

CONSULTATION DOCUMENT¹

NIHR Policy and Guidance for Determining Revenue Sharing Arrangements

1 Introduction

The core sections of this policy comprise:

- Scope
- Terms
 - Definitions
 - Process
- Appendix 1: Illustrative/worked examples

1.1 Scope

This policy sets out the approach that the NIHR will apply to determine revenue share for transactions arising from the Commercial Use of Research outputs².

2 Definitions and terms

2.1 Definitions

In this revenue sharing policy higher case terms not included here will take their meaning from the NIHR Funding Agreement. The following terms shall have the following meaning.

Annual Accounting Date	means [preferred date]
Asset	means Foreground IP, Arising Know-how and/or Research Data that is the subject of a Commercial Use;
Case by Case Criteria	means in respect of an Asset that has received, or is entitled to receive, aggregated NIHR Funding above £2m and/or that: <ul style="list-style-type: none"> (i) is connected to a Research Contribution; and (ii) has provided or is the subject of a binding written offer by the Contractor or its agent to provide, auditable Patient Benefit in the form of prioritised, free or discounted products or services to the NHS; and/or (iii) has paid Revenue calculated in line with clause 2.2.2 (iii) the lower of the value of the NIHR Funding or £250K; and/or (iv) is connected to the Commercial Use of another asset where Case by Case criteria apply; and/or (v) relates, directly or indirectly to a Public Health Emergency; and/or

¹ Subject to revision by NIHR

² Applies to all contractors including HEI, NHS Trusts, Charities, Local Authorities and Businesses

	(vi) is the subject of primary Commercial Use in an LMIC; as confirmed in the Conditions;
Commercialisation Agreement	means an agreement to be entered into between the Authority and the Contractor and which addresses the payment of Revenue;
Commercial Partner	means an entity that wishes to enter into an agreement with the Contractor for the Commercial Use of an Asset who may or may not also make a Research Contribution;
Conditions	means any requirements set out in the Consent Letter(s) with which the Contractor must comply in order for Commercial Use to be permitted;
Consent	means the written authorisation issued by the NIHR to a Contractor pursuant to the NIHR Funding Agreement prior to any Commercial Use that shall specify the Conditions if any;
Contractor	means the party named as Contractor to the NIHR Funding Agreement and any other party that is contractually bound [directly or indirectly] to the terms of NIHR Funding Agreement's Consent and revenue sharing provisions;
Default Funder Share	means up to 60% of the Financial Benefit determined according to the relative proportions of NIHR Funding and other applicable auditable research funding (if any) evidenced to the NIHR by the Contractor;
Direct Costs of Exploitation	<p>means, in respect of costs incurred by the Contractor:</p> <ul style="list-style-type: none"> (i) all reasonable patent and legal costs and other expenses that are incurred directly in connection with exploitation of the Asset, including official patent filing, prosecution, maintenance and renewal fees; and (ii) payment of obligations attached to third party intellectual property encumbrances and freedom to operate requirements disclosed to NIHR in Schedule B of the NIHR Funding Agreement and that do not arise from any Foreground Intellectual Property, Arising Know-how and/or Research Data; and <p>excluding:</p> <ul style="list-style-type: none"> (i) any internal costs, salaries or taxes other than TTO Fees; or (ii) any amounts payable to employees, students, contractors or agents that contributed to, generated and/or invented the Asset; or (iii) any research or proof of concept costs;

Project Costs	means, in respect of costs incurred by the Contractor: (i) costs that can be economically identified, including Programme Award(s), and measured in respect of a relevant cost item or object; and (ii) which are incurred as a direct result of undertaking the Research.
Eligible Deductions	means the Direct Costs of Exploitation and the TTO Fee;
Financial Benefit	means all monies and/or consideration received by and/or due to Contractors arising from Commercial Use, and/or from any Commercial Partner including without limitation: (i) fees and royalties; or (ii) arising from equity such as dividends or equity realisations; or (iii) for research in excess of the full economic cost; in consideration of rights granted or assigned under an Asset;
Funder Share	means, subject to any Eligible Deductions, up to 50% of the Financial Benefit as specified in the Conditions and determined according to the relative proportions of NIHR Funding and other applicable auditable research funding (if any) evidenced to the NIHR by the Contractor when seeking Consent for a Commercial Use (see illustrative example at Appendix 1);
Non-Project Costs	means, in respect of costs incurred by the Contractor: (i) costs which cannot be economically identified with a specific cost object or item including without limitation administrative services such as finance, personnel, and IP; and which are incurred indirectly as a result of undertaking research.
Infrastructure Funding	means any funding provided by the NIHR to the Contractor under an infrastructure award (e.g. a Biomedical Research Centre (BRC)) that is used to support the development of an Asset;
LMIC	means any lower and middle income country;
NIHR Funding	means the Programme Funding and the Infrastructure Funding;
NIHR Funding Agreement	means either of the NIHR Research Contract for Programmes and/or the NIHR Infrastructure Funding Contract as applicable;
Permitted Purpose	means the use of Revenue applied by the Contractor and (where applicable) its Partners, Associate Partners and/or Collaborators in proportions for the purposes of health and social care research and conducted in accordance with the NIHR Funding Agreements or such purpose as directed by the Authority in the Conditions;
Programme Award	means the NIHR funding award(s), excluding Infrastructure Funding, used in the development of the Asset;

Research Contribution	means the provision of financial support or in kind benefit for a NIHR Programme Award through the free supply of or discounting of products e.g., therapeutic drugs or vaccines (whether or not licensed), devices, materials, software and/or training to the Contractor made available by a Commercial Partner for use in the Research;
Revenue	means the share of Financial Benefits due to the Authority;
TTO Fee	means in the case of Universities and NHS Trusts 10% of Financial Benefit net of Direct Costs of Exploitation up to a maximum of £100,000 and then 5% thereafter that may be retained by the Contractor solely for the operating costs of their technology transfer office;

2.2 Process

2.2.1 Accounting requirements for NIHR Funding to determine Revenue Sharing Arrangements

- (i) Under the NIHR Funding Agreement, Contractors are required to maintain proper financial records relating to the NIHR Funding Agreement including such evidence as may reasonably be required to show that the Contractor has used the NIHR Funding in accordance with the NIHR Funding Agreement.
- (ii) In the case of Infrastructure Funding, Contractors shall account for any Project Costs and Non-Project Costs relating to the Asset to which Infrastructure Funding has been allocated.
- (iii) Where the Contractor does not or cannot reasonably provide details of the Non-Project Costs allocation of Infrastructure Funding to:
 - a. an Asset developed via a project that received Project Costs, a pro-rata sum shall be determined according to the following calculation: $\text{pro-rata sum} = (\text{value of Project Costs related to Asset} / \text{value of total Project Costs incurred under the applicable Infrastructure Funding award}) \times \text{value of total Non-Project Costs incurred under the applicable Infrastructure Funding award}$; OR
 - b. an Asset developed via a project that has not received Project Costs, but has incurred Non-Project Costs, the Contractor shall apply a reasonable estimate of the contribution made by the Infrastructure Funding according to the ratio of Project Costs and Non-Project Costs incurred by the Contractor and shall set that out for the NIHR's consideration when seeking Consent. [illustrative examples are provided in Appendix 1]

2.2.2 Determining Revenue Sharing Arrangements

- (i) When seeking Consent, Contractors shall provide the NIHR with sufficient information, to enable NIHR to determine whether the Case by Case Criteria apply to the Commercial Use in question.
- (ii) Where the Authority (acting through NIHR) determines that the Case by Case Criteria apply, or where The Authority determines in its sole discretion that the Case by Case Criteria are deemed to apply, the Contractor and the NIHR shall exchange such information as may be reasonably required to negotiate the Revenue in good faith and enter into a Commercialisation Agreement.
- (iii) Where the Commercial Use is not subject to 2.2.2 (ii), the Revenue shall be the Funder Share [illustrative examples are provided in Appendix 1]; unless, either:

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- a. the Contractor has failed to obtain Consent and the Authority (acting through NIHR) has not, or not yet, determined that the Case by Case Criteria apply; or
- b. the Contractor has breached the terms of this Policy including the Conditions;

in which case the Revenue shall be the Default Funder Share with no Eligible Deductions and shall be applied for the Permitted Purpose or as the Authority may in its sole discretion direct including via the Off-set provisions within the NIHR Funding Agreement.

2.3 Payments/disbursements

2.3.1 Unless otherwise agreed in the writing, the Contractor shall allocate the Revenue in accordance with the Permitted Purpose or as otherwise provided in the Conditions.

2.3.2 Unless provided otherwise in the Conditions, Contractors shall:

2.3.2.1 direct the relative proportion of Revenue arising from Infrastructure Funding for use in accordance with the Permitted Purpose to the ongoing support of the applicable infrastructure programme(s); and/or

2.3.2.2 direct the relative proportion of Revenue arising from Global Health ODA funding for use in accordance with the Permitted Purpose to support health and social care research in LMIC's.

2.4 Reporting requirements and auditing rights

Unless otherwise specified in writing, including in the terms of a Commercialisation Agreement entered into between the Authority and the Contractor, the following reporting and auditing conditions shall apply to clause 2.2.2 (iii):

2.4.1 The Contractor shall send a report to the Authority [on each Annual Accounting Date] detailing: the amount of Revenue and the use made of the Revenue by the Contractor and (where applicable) its Partners, Associate Partners and/or Collaborators in compliance with the Conditions.

2.4.2 Within three (3) months following the Annual Accounting Date, the Contractor shall provide the Authority with a statement or statements setting out financial information for the preceding 12 month period ending on such Annual Accounting Date in respect of the Asset, including Financial Benefit, Direct Costs of Exploitation, TTO Fees, Revenue and taxes. All such statements shall include a breakdown of the calculations on which the amounts involved were determined.

2.4.3 The Contractor shall keep accurate records and accounts, and the Authority shall have the right to audit these in accordance with the standard terms of the Commercialisation Agreement which shall apply. The Contractor shall provide and/or procure to provide the Authority with copies of supporting financial documentation on reasonable request.

a. 2.5 Case by Case Reviews

The NIHR shall review the Reports related to Revenues arising under clause 2.2.2 (iii), and may additionally request information at any time, to determine whether the Case by Case Criteria apply, following which the Revenue shall be determined according to clause 2.2.2 (ii) with prior Revenue payments taken into account at the discretion of the Authority.

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b. 2.6 Term

Termination of the NIHR Funding Agreement for whatever reason shall not affect the accrued rights of the Authority under the NIHR Funding Agreement under or in relation to this Policy.

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Appendix 1: illustrative calculations

The following examples are intended to show the calculations required to determine the **NIHR Funding**

Programme Award calculation

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The NIHR awards and provides a grant of £1.5m. There is no Infrastructure Funding provided to the contractor.

The NIHR Funding is £1.5m

Infrastructure Award calculation with Project Costs incurred

A live infrastructure award has drawn down £10m.

A project to develop a new technology undergoing commercialisation has incurred staffing and consumables costs of £100,000 (Project Costs).

Total project costs incurred from the drawn down sum are £8m

The total Non-Project Costs are deemed to be the balance of drawn down funds that cannot be attributed to Project Costs = £10m - £8m = £2m (or $\frac{1}{5}$ of the total drawn down)

Applying this pro-rata to the Project Costs = £100,000 x $\frac{1}{5}$ = £20,000

NIHR contribution is calculated as project specific Project Costs + pro-rata Non-Project Costs = £100,000 + £20,000 = £120,000

Infrastructure Award calculation no Project Costs

A live infrastructure award has drawn down £10m

Total direct costs incurred from the drawn down sum are £8m

A project to develop a new technology undergoing commercialisation has incurred staffing and consumables costs of £0 (Project Costs) as it was funded by a third party grant of £1m.

The ratio of Project Costs and Non-Project Costs incurred by the the Contractor across the board is 80:20.

Applying this ratio to the third party grant indicates that the Non-Project Costs are £200,000

The following examples are intended to show the calculations required to determine the **Funders Share** for a single transaction:

Single IP asset developed solely with NIHR Funding

The Funders Share is 50%

Single IP asset developed with NIHR Funding and third party funding

The value of the NIHR funding (developed according to the examples above) = £1m

The auditable value of the third party funding = £1m

Total funding = £2m

Funders Share calculation: $(\text{NIHR}/\text{Total}) * 50\% = (1/2) * 50\% = 25\%$

The Funders Share is 25%

Multiple IP assets developed

There are 3 IP assets licensed, one of which (asset 1) the NIHR funded.

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Value of NIHR Funding to asset 1 = £1m

Auditable value of third party funding to asset 2 = £1m

Auditable value of third party funding to asset 3 = £1m

Total funding = £3m

Funders Share calculation: $(\text{NIHR}/\text{Total}) * 50\% = (1/3) * 50\% = 16.7\%$

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