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

# Trial Site to PIC

**This document is intended for use between organisations participating as trial sites in non-commercially sponsored research 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 Trial Site 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 a hospital operated 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 Trial Site and its PIC in a manner consistent with the arrangements agreed between the research Sponsor and the Trial Site (i.e. when used as a contract, it is a subcontract between Trial Site and PIC, consistently delegating data processing activities already contracted between Sponsor and Trial Site).

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 Trial Site, or where the highlighted text is optional. The Trial Site (in agreement with 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 Trial Site prior to sharing with the PIC.

It is the Trial Site’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. Recitals should be agreed between Sponsor and Trial Site prior to proposing the Agreement to the PIC.

### 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 subcontracted to it. This should be completed by the Trial Site (collaboratively with the Sponsor, or otherwise as per Sponsor instruction) prior to providing to the PIC. Any changes to the information provided should be negotiated between PIC and Trial Site (and may need agreement between the Trial Site and Sponsor) prior to this Agreement being executed.

The Trial Site should indicate within which UK nation the Sponsor is established.

### 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 (or, in the case of this Agreement: Controller/Processor/Sub-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 Trial Site, the Sponsor or an Agent 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)). This is unlike the mNCA, on which this Agreement is based, wherein these clauses are only incorporated where such transfer is intended. The difference in approach is explained by the far greater likelihood that Personal Data will be transferred between PIC and Trial Site than between Trial Site and Sponsor.

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

### 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 Trial Site does NOT intend to accept counterparts.

### Schedule 1 Study Support Arrangements

Financial details should be consistent with the agreement between Sponsor and Trial Site. The Trial Site 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 (TRIAL SITE TO PIC)

[**Insert** NAME AND ADDRESS OF TRIAL SITE],

(referred to as “**the Trial Site**”)

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 Trial Site 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 the Principal Investigator, any nurse or other health professional), any such person’s principal employer in the event it is not the Trial Site 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 Trial Site;

* **Trial Site**
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;;
* **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 organisation named on page one of this Agreement, being an organisation sub-contracted by the Trial Site to Process Personal Data on behalf of the Sponsor to identify potential Participants for the Study;
* **Principal Investigator or PI**
the leader responsible for a team of individuals conducting the Study at the Trial Site;
* **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), 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;
* **Sub-Processor**
the PIC contracted by the Trial Site to Process Personal Data on behalf of the Sponsor (as per GDPR Article 28, 2).
	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 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 (or by which the mNCA, to which this Agreement is a sub-agreement, is governed and construed in accordance with Clause 18.2 of that mNCA), namely, the laws of England and Wales/Scotland/Northern Ireland and shall be subject to the exclusive jurisdiction of the Courts of that country. 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.

## 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 Trial Site and the Trial Site 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, the Trial Site is the Sponsor's Processor and the PIC is the Sub-Processor of the Trial Site 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 Trial Site's Sub-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 Trial Site in accordance with the instructions of the Trial Site or Sponsor and for the purpose of the Study and to ensure the Sponsor’s and Trial Site’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 Trial Site or Sponsor unless required to do otherwise by legislation, in which case the PIC shall notify the Trial Site 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 Trial Site and/or 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 Trial Site and/or Sponsor(s) or another auditor appointed by the Trial Site and/or 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 Trial Site/Sponsor complying with all relevant health and safety and security policies of the PIC and/or to provide the Trial Site or 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 Trial Site or 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 Trial Site 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 Trial Site represents that the Sponsor has agreed 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 Trial Site 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 Trial Site 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 Trial Site 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 Trial Site.
	3. At any time within the duration of the Study, the PIC shall at the request of the Trial Site or 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 Trial Site.

## 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 TRIAL SITE**

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

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 Trial Site. No additional per Participant payments will be made by the Sponsor to the Trial Site for patients consented after such notification becomes effective.

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| --- | --- | --- |
|  | **Area of Cost**  | **Payment (£ Sterling)** |
| 1 |  |  |
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| 3 |  |  |
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If VAT is payable, then the Trial Site 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 Trial Site’s VAT registration number. If VAT is not payable, then the Trial Site 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 Trial Site, 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 Trial Site this should be specified in this Schedule. Similarly if the PIC is to pay the Trial Site 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, Sponsor or Trial Site only)** |
| --- | --- | --- | --- |
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