# Model Commercial Participant Identification Centre Agreement (mC-PICA)

**This document is intended for use between organisations participating in 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.**

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 Participating Organisation and its PIC in a manner consistent with the arrangements agreed between the research Sponsor and the Participating Organisation (i.e. when used as a contract, it is a subcontract between Participating Organisation and PIC, consistently delegating data processing activities already contracted between Sponsor and Participating Organisation).

The data processing provisions are consistent with those in the model Clinical Trial Agreements (mCTA and CRO-mCTA) and have been drafted to form a legally binding 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 mC-PICA for execution by the Parties. Further guidance on the use of PICs is available here.

Throughout the Agreement, yellow highlighted text is used to indicate where optional text has been provided, or where additional study specific text should be entered by the Participating Organisation, or where the highlighted text is optional. The Participating Organisation (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 section). Once the text has been selected, entered, removed or retained (as appropriate) yellow highlights should be removed by the Participating Organisation prior to sharing with the PIC.

It is the Participating Organisation’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 Participating Organisation prior to proposing the Agreement to the PIC.

### Definitions

Definitions should not be amended, deleted or added to.

### General

The sub-clauses of Clause 2.5 (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 sub-contracted to it. This should be completed by the Participating Organisation (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 Participating Organisation (and may need agreement between the Participating Organisation and Sponsor) prior to this Agreement being executed.

### Confidentiality and Data Protection

The Participating Organisation shall provide contact details for incident reporting at 3.2.5.h. These details may be those of the Sponsor, or of the Participating Organisation itself, as agreed between Participating Organisation and 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 Participating Organisation does NOT intend to accept counterparts.

### Appendix 1 Financial Arrangements

Financial details should be consistent with the agreement between Sponsor and Participating Organisation. The Participating Organisation 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**

[**INSERT** FULL NAME OF THE CLINICAL TRIAL]

[**INSERT** SPONSOR’S PROTOCOL REFERENCE NUMBER]

# COMMERCIAL PARTICIPANT IDENTIFICATION CENTRE AGREEMENT

**Between**

[**INSERT** NAME OF PARTICIPATING ORGANISATION and ADDRESS OF PARTICIPATING ORGANISATION]

**“Participating Organisation”**

AND

[**INSERT** NAME OF PIC AND REGISTERED ADDRESS OF PIC]

**“Participant Identification Centre (PIC)”**

Each of which shall be a “**Party**” and collectively the “**Parties**”

### Whereas

1. The Sponsor is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans;
2. The Participating Organisation is contracted to act as the Processor of the Sponsor (as Controller) for Personal Data Processed for the purpose of the Clinical Trial;
3. The Participating Organisation wishes to sub-contract with the PIC to undertake Data Processing for the purpose of identifying potential Clinical Trial Subjects for the Clinical Trial.

It is therefore, agreed that the following terms and conditions shall apply to the conduct of the Data Processing undertaken by the PIC for the purpose of the Clinical Trial (as further defined below):

## Definitions

* 1. In this Agreement, the following words shall have the following meanings:
* **Affiliate**
means any business entity that controls, is controlled by or is under the common control with the Sponsor, save where there are contractual arrangements in place to exclude such affiliate. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity;
* **Agent**
shall include but is not limited to, any person (including any nurse or other healthcare professional) providing services to the PIC under a contract for services (commonly known as an honorary contract) or otherwise any such person’s principal employer in the event that it is not the PIC and/or any contracted third party providing services to a Party under a contract for services or otherwise;
* **Agreement**
means this Agreement comprising its clauses, schedules and any appendices attached to it;
* **Clinical Trial**
means the investigation to be conducted at the Site in accordance with the Protocol;
* **Clinical Trial Subject**
means a person enrolled to participate in the Clinical Trial according to criteria detailed in the Protocol;
* **Controller**
shall have the meaning set out in the Data Protection Laws and Guidance;
* **Data Protection Laws and Guidance**
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; and, pending a favourable decision from the competent authorities of the EU on the adequacy of the UK data protection regime will include the requirements set out or referenced in Part Three, Title VII, Article 71(1) of the Withdrawal Agreement signed by the UK and the EU in December 2019;
* **Data Subject**
shall have the meaning set out in the Data Protection Laws and Guidance;
* **EEA**
means the European Economic Area comprising the countries of the European Union as well as Iceland, Liechtenstein and Norway;
* **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;
* **Personal Data**
means 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 the Data Protection Laws and Guidance and which relates to a Clinical Trial Subject (or potential Clinical Trial Subject) and/or their treatment or medical history;
* **Personal Data Breach**
means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data transmitted or otherwise processed;
* **Personnel**
means the persons who will undertake the activities specified at Clause 2.5 on behalf of the PIC;
* **Participant Identification Centre (PIC)**
means the organisation named on page one of this Agreement, being an organisation sub-contracted by the Participating Organisation to Process Personal Data on behalf of the Sponsor to identify potential Clinical Trial Subjects for the Clinical Trial;
* **Process**
shall have the meaning set out in the Data Protection Laws and Guidance (and “process” and “processed” shall be construed accordingly);
* **Processor**
shall have the meaning set out in the Data Protection Laws and Guidance;
* **Protocol**
means the full description of the Clinical Trial with the reference number set out on the front page of this Agreement and incorporated into this Agreement by reference;
* **Pseudonymised Data**
means individual-level data relating to a natural person (as opposed to aggregated data) who is made no longer identified or identifiable from that data by virtue of the replacement of personal identifiers with a code, or equivalent, and which is safeguarded as non-identifiable in accordance with this agreement;
* **Site**
means the physical location(s) where the Clinical Trial will be conducted within the Participating Organisation;
* **Sub-Processor**
means the PIC contracted by the Participating Organisation to Process Personal Data on behalf of the Sponsor (as per GDPR Article 28 (2)).

## General

* 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.
	2. The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.
	3. Where appropriate, words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders.
	4. A reference to this Agreement or to any other agreement or document referred to in this Agreement is a reference to this Agreement or such other agreement or document as amended, varied or novated (in each case other than in breach of the provisions of this Agreement) from time to time.
	5. The PIC will Process Personal Data to identify potential Clinical Trial Subjects 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. 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]
		5. [The PIC will provide the Participating Organisation with documentation to confirm the identification of potential Clinical Trial Subject to support financial reconciliation with the Sponsor].
	6. Where the PIC is constituted in England then this Agreement shall be governed and construed in accordance with the laws of England and Wales and the Courts of England and Wales shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the PIC is constituted in Wales then this Agreement shall be governed and construed in accordance with the laws of England and Wales as applied in Wales and the Courts of England and Wales shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the PIC is constituted in Scotland, this Agreement shall be governed and construed in accordance with the laws of Scotland and the Courts of Scotland shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

Where the PIC is constituted in Northern Ireland, then this Agreement shall be governed and construed in accordance with the laws of Northern Ireland and the Courts of Northern Ireland shall have exclusive jurisdiction to hear any dispute relating to this Agreement.

## Confidentiality and Data Protection Data Protection

* 1. The Parties agree:
		1. To comply with all Data Protection Laws and Guidance in processing the Personal Data of Clinical Trial Subjects. This Clause 3 is in addition to and does not replace, relieve or remove a Party’s obligations or rights under the Data Protection Laws and Guidance.
		2. When one Party is Processing Personal Data, as Controller, for which the other Party is at that time a separate and independent Controller, to promptly and without undue delay, notify and inform that other Party in the event of any Personal Data Breach that relates to that Personal Data.
	2. **Processing of Clinical Trial Subject Personal Data**
		1. For the purpose of the Data Protection Laws and Guidance, the Sponsor is the Controller, the Participating Organisation is the Processor and the PIC is the Sub-Processor of the Participating Organisation in relation to the Processing of Personal Data for the purpose of the Clinical Trial.
		2. The PIC’s Processing of Personal Data, as a Sub-Processor of the Participating Organisation, shall be governed by this Agreement, including the Protocol, which sets out the subject matter, duration, nature, and purpose of the Processing, type of Personal Data and categories of data subjects, and obligations and rights of Sponsor as Controller and Participating Organisation as Sub-Processor.
		3. The PIC is the Controller of Personal Data that it processes for purposes other than the Clinical Trial, e.g. the provision of medical care.
		4. The PIC, in its role as Processor of the Personal Data under Clause 3.2.1, agrees to only Process Personal Data for and on behalf of the Sponsor in accordance with the documented instructions of the Sponsor and/or Participating Organisation, including with regard to transfers of personal data to a third country or an international organisation. If the PIC is required by law to otherwise Process the Personal Data, the PIC shall notify the Participating Organisation before undertaking the Processing, unless such notification is prohibited on important grounds of public interest in accordance with GDPR Article 28(3)(a). In the case of such prohibition, the PIC shall notify the Participating Organisation as soon as possible once the prohibition is lifted, if it is lifted.
		5. The PIC agrees to comply with the obligations applicable to Processors described by Article 28 of the GDPR, as well as those additional obligations required by Participating Organisation pursuant to this Agreement, including but not limited to the following:
			1. implementing and maintaining appropriate technical and organisational security measures for Personal Data Processed in its systems, in keeping with its obligations as an NHS organisation, thereby providing guarantee to the Sponsor pursuant to GDPR Article 28(1);
			2. ensuring that Personnel authorised to Process Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality (Article 28(3)(b));
			3. taking all measures required by GDPR Article 32 in relation to the security of processing (GDPR Article 28(3c));
			4. complying with the conditions described in GDPR Article 28(2) and (4) for engaging another Processor (GDPR Article 28(3d));
			5. taking into account the nature of the Processing, assist the Sponsor and/or the Participating Organisation, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (GDPR Article 28(3e));
			6. assisting 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(3f));
			7. maintaining a record to demonstrate compliance with this Clause and Data Protection Laws and Guidance, including the records required pursuant to GDPR Article 30(2);
			8. in the event of any Personal Data Breach by the PIC as a Sub-Processor of the Participating Organisation, the PIC shall: (i) promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via e-mail to [**insert**] (ii) not make any statements or notifications about the Personal Data Breach, as it relates to the Processing for the purpose of the Clinical Trial, to any individual affected by the incident, the public or any third party without Sponsor or Participating Organisation’s prior written approval; and (iii) immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with Sponsor and the Participating Organisation.
		6. In furtherance of its obligations under Article 28 GDPR, the PIC agrees that it will not engage another Processor for the purpose of the Clinical Trial without the prior written authorisation of the Sponsor or Participating Organisation (GDPR Article 28(2)).
		7. At the expiry or lapse of this Agreement, the PIC shall, at the choice of the Participating Organisation, destroy or return all Personal Data to the Sponsor or Participating Organisation unless there is a legal requirement for retention and storage (GDPR Article 28(3g)) and/or where that Personal Data is held by the PIC as Controller for its own purpose(s).
		8. The PIC will:
			1. ensure that its Personnel do not Process Personal Data except in accordance with the Protocol and this Agreement;
			2. take all reasonable steps to ensure the reliability and integrity of any of its Personnel who have access to the Personal Data and ensure that the Personnel:
				1. are aware and comply with the PIC’s duties under this Clause 3 (Confidentiality and Data Protection);
				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 Personal Data; and
				3. are informed of the confidential nature of the Personal Data and understand their responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose it for lawful and appropriate purposes.
		9. The PIC agrees to:
			1. provide the Sponsor and/or the Participating Organisation with evidence of its compliance with the obligations set out in this Agreement, or, at the Sponsor and/or Participating Organisation’s discretion and on reasonable notice, to allow the Sponsor, Participating Organisation or a third party appointed by the Sponsor or Participating Organisation, to audit the PIC’s compliance with the obligations described in this Agreement, Data Protection Legislation and Guidance (including but not limited to Article 28 GDPR), subject to the Sponsor, Participating Organisation or appointed third party, complying with all relevant health and safety and security policies of the PIC;
			2. obtain prior written agreement of the Sponsor or Participating Organisation to Process Personal Data outside of the UK and the EEA.
		10. In addition to the PIC’s obligations under Clause 3.2.9.b, where the PIC, acting as the Participating Organisation’s Sub-Processor, Processes Personal Data outside of the UK and the EEA, the PIC warrants that it does so in compliance with the Data Protection Laws and Guidance.

## Intellectual Property

* 1. All Intellectual Property Rights and Know-How owned by or licensed to the Sponsor, Participating Organisation or Affiliate(s) prior to and after the date of this Agreement, other than any Intellectual Property Rights and Know-How arising from the Clinical Trial, are and shall remain the property of the Sponsor, Participating Organisation or Affiliate(s), as the case may be.
	2. All Intellectual Property Rights and Know-How owned by or licensed to the PIC prior to and after the date of this Agreement, other than any Intellectual Property Rights and Know-How arising from the Clinical Trial, are and shall remain the property of the PIC.
	3. All Intellectual Property Rights and Know-How arising from and relating to the Clinical Trial, the IMP (including but not limited to its formulation and use alone or in combination with other drugs), and/or the Protocol, but excluding any clinical procedure and improvements thereto that are clinical procedures of the PIC, shall vest in the Sponsor in accordance with Clauses 4.4 and 4.5 of this Agreement.
	4. In accordance with Clause 4.3, the PIC hereby assigns, and shall procure that its Agents assign, its rights in relation to all Intellectual Property Rights and Know-How, falling within Clause 4.3, to the Sponsor or its nominee. At the request and expense of the Sponsor, the PIC shall execute, and shall procure that its Agents shall execute, all such documents and do all such other acts as the Sponsor may reasonably require in order to vest fully and effectively all such Intellectual Property Rights and Know-How in the Sponsor or its nominee.
	5. PIC shall and will ensure that the Personnel promptly disclose to the Participating Organisation any Know-How generated pursuant to this Agreement and falling within Clause 4.3 and undertakes not to use or disclose such Know-How other than for the purposes of this Agreement.
	6. Nothing in this Clause 4 shall be construed so as to prevent or hinder the PIC from using its Know-How generated during the performance of the Clinical Trial in the furtherance of its normal activities, to the extent that such use does not result in the disclosure or misuse of Confidential Information or the infringement of any Intellectual Property Right or Know-How of the Sponsor or Participating Organisation.

## 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.

Signed by the duly authorised representatives of the Parties.

**SIGNED ON BEHALF OF THE PARTICIPATING ORGANISATION**

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

Name Position Signature Date

**SIGNED ON BEHALF OF THE PIC**

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

Name Position Signature Date

\* 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.

# Appendix 1 – Financial Arrangements

The interactive Costings Tool (iCT) should be used by the Sponsor to formulate the budget with respect to the Clinical Trial. The agreed financial arrangements relevant to the activities to be performed by the PIC should form this Appendix, including the arrangements for invoicing.

**Note**: This Appendix should only be used to specify financial matters and should not be used to include additional or different terms to those set out in the Agreement.

**Please remove this text once the document has been agreed for the Clinical Trial**