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

**This document is intended for use between Trial Sites undertaking 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 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 the commercial model Agreements ([mCTA, CRO-mCTA](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#mCTA-CROmCTA), [ATMP-mCTA, CRO-ATMP-mCTA](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#Advanced-therapy), [PC-mCTA](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#PC-mCTA), [mNISA](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#mNISA-CROmNISA), [CRO-mNISA](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#mNISA-CROmNISA), [mCIA and CRO-mCIA](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#mCIA-CROmCIA)) 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](https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#PIC).

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 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 2.7 (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 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.

### Confidentiality and Data Protection

The Trial Site shall provide contact details for incident reporting at 3.2.5.h.(i). These details may be those of the Sponsor, or of the Trial Site itself, as agreed between Trial Site 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 Trial Site does **NOT** intend to accept counterparts.

### Appendix 1 Financial Arrangements

The Localised OnlineiCT generated Finance Schedule should be inserted into this Financial Arrangements Appendix. Further detailed guidance for completion is included within the Financial Arrangements Appendix itself.

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

[**INSERT** FULL NAME OF THE STUDY]

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

# COMMERCIAL PARTICIPANT IDENTIFICATION CENTRE AGREEMENT

**Between**

[**INSERT** NAME OF TRIAL SITE and REGISTERED ADDRESS OF TRIAL SITE]

**“Trial Site”**

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 / Medical Device / Other [PLEASE SPECIFY] company involved in [insert company’s interests e.g. post marketing surveillance etc];
2. The Trial Site is contracted to act as the Processor of the Sponsor (as Controller) for Personal Data Processed for the purpose of the Study;
3. The Trial Site wishes to sub-contract with the PIC to undertake Data Processing for the purpose of identifying potential Participants for the Study.

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 Study (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, by contract or otherwise;
* **Agent**
shall include but is not limited to, (1) 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 (2) any contracted third party providing services to a Party under a contract for services or otherwise (including but not limited to a chief investigator engaged under a model commercial chief investigator agreement between the Sponsor and an NHS chief investigator employer);
* **Agreement**
means this Agreement comprising its clauses, schedules and any appendices attached to it;
* **Confidential Information**

means all confidential information (however recorded or preserved) disclosed by a Party and / or its Affiliate and / or its Agent to the other Party, in connection with the Study, which is information that would be regarded as confidential by a reasonable business person, including (but not limited to):

* business, affairs, plans, intentions or market opportunities;
* operations, processes, product information, designs, trade secrets or Know-How;
* any information developed by the Parties in connection with the Study in the course of carrying out this Agreement;
* the Protocol, the investigator brochure(s) relating to the Study, where applicable, and Appendix 1 to this Agreement (‘Financial Arrangements’);
* **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;
* **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;
* **Effective Date**means the date on which the final signature is placed on this Agreement;
* **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;
* **Intellectual Property Rights**
patents, trademarks, trade names, service marks, domain names, copyrights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;
* **Know-How**
all technical and other information which is not in the public domain, including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, manufacturing data and information contained in submissions to regulatory authorities;
* **Localised Online iCT**

means the localised, PIC-specific output from the online interactive Costing Tool (iCT), which is used by the Sponsor to agree the prices for the conduct of the Study, together with any amendments thereof made in accordance with Clause 5.2 of this Agreement and Clause 4 of Appendix 1 of this Agreement, as agreed between the Parties and incorporated into this Agreement by reference;

* **Participant**
means a person enrolled to participate in the Study according to criteria detailed in the Protocol;
* **Participant Identification Centre (PIC)**
means 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;
* **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 Participant (or potential Participant) 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, stored or otherwise Processed;
* **Personnel**
means the persons who will undertake the activities specified at Clause 2.7 on behalf of the PIC;
* **Process**
shall have the meaning set out in the Data Protection Laws and Guidance (and “**Processing**” 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 Study 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;
* **Retention Period**

means the time period in which the Study records are retained by the Trial Site after the completion of the Study at the Trial Site, as specified in the Agreement between the Sponsor and the Trial Site for the Study;

* **Sponsor**

means the individual, company, institution, organisation or group of organisations that has taken on the responsibility for initiation, managing and financing (or arranging the financing) the Study;

* **Study**
means the investigation to be conducted at the Trial Site in accordance with the Protocol;
* **Sub-Processor**
means the PIC contracted by the Trial Site 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. Where either Party is or both Parties are a Health and Social Care (HSC) organisation in Northern Ireland, references throughout this document to the NHS should be construed to include HSC as applicable.
	5. 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.
	6. If any Clause or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision shall, to the extent required, be severed from this Agreement and shall be ineffective without, as far as possible, modifying any other clause or part of this Agreement and shall not affect any other provisions of this Agreement which shall remain in full force and effect.
	7. The PIC will Process Personal Data to identify potential 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. 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 Trial Site with documentation to confirm the identification of potential Participant to support financial reconciliation with the Sponsor].
	8. 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.

* 1. **Updating Contact Details, Including for Notices and Payments**

Both Parties shall ensure that they notify the other as soon as reasonably practicable of changes to their contact details for notices, other contacts and / or changes to payment details set out in this Agreement. This shall apply from the Effective Date of this Agreement to the end of the Retention Period. Updating contact and / or payment details does not constitute a variation to the 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 actual and potential Participants. 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 Participant Personal Data**
		1. For the purpose of the Data Protection Laws and Guidance, 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 the Processing of Personal Data by the PIC for the purpose of the Study.
		2. The PIC’s Processing of Personal Data, as a Sub-Processor of the Trial Site, shall be governed by this Agreement, including the Protocol, which sets out the subject matter, duration, nature, and purpose of the Processing, the type of Personal Data and the categories of Data Subjects, and obligations and rights of Sponsor as Controller and Trial Site as Sub-Processor.
		3. The PIC is the Controller of Personal Data that it processes for purposes other than the Study, for example 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 Trial Site, 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 Trial Site before undertaking the Processing, or as soon as possible thereafter, 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 Trial Site 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 Trial Site 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(3)(c));
			4. complying with the conditions described in GDPR Article 28(2) and (4) for engaging another Processor (GDPR Article 28(3)(d));
			5. taking into account the nature of the Processing, assist the Sponsor and / or the Trial Site, 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));
			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(3)(f));
			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 Trial Site, the PIC shall:
				1. promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via e-mail to [**insert**];
				2. not make any statements or notifications about the Personal Data Breach (as it relates to the Processing for the purpose of the Study) to any individual affected by the incident, the public or any third party without Sponsor or Trial Site’s prior written approval; and
				3. immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with Sponsor and the Trial Site.
		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 Study without the prior written authorisation of the Sponsor or Trial Site (GDPR Article 28(2)).
		7. At the expiry or lapse of this Agreement, the PIC shall, at the choice of the Trial Site, destroy or return all Personal Data to the Sponsor or Trial Site unless there is a legal requirement for retention and storage (GDPR Article 28(3)(g)) 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 Trial Site with evidence of its compliance with the obligations set out in this Agreement, or, at the Sponsor and / or Trial Site’s discretion and on reasonable notice, to allow the Sponsor, Trial Site or a third party appointed by the Sponsor or Trial Site, to audit the PIC’s compliance with the obligations described in this Agreement, Data Protection Laws and Guidance (including but not limited to Article 28 GDPR), subject to the Sponsor, Trial Site 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 Trial Site 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 Trial Site’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.
	3. **Sharing of Personal Data and / or Participant Pseudonymised Data**
		1. Neither Personal Data nor Pseudonymised Data of actual or potential Participants shall be transferred by the PIC to the Trial Site unless this is required directly or indirectly to satisfy the purposes of this Agreement, or for the purposes of monitoring and reporting of adverse events or in relation to a claim or proceeding brought by a Participant in connection with the Study or is otherwise required by applicable law.
		2. The Trial Site agrees not to pass Personal Data or Pseudonymised Data of actual or potential Participants provided under this Agreement to a third party, unless that third party is bound by contractual obligations at least as stringent as in this Clause 3 (for the avoidance of doubt, the Trial Site represents and warrants that the Sponsor is so bound).
		3. The Trial Site represents and warrants that the Sponsor has agreed to use Personal Data and / or Pseudonymised Data of Participants for the purpose of the Study or otherwise as permitted in the approved consent form and in all circumstances for no purpose which is incompatible with the Study purpose. The Trial Site agrees and represents and warrants that the Sponsor has agreed to not disclose the Personal Data or Pseudonymised Data of Participants to any person except as required or permitted by the Protocol, law or applicable guidance.
		4. The Trial Site represents and warrants that the Sponsor has agreed to comply with the obligations placed on it as a Controller pursuant to Data Protection Laws and Guidance, including but not limited to demonstrating compliance with the principles relating to Processing of Personal Data (Article 5 GDPR).
		5. The Trial Site represents and warrants that the Sponsor has agreed to ensure persons Processing Personal Data and / or processing Pseudonymised Data of actual or potential Participants under this Agreement are equipped to do so respectfully and safely. In particular:
1. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the PIC or Trial Site) understand the responsibilities for information governance, including their obligation to Process Personal Data and / or process Pseudonymised Data of Participants securely and to only disseminate or disclose for lawful and appropriate purposes;
2. to ensure any such persons (excluding employees, honorary employees, students, researchers, consultants and sub-contractors of the PIC or Trial Site) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable Personal Data Breaches.
	* 1. The Trial Site represents and warrants that the Sponsor has agreed to take reasonable steps to proactively prevent Personal Data Breaches, and / or equivalent breaches relating to Pseudonymised Data of Participants, and to respond appropriately to incidents or near misses. In particular:
3. to ensure that Personal Data and / or Pseudonymised Data of Participants 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;
4. to ensure all access to Personal Data and / or Pseudonymised Data of Participants on IT systems Processed for Study purposes can be attributed to individuals;
5. to review processes to identify and improve processes which have caused Personal Data Breaches or near misses, or which force persons Processing Personal Data and / or processing Pseudonymised Data of Participants to use workarounds which compromise data security;
6. to adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;
7. to take action immediately following a Personal Data Breach or near miss.
	* 1. The Trial Site represents and warrants that the Sponsor has agreed to ensure Personal Data and / or Pseudonymised Data of Participants are Processed / processed using secure and up-to-date technology. In particular:
8. to ensure no unsupported operating systems, software or internet browsers are used to support the Processing of Personal Data and / or processing of Pseudonymised Data of Participants for the purposes of the Study;
9. to put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework;
10. to ensure IT suppliers are held accountable via contracts for protecting Personal Data and / or Pseudonymised Data of Participants that they Process / process and for meeting all relevant information governance requirements.

## Intellectual Property

* 1. All Intellectual Property Rights and Know-How owned by or licensed to the Sponsor, Trial Site or Affiliate(s) prior to and after the date of this Agreement, other than any Intellectual Property Rights and Know-How arising from the Study, are and shall remain the property of the Sponsor, Trial Site 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 Study, are and shall remain the property of the PIC.
	3. All Intellectual Property Rights and Know-How arising from and relating to the Study, 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 Trial Site 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. The Parties represent and warrant that they will not attempt to seek commercial advantage or infringe the IPR of the other Party or any third party, nor knowingly allow any third party to do so, by the analysis of bodily material or any other process designed or intended to derive privileged information in relation to the chemical, biological or other properties of any investigational medicinal product to which Participants may have been exposed by virtue of involvement in other research.
	7. 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 Study 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 Trial Site.

## Finances

* 1. Arrangements relating to the financing of the PIC by the Trial Site (on behalf of the Sponsor / CRO) for this Study are set out in Appendix 1. All payments will be made according to Appendix 1.
	2. In the event that any changes to the Protocol result in amendment to the financial arrangements set out at Appendix 1, it is agreed that the Parties will vary Appendix 1 in accordance with Clause 6.1.
	3. Subject to clause 5.2, changes to the identification target (if applicable) will be made without renegotiating the per capita payments in Appendix 1.
	4. Any payment adjustments for identification (over or under identification target – if applicable) will be made according to the per capita payments and other values specified in Appendix 1, including (as applicable) any inflationary uplifts in accordance with Clause 4 of Appendix 1.
	5. The PIC agrees that the Sponsor may make public the financial support provided to the PIC by the Trial Site (on behalf of the Sponsor / CRO) for the conduct of the Study and may identify the PIC as part of this disclosure.
	6. The Trial Site shall have no liability for any failure to make payments if required funding is not provided to the Trial Site by the Sponsor or CRO.

## Agreement and Modification

* 1. Any change in the terms of this Agreement shall be valid only if the variation is made in writing, agreed and signed by the Parties.
	2. This Agreement including its Appendices contains the entire understanding between the Parties and supersedes all other agreements, negotiations, representations and undertakings, whether written or oral of prior date between the Parties relating to the Study that is the subject of this Agreement.

## 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 for and on behalf of:[**INSERT** NAME OF TRIAL SITE]Signature:Print name:Title: Date: | Signed for and on behalf of:[**INSERT** NAME OF PIC]Signature:Print name:Title: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.

*N.B. 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.*

# Appendix 1 – Financial Arrangements

### [Financial Arrangements Appendix Instructions

*Please delete instruction text prior to sharing the Agreement with the Trial Site.*

* **Clauses 1.2 and 1.3**: All NHS organisations in the UK are under a policy obligation to adhere to the contract value generated by the National Contract Value Review (NCVR). This obligation does not currently extend to independent contractors of NHS services, although it does apply to general medical practices in England that have [voluntarily signed up](https://www.nihr.ac.uk/news/new-voluntary-scheme-gps-speed-commercial-study-set) to adhere to NCVR. In all cases where a PIC is subject to NCVR, the finance appendix should be generated using NCVR values and these should not be modified by either party. These values will either be the unmodified finance schedule output from the iCT following NCVR national resource review (which will occur for all commercial contract research with one or more NHS site) or the PIC values taken from the [iCT tariff data spreadsheet](https://www.nihr.ac.uk/how-interactive-costing-tool-ict-calculates-costs-studies-sites#ict-tariff-data) (with capacity build, indirect costs and PIC specific market forces factor added) current at the time of contract execution (if the only NHS involvement in the Study is PIC activity). If the PIC is not subject to NCVR, the Sponsor or Trial Site acting on its behalf should propose to the PIC the NCVR prices but the PIC is at liberty to negotiate from this basis.

Where the PIC is subject to NCVR, clause 1.3 should be retained. Clause 1.3 should be deleted if the PIC is an independent contractor of NHS services that is not voluntarily signed up to NCVR. Further support on use of iCT to generate PIC prices where no NCVR national resource review has occurred, and / or on the voluntary scheme for NHS general practices may be obtained from the [Regional Research Delivery Network (RRDN)](https://rdn.nihr.ac.uk/contact-us) for your lead NHS organisation in England, or from supportmystudy@nihr.ac.uk.

* **Clause 2.2:** Four options to describe the frequency of invoicing are provided to the Trial Site, or party acting on its behalf. A single option should be selected. If the final option is selected (another frequency to be agreed by the Parties) this should be based on a calendar frequency (for example twice annually), not Study, Trial Site or PIC milestones (for example, upon recruitment of 10 Participants).
* **Clause 2.3:**Five options, to describe the arrangements for raising invoices for this Study, are provided to the Trial Site or its Agent. The Parties can agree that more than one option may be appropriate to include in the Agreement; only the relevant option(s) should be retained. Where multiple options are chosen, the sub-option within each retained clause should also be retained and detail added. At least one option must be chosen. If only a single option is chosen, the sub-option should be removed.
* **Clause 6.1:** The Trial Site or its Agent should provide here the contact details to which invoices should be sent by the PIC. The Trial Site or its Agent should state here whether their preference is to receive invoices physically at this address or by email. The physical address should be provided regardless of preference.
* **Clause 6.2:** The contact details for invoice requests and invoice queries to be sent to the PIC should be completed by the Trial Site or its Agent following discussion with the PIC and prior to sharing the Agreement with the PIC. Whether the PIC chooses to receive the invoice requests or queries to its physical address or by email should be specified here.
* **Clause 6.3:**Payment details for the PIC should be completed by the Trial Site or its Agent following discussion with the PIC and prior to sharing the Agreement with the PIC.
* **Clause 7:**The Localised Online iCT generated Finance Schedule should be inserted here, after completion of iCT study resource review (where applicable) and prior to sharing the Agreement with the PIC. No modifications to the Finance Schedule should be made by either Party for studies within scope of the National Contract Value Review.
* Remove all brackets and yellow highlights prior to execution of this Agreement.

***END OF INSTRUCTIONS****]*

## Payments

* 1. This Appendix specifies all payments to be made by, or on behalf of, the Trial Site, to the PIC, under the Financial Arrangements within this Agreement.
	2. For PICs that are subject to [National Contract Value Review](https://www.england.nhs.uk/aac/what-we-do/embedding-research-in-the-nhs/national-contract-value-review/) (“NCVR”), including independent contractors of NHS primary care services that are [voluntarily subject to NCVR](https://www.nihr.ac.uk/news/new-voluntary-scheme-gps-speed-commercial-study-set), Clause 7 of this Appendix (Finance Schedule) is either:
		1. the PIC values specified in the interactive Costing Tool, where the only involvement of the NHS in the Study is PIC activity and hence no interactive Costing Tool (iCT) has been populated for the study and no NCVR national resource review concluded, or;
		2. the Finance Schedule generated by the iCT, where an NCVR national resource review has occurred (that is, all commercial contract research in the NHS other than that in which the only NHS involvement is PIC activity).
	3. Changes by either Party to the values specified in Clause 1.2.1 or 1.2.2 of this Appendix (as applicable), prior to the Effective Date of this Agreement, are not permitted under the terms of the [National Directive on Commercial Contract Research Studies](https://www.england.nhs.uk/publication/national-directive-on-commercial-contract-research-studies/), in England, and equivalent policy positions in each of the devolved administrations for PICs subject to NCVR.  For PICs not subject to NCVR, it is expected that the values specified at Clause 1.2.1 or 1.2.2 of this Appendix (as applicable) are provided by the Trial Site to the PIC as a recommended price and agreed between the Parties prior to execution of the Agreement.
		1. **[Delete if the PIC is not subject to NCVR]** In accordance with the above, the Trial Site represents and warrants that the Finance Schedule, incorporated into this Appendix by or on behalf of the Trial Site, is either an unmodified version of the Finance Schedule generated by the Localised Online iCT for this Study, following the conclusion of the study resource review, or reflects in unmodified form the PIC prices stated in the iCT current at time of execution of this Agreement.
	4. The Trial Site reserves the right to withhold payments to the PIC for activities conducted which were:
		1. not required by the Protocol; and / or
		2. conducted in breach of the Protocol.

## Invoicing and Value Added Tax (VAT)

* 1. Invoices will be based on the services performed and / or data monitored. Where possible, data will be confirmed as complete and evaluable in a timely manner by (or on behalf of) the Trial Site for the invoice period, prior to the raising of the invoice. No payment will be made (unless an automatic payment has been arranged) by or on behalf of the Trial Site until a valid invoice for the amount payable has been received.
	2. The first invoice is to be raised after contract execution. Subsequent invoices will be raised on a [monthly] [quarterly] [ad hoc] [other: insert as agreed between the Parties] **(DELETE THREE AND RETAIN ONE OPTION)** basis, with the final invoice raised in accordance with Clause 2.9 of this Appendix.
	3. The Parties agree to use the following method(s) to manage invoicing:
		1. **[OPTION 1 (delete if not applicable):** The Trial Site, or party acting on its behalf, will issue invoice requests, detailing visits and any additional procedures completed. The PIC shall invoice the Trial Site or its Agent in arrears upon receipt of an invoice request. **[Sub-Option (delete if not applicable):** This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		2. **[OPTION 2 (delete if not applicable):** The Trial Site or its Agent will liaise with the PIC to agree the value and content of invoices to be raised. **[Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].**]**
		3. **[OPTION 3 (delete if not applicable):** The Trial Site or its Agent will use a self-invoicing system to raise invoices on behalf of the PIC **[Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		4. **[OPTION 4 (delete if not applicable):** The Trial Site or its Agent will use an automated payment system to pay PIC. The PIC shall be paid according to the evidence provided within the automated payment system of costs incurred. [**Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to [**insert activities which will be invoiced using this method**]].]
		5. **[OPTION 5 (delete if not applicable):** The Trial Site or its Agent will delegate responsibility to manage invoicing to the PIC. The PIC will invoice the Trial Site, or party acting on its behalf, in arrears. [**Sub-Option (delete if not applicable)**: This Clause is effective for invoicing relating to **[insert activities which will be invoiced using this method**]].**]**

Payments will be made in arrears within forty-five (45) calendar days of the date of receipt of a valid invoice (excluding disputed amounts, which will be resolved in good faith in a timely manner in accordance with Clause 2.7 of this Appendix).

* 1. Valid invoices (and, if required due to a limit being in place on the amount of information able to be included on the invoice, supporting documents sent alongside the invoice to detail any further information required by this Clause) issued by the PIC shall:
		1. be valid tax invoices for the purposes of VAT legislation;
		2. identify the PIC and IRAS ID;
		3. contain a breakdown of prices per activity covering:
			1. set-up prices and
			2. Per Participant prices.
		4. clearly state the corresponding period being invoiced for any periodic prices;
		5. identify the purchase order number (if applicable) assigned to the PIC; and
		6. be sent to the Trial Site or its Agent at the email address provided below.
	2. The PIC’s failure to comply with the above invoice requirements may result in a delay in payment.
	3. Any delay in the payment of the payee invoices by or on behalf of the Trial Site will incur an interest charge on any undisputed amounts overdue of two (2) per cent per month above the National Westminster Bank plc base rate prevailing on the date the payment is due.
	4. If the Trial Site or its Agent disputes any invoice, or part of any invoice, or receives an invoice in respect of activities not provided in accordance with this Agreement, or which the Trial Site believes (acting reasonably) have not been properly provided, then the Trial Site or its Agent will make contact in a timely manner with the PIC’s finance team as per Clause 6.2 of this Appendix to resolve the query. If the query is not resolved, then the Trial Site or its Agent may either:
		1. withhold payment of the disputed part of the invoice in respect of the disputed amounts and / or activities, including an explanation as to why payment is withheld, in which case the PIC shall issue the Trial Site or its Agent with a credit note for the disputed amount and the Trial Site or its Agent will pay the undisputed amount in accordance with the Finances clause of this Agreement, or;
		2. reject the PIC’s invoice and request that the PIC submit a new invoice for the undisputed amount. On receipt of the new valid invoice, the Trial Site or its Agent shall pay the new invoice in accordance with the Finances clause of this Agreement.
	5. The Trial Site or its Agent will notify the PIC of termination of this Agreement, in order to trigger the generation of a final invoice. Notification will be made to: [insert email address].
	6. Upon termination of this Agreement, all remaining amounts due shall be invoiced as per the terms detailed in this Financial Arrangements Appendix.
	7. The Trial Site or its Agent shall promptly respond to any reasonable request for invoicing data received from the PIC for the purposes of the final invoice, provided that the request is received within forty-five (45) days of the notification of termination of the Agreement.
	8. **Longstop Dates**
	It is agreed that the Trial Site shall not be required to make payment for any amounts that the PIC fails to notify the Trial Site of within sixty (60) calendar days of the Trial Site providing the final invoicing information (if requested), in accordance with Clause 2.10 of this Appendix, or sixty (60) calendar days from termination of this Agreement, if invoicing information is not requested (“**Longstop Dates**”). For the avoidance of doubt these notifications should be in accordance with table 6.1, and it is not an obligation for the Trial Site to pay invoices dated after the Longstop Date. Notwithstanding the above, this Clause does not take effect until any dispute regarding invoicing in line with Clause 2.7 of this Appendix is resolved.
	9. The final invoice payment may be held by the Trial Site or its Agent until all outstanding queries have been resolved.
	10. All figures in the Finance Schedule are INCLUSIVE of all indirect costs, capacity building and PIC specific multipliers. All figures include all relevant taxes EXCEPT VAT which should be added to invoices where applicable.

## Pass-through Payments

* 1. It shall be the responsibility of the PIC to make any appropriate agreed pass-through payments, to other Agents of the PIC.

## Inflation

* 1. Adjustment to the Finance Schedule to account for inflation (**“Adjustment”**) may be undertaken, at PIC request or as initiated by the Trial Site, a minimum of two years (twenty-four consecutive months) from the Effective Date of the Agreement and thereafter every twelve months.
		1. The prices presented in the revised Finance Schedule, accounting for inflation, will be the prices generated by the interactive Costing Tool (iCT) on the day agreed by the Parties and the revised prices will be applied to all Study payments made as a result of the first and any subsequent invoices following execution of contract variation.
		2. The revised iCT Finance Schedule generated on the day agreed, will be provided by the Trial Site to the PIC and incorporated into this Agreement, with subsequent invoices reflecting the uplifted Finance Schedule, subject to Clause 4.1.1 of this Appendix.
		3. For the avoidance of doubt, a contract variation in line with Clause 6.1 of this Agreement is required to update the prices in the Finance Schedule to take account of inflation.

## Set-up Fees

* 1. The one-off payments described in the tables under Clause 7.1 of this Appendix (Set-up Fees) are non-refundable and will be payable upon execution of the Agreement (unless otherwise noted in the Task Breakdown).
	2. The Trial Site or its Agent will make payments to the PIC for prices incurred by any regulatory inspection triggered by actions outside of the PIC’s control.

## Payment Details

* 1. Invoices should be sent to the following invoice address:

|  |  |
| --- | --- |
| Job title: | *[insert relevant details]* |
| Address:(If this address is in the UK, VAT should be added to the invoice at the appropriate rate) | *[insert relevant details]* |
| Reference on Invoice: | *[insert relevant details]* |
| Telephone No:  | *[insert relevant details]* |
| Email: | *[insert relevant details]* |
| Contact for escalation: (**OPTIONAL** – remove if not applicable) | *[insert generic email address]* |

The preferred method for sharing the invoice is [post] [email]. **(delete one option)**

* 1. Invoicing requests and invoicing queries to PIC should be sent to:

|  |  |
| --- | --- |
| Job title: | *[insert relevant details]* |
| Address: | *[insert relevant details]* |
| Reference on Invoice: | *[insert relevant details]* |
| Telephone No:  | *[insert relevant details]* |
| Email: | *[insert relevant details]* |

The preferred method for sharing the invoicing requests and invoicing queries is [post] [email]. **(delete one option)**

* 1. Payments by the Trial Site or its Agent will be made by BACS to:

|  |  |
| --- | --- |
| Bank: | *[insert relevant details]* |
| Bank Address: | *[insert relevant details]* |
| Account Name: | *[insert relevant details]* |
| Account No: | *[insert relevant details]* |
| Sort Code: | *[insert relevant details]* |
| Swift Code: | *[insert relevant details]* |
| IBAN No: | *[insert relevant details]* |
| VAT Code: | *[insert relevant details if applicable or mark as Not Applicable]* |
| Payee Reference:(Recommend that IRAS ID is used) | *[insert relevant details]* |
| Email for remittance:(Delete row if this is the same email address provided in Clause 9.2) | *[insert relevant details]* |

## Finance Schedule

[The Trial Site or its Agent should insert here the Finance Schedule generated from the site-level Localised Online iCT relevant to this PIC, following completion of iCT study resource review (where applicable) and prior to sharing this Agreement with the PIC for contract execution. Modifications to the Finance Schedule generated by the Localised Online iCT are not permitted for studies within the scope of National Contract Value Review. **DELETE THIS GUIDANCE FOLLOWING INSERTION OF FINANCE SCHEDULE**]

* 1. **Set-up Fees**

[Insert relevant content in the Set-up, Management and Close-Down Fees section of the Localised Online iCT export here.]

**FINAL PAGE**