

**NIHR RESEARCH**

**INFRASTRUCTURE AND PROGRAMME AWARDS**

**CONSENT APPLICATION FORM FOR IP EXPLOITATION (v5) AND  
DETERMINING REVENUE SHARING ROUTE**

**Guidelines for completing this form:**

- Please complete this form as fully as possible
- State 'N/A' where questions do not apply
- Attach latest versions of all relevant agreements
- Google Documents & Microsoft Word users can mark check-boxes by left-clicking on them, highlighting them and then using the highlight tool to colour over the box
- For guidance and advice on completing this form, please contact the NIHR IP Unit, as detailed on your NIHR contract, via IP.Unit@nihr.ac.uk
- Send the completed form to your relevant Programme Manager and to the IP.Unit@nihr.ac.uk
- The NIHR IP Unit will then contact you to:
  - help process the consent request
  - obtain any additional information or documentation required
  - determine the revenue sharing arrangements in accordance with the NIHR revenue sharing policy in terms of whether the arrangements should be determined by the formula or on a case-by-case basis.

**NOTE: *Revenue sharing arrangements deemed to require a case-by-case approach may be subject to additional information requirements not set out here.***

**CONFIDENTIAL**

**Confidentiality:**

- The National Institute of Health Research (“NIHR”), in receiving any **Confidential Information** (see end of Form) about exploitation activities pursuant to this Consent Application Form, shall keep such information confidential

<b>CONTACT DETAILS</b> (the person submitting this form)			
Contact name:			
Address:			
Tel:		Email:	
Date:			

<b>NIHR RESEARCH PROGRAMME AND/OR INFRASTRUCTURE AWARD(S)</b> (copy table and add further details if more than one NIHR award applies)	
Investigator(s):	
Institution:	
Title of award(s) (e.g. i4i, EME, BRC or other):	
NIHR ref no('s) and Institution ref no ('s): (if any)	

<b>THE PROBLEM(S), SOLUTION(S) &amp; BENEFIT(S)</b>	
Describe how the proposed Commercial Use will meet the NIHR’s primary objectives of Patient Benefit <sup>1</sup>	<i>(Describe the expected health, patient and/or cost benefits from the exploitation)</i>

<sup>1</sup> as defined in NIHR funding terms

**CONFIDENTIAL**

<p>Is the NHS a potential customer of the proposed solution</p> <p>Is there a plan to provide discounted or preferential access to the NHS</p> <p>What is the timeline for the NHS to deploy the proposed solution</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> immediately</p> <p><input type="checkbox"/> 1-3 years</p> <p><input type="checkbox"/> more than 3 years</p> <p><input type="checkbox"/> unknown</p>
<p>Noting that, the Authority encourages any requests to commercialise NIHR-funded IP to consider the global health system, in particular, seek to increase access to medicines and health and care-related technologies at affordable prices for LMICs,</p> <p>Does the proposed solution have scope to provide health and/or social care benefits in lower and middle income countries (LMICs)</p>	<p><input type="checkbox"/> Yes (describe)</p> <p><input type="checkbox"/> No</p>

**CONFIDENTIAL**

<p>Is there a plan to provide discounted or preferential access in LMIC markets</p> <p>Does the agreement(s) related to the commercial use incorporate provisions that underpin the Authority's position on LMIC healthcare</p>	<p><input type="checkbox"/> Yes (describe)</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (describe)</p> <p><input type="checkbox"/> No</p>
<p>Does the proposed solution relate to any current Public Health Emergency as defined by the NIHR research contract?</p>	<p><input type="checkbox"/> Yes (describe)</p> <p><input type="checkbox"/> No</p>
<p>Does the proposed solution relate to another transaction to which the NIHR has previously given consent</p>	<p><input type="checkbox"/> Yes (describe)</p> <p><input type="checkbox"/> No</p>

CONFIDENTIAL

<p><b>WHAT FOREGROUND IP, ARISING KNOW-HOW AND/OR RESEARCH DATA (“ASSETS)” IS BEING LICENSED OR ASSIGNED?</b></p>	
<p><b>NIHR funded FOREGROUND IP (FIP)</b> <b>(e.g. registered IP: the patent, trade mark, design right etc.)</b></p>	<p><i>(Please give a short description of the patent/trade mark/design right, its title, priority date and number and its status: filed, published, PCT, national filings stage, granted in X, Y or Z countries etc.)</i></p>
<p><b>NIHR funded ARISING KNOW HOW (AKH)</b></p>	<p><i>(Please outline the Arising Know-How)</i></p>
<p><b>NIHR funded RESEARCH DATA (RD)</b></p>	<p><i>(Please describe the Research Data and its value to the licensee: e.g. to obtain regulatory approval and/or CE marking in X, Y or Z countries or continents etc.)</i></p>
<p><b>Indicate the type(s) of IP being licensed:</b> <i>(Mark as many as apply)</i></p>	<p> <input type="checkbox"/> Patent           <input type="checkbox"/> Materials           <input type="checkbox"/> Copyright           <input type="checkbox"/> other  <input type="checkbox"/> Know-how           <input type="checkbox"/> Database           <input type="checkbox"/> Design right <i>(Specify)</i> </p>
<p><b>Non-NIHR funded IP</b></p> <p>Is there any IP or data that was not funded or contributed to by the NIHR included in the proposed licence or assignment</p>	<p> <input type="checkbox"/> Yes (describe)  <input type="checkbox"/> No           </p>
<p><b>Value of NIHR Programme Funding</b> used to develop the licensed or assigned IP:</p>	<p>£</p>
<p><b>Value of NIHR Infrastructure Funding</b> used to develop the licensed or assigned IP (include direct costs and</p>	<p>£</p>

**CONFIDENTIAL**

<p>appropriate calculation of indirect costs) - see guidance at the bottom of the form.</p> <p>Non-NIHR funding used to develop the licensed or assigned IP:</p>	<p>List the sources and value of each funding source in relation to each asset covered by the licence or assignment:</p>
--	--

<p>Are there any revenue share agreements with other funders/parties in relation to the transaction?</p>	<p><input type="checkbox"/> Yes      If yes, please outline/attach these terms.</p> <p><input type="checkbox"/> No</p>
--	--

**THE BUSINESS VEHICLE**

<p>Describe why the chosen business vehicle(s)/licensee(s) or assignee(s) is/are the most appropriate (e.g. established company/ies vs. spinouts) to exploit the</p>	<p>E.g: company experience, manufacturing expertise in this particular space and/or established route to market and/or customers (NHS trusts/private hospitals).</p> <p>[PROVIDE ALL RELEVANT DOCUMENTATION, e.g., termsheet, licences, pitch deck, business plan, shareholder arrangements as applicable to the transaction in question]</p>
--	---

**CONFIDENTIAL**

<p>licensed FIP,AKH and/or RD</p> <p>Did the chosen business vehicle provide any background IP or other contribution to the research that led to the asset being commercialised</p>	<p><input type="checkbox"/> Yes (describe)</p> <p><input type="checkbox"/> No</p>	
<p>Name and address of the proposed University spinout* and/or licensee(s)( company registration number)</p>		
<p>Type of transaction for which consent is being sought: <i>(Mark as many as apply)</i></p>	<p><input type="checkbox"/> Exclusive                      <input type="checkbox"/> Option                      <input type="checkbox"/> other <i>(Give details)</i></p> <p><input type="checkbox"/> Non-exclusive                      <input type="checkbox"/> Start-up</p> <p><input type="checkbox"/> Licence                      <input type="checkbox"/> Non-academic MTA</p> <p><input type="checkbox"/> Assignment                      <input type="checkbox"/> Collaboration</p>	
<p>Transaction Status:</p>	<p><input type="checkbox"/> In negotiation</p> <p><input type="checkbox"/> Agreement(s) finalised</p>	<p>Estimated completion date: <i>(to nearest month if possible)</i></p>

**CONFIDENTIAL**

Transaction documentation check list	<p><b>Licence/assignment</b></p> <p><input type="checkbox"/> Available    <input type="checkbox"/> Not Available    <input type="checkbox"/> Provided</p> <p><b>Spin-out</b></p> <p><i>Business plan</i></p> <p><input type="checkbox"/> Available    <input type="checkbox"/> Not Available    <input type="checkbox"/> Provided</p> <p><i>Pitch deck</i></p> <p><input type="checkbox"/> Available    <input type="checkbox"/> Not Available    <input type="checkbox"/> Provided</p> <p><i>Shareholder agreement</i></p> <p><input type="checkbox"/> Available    <input type="checkbox"/> Not Available    <input type="checkbox"/> Provided</p> <p><i>Articles of association</i></p> <p><input type="checkbox"/> Available    <input type="checkbox"/> Not Available    <input type="checkbox"/> Provided</p> <p><i>Cap table</i></p> <p><input type="checkbox"/> Available    <input type="checkbox"/> Not Available    <input type="checkbox"/> Provided</p>	
What direct legal and/or IP costs are anticipated in concluding the transaction:	£	
Have technology transfer experts been consulted and used in concluding the transaction:	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Income/royalty/equity returns expected/received:  Explain on what basis these	<p>£</p> <p><input type="checkbox"/> Negotiated</p> <p><input type="checkbox"/> Standard Terms</p>	



**CONFIDENTIAL**

<p>royalties, and/or revenues, including arising from equity,, have been concluded.</p> <p>What is the earliest date that revenues are anticipated?</p>	<p><input type="checkbox"/> Terms proposed by commercial partner</p>
<p>Annual accounting date:</p>	<p><i>(Specify annual day/month that royalty payments will be accounted for, e.g. 30 September)</i></p>
<p>Outline IP exploitation safeguards:</p>	<p><i>(State what will happen to the IP if the licensee(s) fails to exploit it, e.g. in whole or in part, or in selected markets)</i></p>
<p><b>PUBLICITY</b></p>	
<p>Please specify if there is any anticipated press release related to the Commercial Use</p>	<p><input type="checkbox"/> Yes            If yes, [date] and [channel].</p> <p><input type="checkbox"/> No</p>
<p><b>ADDITIONAL DETAILS</b></p>	
<p>Specify any other relevant information:</p>	

**CONFIDENTIAL**

--	--

**GUIDANCE ON DETERMINING INFRASTRUCTURE FUNDING**

- (A) Total expenditure under the applicable NIHR Infrastructure funding award to date (£):
- (B) Total Direct costs incurred on research under the infrastructure award to date (£):
- (C) Direct costs incurred in developing the asset(s) which this consent request relates to (please refer to Section 3 in the BRC4 contract, and table below):

<b>Direct costs</b>	<b>Contribution (£)</b>
Salary - NHS Research and Research support staff and training (PhDs, MDs, etc..)	
Consumables	
Equipment (<£5000)	
Travel and conferences	
Patient and public involvement	
Sub-Contract costs	
Patent and Legal costs	
Other direct costs	
<b>Total Direct costs</b>	

**Indirect costs**

To be calculated as follows:

$$(A-B) \times (C/B)$$

“**Confidential Information**” should be positively identified as “confidential” and includes but is not limited to any data, results, inventions, intended publications, intended or pending patent applications, designs, plans, agreements, commercial and/or financial information, whether disclosed in writing or orally. However, “Confidential Information” does not include information which is already in the public domain; which is otherwise lawfully know to NIHR at the time of disclosure; is obtained lawfully from a third party or independently developed by NIHR; or which is required to be disclosed in order to comply with a legal requirement.