have their current respective IP policies – the Trust “Intellectual Property (IP), Revenue Sharing and Equity Policy” dated January 2017 and the University “Staff Intellectual Property Policy” dated July 2013. The two policies have previously been aligned to ensure that employees of both institutions receive similar treatment with respect to IP matters. These two policies shall continue to guide the treatment of IP by both organisations with the exception of BRC funded work where the contractual obligations of BRC agreement require additional or alternative IP measures to be put in place. The present BRC IP Policy describes the manner in which IP associated with BRC funding from April 2017 onwards is to be treated.

2. Policy Scope

This policy applies to all Trust and University staff who are supporting, working on or wish to work on activities directly funded by the BRC. Where only part of a member of staff’s time is dedicated to BRC-related work, this Policy only applies to those BRC-funded elements.

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3. Aim of Policy

The aim of this Policy is to ensure that IP associated with and arising from NIHR Newcastle BRC directly funded activities is managed in accordance with the requirements of the BRC Contract in which clause 16.1 states “The Contractor (i.e. Trust) will agree and maintain with the Partner (i.e. University) an Intellectual Property policy for the NIHR BRC (“Contractor IP Policy”) covering aspects of the management of Foreground IP including the identification, protection, prosecution, maintenance, dissemination and exploitation of IP rights”.

This Policy is not intended to re-iterate IP principles that have been established in the respective existing Trust and University IP Policies. Rather, it defines those IP principles where there may be some differences between current Trust and University practices and those agreed in the BRC Contract. An important aspect of the BRC Contract is that it requires the implementation of a robust system for the identification, management and monitoring of IP associated with BRC awards (i.e. as summarised in this policy).

4. General Principles

4.1. Existing IP Policies
There are no changes to the current Trust or University IP Policies and they continue to apply to all non-BRC funded activities. However, there is an expectation that references will be made in each of these Policies to this BRC IP Policy when they are next updated.

4.2. Precedence
In the event of any discrepancy between the guiding principles of either the Trust or the University IP policies and the BRC IP Policy in relation to BRC-funded work, the BRC IP Policy shall prevail. It should be a condition of a BRC award that researchers are provided with a copy of the Newcastle BRC IP Policy and confirm in writing that they accept its principles. In particular, on BRC IP matters where the approval of NIHR is required, researchers will be expected to agree to whatever arrangements may be finalised between the Trust and University with NIHR – this could impact upon the revenue or equity shares attributable to inventors and/or institutions where BRC funding is involved.

4.3. IP Ownership and Access

The BRC Contract requires that Foreground IP and data from BRC-funded work should EITHER be assigned to the Trust OR where Foreground IP vests in University it shall be managed in accordance with the requirements of the BRC Contract (and the University accepts the authority of NIHR to enforce the Contract against them). The decision of ownership of Foreground IP is best determined on a case-by-case

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basis depending on, for example, the ownership of IP leveraged during the study and the technology readiness level. The default position is that Foreground IP is assigned to the Trust unless agreed otherwise at a suitable joint Trust-University decision-making body, in the first instance the ‘Opportunities Meeting’. In the event of any dispute over IP ownership, the decision will be escalated to the Joint Business Executive (JBE).

In accordance with the BRC Contract NIHR are automatically granted a licence to use non-confidential Foreground IP from BRC studies for non-commercial purposes. In addition, NIHR will be offered the option to take assignment of any BRC-related Background or Foreground IP that the Trust or University intend to allow to lapse.

The BRC Contract also requires any third party collaborators allow fair and reasonable access to both their Background and Foreground IP. Due diligence will be carried out to ensure that third parties are willing to accept these requirements and alternative collaborators will be sought if third party consent is considered a barrier to the execution or exploitation of BRC-funded studies.

4.4. IP Management Systems

The BRC Contract requires that suitable and robust procedures are put in place to manage and monitor the Background and Foreground IP associated with BRC-funded studies. These procedures will cover the entire period from conception of the work through to completion and exploitation. Figure 1 provides a flowchart summarising the manner in which IP associated with the BRC will be managed. This management system will include:

4.4.1. Personnel

A Trust or University Business Development Manager (BDM) will be allocated to advise on IP issues for each application for BRC funding.

The dedicated BDM will also be sent all applications before the panel meets to consider them to ensure that all IP issues have been appropriately dealt with.

4.4.2. Documentation

The application form for BRC funding shall include an IP section – this section is to be completed in consultation with the allocated BDM and will refer to:

- Identification and documentation of Background IP proposed for use in the study
- Identification of anticipated Foreground IP and data arising from the study
• Opportunities for, and barriers to, exploitation and dissemination of Foreground IP

BRC-funded projects will be reviewed annually and at the completion of the work, a final report documenting the IP generated during the work is required. This report should be prepared by the recipient of the award (PI) in consultation with a BDM. It will be a condition of the original award that this report is submitted within 28 days of the end of the study. This report will refer to:

• Identification and documentation of Foreground IP and data
• Identification of whether any Foreground IP has potential for commercial exploitation
• Identification of means by which Foreground IP could be disseminated and/or exploited to maximise patient benefit

4.5. Commercial Exploitation

For those studies where the parties involved identify that Foreground IP that has the potential for commercial exploitation, the BDM will prepare and submit papers for consideration by appropriate Trust and/or University bodies that make decisions on IP Protection and commercialisation matters (in the first instance by joint ‘Opportunities Meeting’, followed by Executive level committees as appropriate). All decisions will be made in accordance with established Trust and University policies and in recognition of NIHR expressed wishes that wherever possible arising IP should be protected and exploited to generate revenue or capital.

4.5.1 Both the Trust and University have well-established policies and procedures in place to ensure that commercial rewards are shared on a basis which both incentivises inventorship and bestows benefit institutionally. Further, both organisations have internal policies which ensure that financial returns are re-invested in innovation support and patient benefit (in the case of the Trust) and in medical research (in the case of the University)

4.6. Interaction with NIHR

NIHR engagement and approval will be required for the proposed actions concerning the exploitation of BRC-related Foreground IP, including:

• NIHR to be informed of any proposal to make commercial use of or exploit Foreground IP/data arising from BRC studies
• No such commercial exploitation through either the Trust or the University will commence until NIHR approval has been granted
• NIHR are also informed of any decision not to exploit or protect Foreground IP. In accordance with the BRC Contract, NIHR require a minimum 6 months’ notice of intention not to protect registrable Foreground IP. Full co-operation will be given by the Trust and University to NIHR in these discussions and any arising outcomes.

• Approval will be sought from NIHR for the identity and proposed commercial terms with any company or other provider with whom it is intended to collaborate in the commercial exploitation of Foreground IP arising from BRC studies. Due consideration will be given to NIHR’s viewpoint in any commercial negotiations and will recognise that it is a condition of the BRC Contract that any proposed third party collaborator allows access to both their Background and Foreground IP on fair and reasonable terms.

In the event that NIHR do not provide the requested guidance within 30 days, the Trust and University reserve the right to proceed with the actions they consider appropriate in accordance with their current IP Policies and the principles of the BRC Contract.

Interaction with NIHR will be co-ordinated through the BRC management team. A BDM (chosen on a case-by-case basis relevant to that study) will manage the actual dialogue with NIHR.

4.7. IP Tracking System

Systems will be put in place by which IP arising from BRC-funded activities can be tracked as/when they become embedded in further studies from other funding streams. This will enable due recognition and return to come to NIHR and Newcastle BRC for their contribution to the overall IP of such further studies. The input to the tracking system will be provided through the final reports referenced under 4.4.2 documenting IP generation during BRC studies. A BDM will review the IP position and make appropriate recommendations as and when a decision to exploit a particular piece of IP is considered to have used BRC-derived information as part of the Background IP.