# Model Non-Commercial Participant Identification Centre Agreement (mNC-PICA)

# Sponsor to PIC

**This document is intended for use between non-commercial Sponsors and NHS/HSC organisations acting as their Participant Identification Centres (PICs). When entered into between separate legal entities it forms a legally binding contract.**

This document has been endorsed by the national coordinating functions for healthcare research in each of the four UK nations. When used as instructed and without modification to templated elements, the document protects both PIC and Sponsor and should be used without further legal review of the content.

In Scotland or Wales, where a General Practitioner who is a Health Board employee (rather than part of a GP practice engaged by the Health Board as a contractor) refers potential participants to study sponsored by that Health Board, it is not appropriate that the General Practitioner and Health Board enter into the agreement set out in this document. In this instance, the General Practitioner is part of the Health Board. However, many of the principles and considerations in this document may be used as internal guidance and policy in relation to the activities undertaken by the General Practitioner and other Health Board colleagues based at the hospital.

The document is intended to formally agree arrangements between the Sponsor and the PIC. The data processing provisions are consistent with those in both the model Non-Commercial Agreement (mNCA) and the non-commercial Organisation Information Document and have been drafted to form an agreement as required under Article 28(3) of the General Data Protection Regulation (GDPR).

The information set out in the following instruction pages provides a checklist of actions that need to be undertaken in preparing the mNC-PICA for execution by the Parties. Further guidance on the use of PICs is available [here](https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#PIC).

Throughout the template, yellow highlighted text is used to indicate where optional text has been provided, or where additional Study specific text should be entered by the Sponsor. The Sponsor should tailor the template to their Study only by use of these yellow highlighted sections of text (these instruction pages do NOT provide an exhaustive list of these sections). Once the text has been selected, entered, removed or retained (as appropriate) yellow highlights should be removed by the Sponsor prior to sharing with the PIC.

It is the Sponsor’s responsibility to provide the required information for review by the PIC.

### Footers

Complete the information set out in the footer of this Agreement.

### Front Page

Complete all of the yellow highlighted information.

### Recitals

Recitals may be added or removed as appropriate to the Study. The recitals do not form part of the Agreement but are intended to provide context and to support interpretation.

### Definitions

Definitions should not be amended, deleted or added to.

### General

The sub-clauses of Clause 2.2 (in yellow highlight) are to be edited, and may be added to and/or deleted, to provide the PIC with clear instruction as to the activities being contracted to it. This should be completed by the Sponsor prior to providing to the PIC. Any changes to the information provided should be negotiated between the Sponsor and the PIC prior to this Agreement being executed.

The Sponsor should indicate within which UK nation it is established at Clause 2.3 and delete Clause 2.4, or, if the Sponsor is not established in the UK, the Sponsor should delete the highlighted text at Clause 2.3 and retain Clause 2.4.

### Confidentiality and Data Protection

The Data Processing Terms form the core of this Agreement. The definition of a PIC is an NHS/HSC Organisation processing Personal Data on behalf of a research Sponsor for the purpose of identifying and/or inviting potential research participants to take part in healthcare research. Where such a Data Controller/Processor relationship exists, GDPR requires the Controller to manage this relationship via a legally binding agreement that includes the specific terms included within this Agreement.

Data Sharing Terms (Clauses 3.11 to 3.16) form part of this Agreement irrespective of whether it is intended that Personal Data is transferred by the PIC to the Sponsor or an Agent of the Sponsor of either (Personal Data may include pseudonymised data – for further guidance on this point refer to the [ICO Anonymisation Code of Practice](https://ico.org.uk/media/1061/anonymisation-code.pdf)).

The primary purpose of the IPR clauses are to ensure that the PIC discloses to the Sponsor in the unlikely event of IP or Know-How arising from the participation of the PIC in the Study, thereby allowing the Sponsor to fulfil its own obligations.

### Sign Off

It is a requirement in Scotland, and best practice throughout the UK, that the signature pages of the Agreement are part of the body of the Agreement. Please therefore ensure that the last clause of the Agreement appears on the same page as the signature block.

Remove ‘Duly authorised scanned signatures shall be mutually acceptable and email deemed a valid medium for exchanging signed copies of this Agreement, which may be executed in counterpart.’ if the Sponsor does NOT intend to accept counterparts.

### Schedule 1 Study Support Arrangements

The Sponsor should enter the financial details prior to sharing this Agreement with the PIC. Payment details should be entered prior to Agreement sign-off by the Parties.

**Delete these instruction pages after completing the Agreement**

# MODEL NON-COMMERCIAL PARTICIPANT IDENTIFICATION CENTRE AGREEMENT (SPONSOR TO PIC)

[**Insert** NAME AND ADDRESS OF THE SPONSOR]

**(referred to as “the Sponsor”)**

AND

[**Insert** NAME AND ADDRESS OF PARTICIPANT IDENTIFICATION CENTRE]

**(referred to as “the PIC”)**

Which are collectively referred to as the “**Parties**” or individually referred to as a “**Party**”

**NOW**

**WHEREAS** the Sponsor is an NHS organisation / University / OTHER;

**WHEREAS** the Co-sponsors / Joint-Sponsors are an NHS organisation / University / OTHER and NHS organisation / University / OTHER;

**WHEREAS** the Study is coordinated on behalf of the Sponsor by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ which is a [Clinical Trials Unit / Experimental Cancer Medicine Centre / Biomedical Research Unit/Centre/OTHER];

**WHEREAS** the Funder is / are \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ which is an NHS Trust / NHS Foundation Trust / NHS Board / Local Health Board / University / Charity / Government Funding Stream / OTHER;

**WHEREAS** the Sponsor wishes to sub-contract with the PIC to undertake Data Processing for the purpose of identifying potential Participants for the Study;

**WHEREAS** the Study is multi-centred, having more than one investigator site;

**WHEREAS** the Study is a [IRAS STUDY TYPE].

**In respect of the clinical research Study entitled [Insert FULL TITLE] the above Parties HEREBY AGREE AS FOLLOWS:**

## Definitions

* 1. The following words and phrases have the following meanings:
* **Agent(s)**
includes, but shall not be limited to, any person undertaking a function in connection with this Agreement (including any nurse or other health professional), any such person’s principal employer in the event it is not the Sponsor or PIC and where such person is providing services to a Party under a contract for services or otherwise (including clinical academics), and/or any contracted third party providing services to a Party under a contract for services or otherwise;
* **Agreement**
this Agreement, together with the schedules annexed hereto;
* **Controller**
shall have the meaning set out in the Data Protection Legislation;
* **Data Protection Legislation**
means the GDPR, the Data Protection Act 2018, the Privacy and Electronic Communications (EC Directive) Regulations 2003, as well as any legally enforceable NHS requirements, Codes of Practice or Guidance issued by the Information Commissioner’s Office, in each case in force from time to time in England, Northern Ireland, Scotland and/or Wales;
* **Data Subject**
as defined in the Data Protection Legislation;
* **GDPR**
means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019;
* **Participant**
any person who consents (where consent is necessary) and is enrolled to take part in the Study. All references to Participants in this Agreement should be construed to include potential Participants who are identified by and referred by or through the PIC;
* **Personal Data**
any and all information, data and material of any nature received or obtained by any Party in connection with this Agreement which is personal data as defined in Data Protection Legislation and which relates to any Participant or their treatment or medical history;
* **Participant Identification Centre (PIC)**
the NHS/HSC organisation named on page one of this Agreement, being an NHS/HSC organisation contracted by the Sponsor to Process Personal Data on behalf of the Sponsor to identify potential Participants for the Study;
* **Process**
as defined in the Data Protection Legislation (and "Process" and "Processed" shall be construed accordingly);
* **Processor**
shall have the meaning as set out in the Data Protection Legislation;
* **Protocol**
the full description of the Study with the reference number set out on the front page of this Agreement, together with any amendments thereof, and incorporated into this Agreement by reference. Reference in the Agreement to Protocol should be construed to include reference to the clinical investigation plan for the Study, where the Study is a clinical investigation of a medical device;
* **Sponsor**
the individual, company, institution or organisation that is (or the institutions or organisations, where there is more than one sponsor under a co-sponsorship or joint-sponsorship arrangement, that are) signatory to this Agreement, that takes responsibility for the initiation, management and financing (or arranging the financing) of the Study;
* **Study**
the clinical research study that is the subject of this Agreement.
	1. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

## General

* 1. As the mutual exchange of obligations and promises is regarded as consideration, this Agreement forms a legally binding contract.
	2. The PIC will Process Personal Data to identify potential Study Participants as follows:
		1. The PIC will undertake a [**DELETE** AS APPLICABLE [database search] [search of paper records] for potential Participants meeting the following criteria:
			1. [PROVIDE INCLUSION/EXCLUSION CRITERIA OR OTHERWISE DESCRIBE THE PATIENT COHORT/S TO BE IDENTIFIED]
		2. [[**DELETE** AS APPLICABLE]The PIC will be provided with the following information to provide to potential participants:
			1. [list any leaflets, etc. to be provided for the PIC to use with potential participants];
		3. Potential Participants will be approached [by PIC staff at usual clinic visits] [by letter from PIC staff] [OTHER – PLEASE SPECIFY];
		4. [The PIC will use its best endeavours to identify XX number of potential Participants] AND/OR [state start and end dates or events for PIC activities].
	3. By entering into this Agreement, the Parties agree that the conduct of the Study at the PIC is governed by and subject to the national laws and regulations of the PIC. However, subject to Clause 2.4, any other issue, including any issue as to the construction of this Agreement, shall be governed and construed in accordance with the laws governing the country of the United Kingdom in which the Sponsor is established namely, the laws of England and Wales/Scotland/Northern Ireland and shall be subject to the exclusive jurisdiction of the Courts of the Sponsor. Save, that where both Parties agree, having taken into consideration that it would be more reasonable and expeditious both as to time and costs, in such instance to do so, for the agreed issue pertaining to this Agreement, to be subject to the jurisdiction of the defendant.
	4. Where the Sponsor is not established in the UK, the laws and jurisdiction of the UK country in which the PIC is established, namely England and Wales/Scotland/ Northern Ireland, shall apply.

## Confidentiality and Data Protection

### Confidentiality

* 1. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to Participants and persons identified as potential Participants.
	2. The PIC agrees to treat the Confidential Information in this Agreement (including the Protocol) and the Results, excluding any Clinical Data of the Study, as Confidential Information of the Sponsor and the Sponsor agrees to treat Personal Data and confidential patient information as Confidential Information.

### Data Processing Terms

* 1. For the purposes of the Data Protection Legislation, the Sponsor is the Controller and the PIC is the Sponsor's Processor in relation to all Processing of Personal Data that is Processed for the purpose of this Study and for any future research use under the Controllership of the Sponsor, that would not have taken place but for this Agreement regardless where that Processing takes place.
	2. The Parties acknowledge that whereas the Sponsor is the Controller in accordance with Clause 3.3, the PIC is the Controller of the Personal Data Processed for the purpose of providing clinical care to the persons identified as potential Participants. This Personal Data may be the same Personal Data, collected transparently and processed for research and for care purposes under the separate Controllerships of the Sponsor and PIC.
	3. Where the PIC is the Sponsor’s Processor and thus where the Processing is undertaken by the PIC for the purposes of the Study, Clauses 3.6 to 3.10 below will apply. For the avoidance of doubt, such Clauses do not apply where the PIC is Processing the Participant Personal Data as a Controller.
	4. The PIC agrees only to Process Personal Data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the Study and to ensure the Sponsor’s compliance with the Data Protection Legislation.
	5. The PIC agrees to comply with the obligations applicable to Processors described by Article 28 GDPR including, but not limited to, the following:
		1. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the Controller by GDPR Article 28(1);
		2. to not engage another Processor without the prior written authorisation of the Sponsor (GDPR Article 28(2));
		3. to Process the Personal Data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the PIC shall notify the Sponsor before Processing, or as soon as possible after Processing if legislation requires that the Processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (GDPR Article 28(3)(a));
		4. to ensure that personnel authorised to Process Personal Data are under confidentiality obligations (GDPR Article 28(3)(b));
		5. to take all measures required by GDPR Article 32 in relation to the security of processing (GDPR Article 28(3)(c));
		6. to respect the conditions described in GDPR Article 28(2) and (4) for engaging another Processor (GDPR Article 28(3)(d));
		7. to, taking into account the nature of the Processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (GDPR Article 28(3)(e));
		8. to assist the Controller, to ensure compliance with the obligations pursuant to GDPR Articles 32 to 36 taking into account the nature of the Processing and the information available to the PIC (GDPR Article 28(3)(f));
		9. to, at the choice of the Sponsor, destroy or return all Personal Data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (GDPR Article 28(3)(g)) or where that Personal Data is held by the PIC as Controller for the purpose of clinical care or other legal purposes; and
		10. to maintain a record of Processing activities as required by GDPR Article 30(2).
	6. The PIC shall ensure that:
		1. its Agents do not Process Personal Data except in accordance with this Agreement (and in particular the Protocol);
		2. it takes all reasonable steps to ensure the reliability and integrity of any of its Agents who have access to the Personal Data and ensure they:
			1. are aware and comply with the PIC's duties under this clause;
			2. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and
			3. are informed of the confidential nature of the Personal Data and understand the responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose for lawful and appropriate purposes.
	7. The PIC agrees to:
		1. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the PIC’s compliance with the obligations described by this Agreement, Data Protection Legislation in general and GDPR Article 28 in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the PIC and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and
		2. obtain prior agreement of the Sponsor to store or Process Personal Data outside of the UK and the European Economic Area.
	8. Where the PIC stores or otherwise Processes Personal Data outside of the UK and the European Economic Area as the Sponsor’s Processor, it warrants that it does so in compliance with the Data Protection Legislation.

### Data Sharing Terms

* 1. Personal Data shall not be disclosed to the Sponsor by the PIC, save where this is required directly or indirectly to satisfy the requirements of the Protocol, or in relation to a claim or proceeding brought by a Participant in connection with the Study.
	2. The Sponsor agrees to use Personal Data solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (GDPR Article 5(1)(b)), and not otherwise. In particular:
		1. not to disclose Personal Data to any person except in accordance with applicable legal requirements and codes of practice.
	3. The Sponsor agrees to comply with the obligations placed on a Controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to Processing of Personal Data (GDPR Article 5).
	4. The Sponsor agrees to ensure persons processing Personal Data under this Agreement are equipped to do so respectfully and safely. In particular:
		1. to ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the PIC) Processing Personal Data understand the responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose for lawful and appropriate purposes;
		2. to ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the PIC) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
	5. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular to:
		1. ensure that Personal Data are only accessible to persons who need it for the purposes of the Study and to remove access as soon as reasonably possible once it is no longer needed;
		2. ensure all access to Personal Data on IT systems processed for Study purposes can be attributed to individuals;
		3. review processes to identify and improve processes which have caused breaches or near misses, or which force persons Processing Personal Data to use workarounds which compromise data security;
		4. adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;
		5. take action immediately following a data breach or near miss.
	6. The Sponsor agrees to ensure data are Processed using secure and up to date technology. In particular, to:
		1. ensure no unsupported operating systems, software or internet browsers are used to support the processing of Personal Data for the purposes of the Study;
		2. put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials;
		3. ensure IT suppliers are held accountable via contracts for protecting Personal Data they Process and for meetings all relevant information governance requirements.

### Intellectual Property Rights

* 1. All Background Intellectual Property Rights (including licences) and Background Know-How and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party’s rights.
	2. All Intellectual Property Rights and Know-How in the Protocol and other documents and information disclosed by the Sponsor, and in the Study Data, excluding clinical procedures developed or used by the PIC independently of the Study, shall belong to the Sponsor. The PIC hereby assigns all such Intellectual Property Rights, and undertakes to disclose all such Know-How, to the Sponsor.
	3. At any time within the duration of the Study, the PIC shall at the request of the Sponsor and at the expense of the Sponsor execute all such documents and do all acts necessary to fully vest the Intellectual Property Rights in the Sponsor. To give effect to this Clause 3.19, the PIC shall ensure that its Agents involved in the Study assign such Intellectual Property Rights and disclose such Know-How to the Sponsor.

## Sign Off\*

Each Party represents that it has ‘redlined’ or otherwise called attention to all changes that it made and sent to the other Party in previously sent drafts of this Agreement, including but not limited to drafts of the schedule.

Signed by the duly authorised representatives of the Parties.

**SIGNED ON BEHALF OF THE SPONSOR**

………………………… ……………………… ………………………… ………………

Name Position Signature Date

**SIGNED ON BEHALF OF THE PIC**

………………………… ……………………… ………………………… ………………

Name Position Signature Date

\* Duly authorised scanned signatures shall be mutually acceptable and e-mail deemed a valid medium for exchanging signed copies of this Agreement, which may be executed in counterpart.

# Schedule 1

## Study Support Arrangements

### A. Financial Arrangements

Where no payments are to be to made to the PIC under this Agreement tick this box [ ]  and delete the rest of this Section A.

The overall, study-wide recruitment for this Study is competitive with a maximum figure of [X] Participants. Once this target has been reached, the Sponsor will notify the PIC. No additional per Participant payments will be made by the Sponsor to the PIC for potential Participants referred after such notification becomes effective.

|  |  |  |
| --- | --- | --- |
|  | **Area of Cost**  | **Payment (£ Sterling)** |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
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| 5 |  |  |

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment of the agreed costs on presentation of a VAT invoice in which the VAT is stated as a separate item. Such invoices should quote the PIC’s VAT registration number. If VAT is not payable, then the PIC shall issue a VAT exemption certificate.

### Schedule of payments and details of payment arrangements

Invoices to be submitted [**Insert** FREQUENCY OR INTERVAL e.g. quarterly] to:

[**Insert** JOB TITLE, NAME OF BODY & ADDRESS]

Payment to be made by cheque payable to:

[**Insert** NAME OF PIC]

and remitted to:

[**Insert** JOB TITLE/POSITION]

[**Insert** ADDRESS]

Or arrange BACS Transfer to: [**Insert** BANK NAME].

Sort code: [**Insert** SORT CODE]

Account: [**Insert** ACCOUNT NUMBER]

And send the relevant paperwork to [**Insert** ADDRESSEE FOR PAPERWORK] at the above address.

Invoices must be paid promptly [within XX days of receipt]. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding has been irrecoverably reclaimed by the Funder as a result of such delay or inadequacy.

### B. Supplies Arrangements

Where no items are to be provided to, or procured for/by, the PIC under this Agreement tick this box [ ]  and delete the rest of this Section B.

Any medicine, equipment, materials, consumables, software or other items being provided by the Sponsor, or procured by the PIC for use in the Study shall be specified below.

**Note 1**: Parties should complete the table below. If the PIC is to procure any Items and is to be reimbursed by the Sponsor this should be specified in this Schedule. Similarly, if the PIC is to pay the Sponsor for any Items provided to the PIC by or on behalf of the Sponsor this should be specified in this Schedule.

**Note 2**: Parties should specify in this Schedule, as appropriate, arrangements for:

* Items
* Insurance
* Storage instructions
* Instructions for use, return and/or destruction
* Any training to be provided
* Maintenance of equipment

| **Item** | **Quantity** | **Frequency of supply** | **Responsibility to supply/procure (either PIC or Sponsor only)** |
| --- | --- | --- | --- |
|  |  |  |  |
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