# Organisation Information Document (Data Processing Agreement ONLY) – Non-commercially sponsored projects

**(Template version: 1.2 March 2024)**

## Guidance on using this document

Article 28 (3) of the General Data Protection Regulation (GDPR) requires that processing undertaken by a Processor on behalf of a Controller “shall be governed by a contract […]”. In response to this requirement, the model Non-Commercial Agreement (mNCA) has been updated to include GDPR compliant data processing clauses. The non-commercial Organisation Information Document includes the same data processing clauses, allowing them to be invoked when used as the contract with the Participating NHS / HSC Organisation (that is, for studies other than clinical trials and clinical investigations). This document is intended for use as the data processing agreement between Sponsor and Participating NHS / HSC Organisation where neither a mNCA or Organisation Information Document are appropriate (that is, for use between University Sponsor and Participating NHS / HSC Organisation, which share a Joint Research Office and hence do not need to use the Local Information Pack to set up their ‘own’ organisation, for studies that are not clinical trials or clinical investigations).

## Study Information

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| **1. IRAS Project ID** | Enter IRAS Project ID |
| **2. Full Title of the Study** | Enter full title of study |
| 3. Name of Participating NHS / HSC Organisation (for example Trust or Board – hereafter known as Participating NHS / HSC Organisation or one of the Parties):Please enter the name of the Participating NHS Organisation here prior to agreement. | Enter name of participating NHS / HSC Organisation  |
| 4. Name of Sponsor (for example higher education institution – hereafter known as Sponsor or one of the Parties):Please enter the name of the Sponsor prior to agreement. | Enter name of sponsor |

In respect of the above-named Study the above-named Parties agree as follows.

1. The above-referenced Protocol, including appropriately made amendments thereto, is hereby incorporated into this Agreement by reference in this clause. Should there be any inconsistency between the Protocol and the terms of this Agreement, the terms of this Agreement shall prevail to the extent of such inconsistency.
2. For the purposes of the Data Protection Legislation, the Sponsor is the Controller and the Participating NHS / HSC Organisation is the Sponsor's Processor in relation to all Processing of Personal Data that is Processed for the purpose of this Study and for any future research use under the Controllership of the Sponsor, that would not have taken place but for this Agreement regardless where that Processing takes place.
3. The Parties acknowledge that whereas the Sponsor is the Controller in accordance with Clause 2, the Participating NHS / HSC Organisation is the Controller of the Personal Data collected for the purpose of providing clinical care to the 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 Participating NHS / HSC Organisation.
4. Where the Participating NHS / HSC Organisation is the Sponsor's Processor and thus where the Processing is undertaken by the Participating NHS / HSC Organisation for the purposes of the Study, Clauses 5 to 9 below will apply. For the avoidance of doubt, such Clauses do not apply where the Participating NHS / HSC Organisation is Processing the Participant Personal Data as a Controller.
5. The Participating NHS / HSC Organisation agrees only to Process Personal Data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the Study and to ensure the Sponsor’s compliance with the Data Protection Legislation.
6. The Participating NHS / HSC Organisation 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 Article 28(1);
	2. to not engage another Processor without the prior written authorisation of the Sponsor (Article 28(2));
	3. to Process the Personal Data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Participating NHS / HSC Organisation shall notify the Sponsor before Processing, or as soon as possible after Processing if legislation requires that the Processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a));
	4. to ensure that personnel authorised to Process Personal Data are under confidentiality obligations (Article 28(3b));
	5. to take all measures required by Article 32 GDPR in relation to the security of Processing (Article 28(3c));
	6. to respect the conditions described in Article 28(2) and (4) for engaging another Processor (Article 28(3d));
	7. to, taking into account the nature of the Processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (Article 28(3e));
	8. to assist the Controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the Processing and the information available to the Participating NHS / HSC Organisation (Article 28(3f));
	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 (Article 28(3g)) or where that Personal Data is held by the Participating NHS / HSC Organisation as Controller for the purpose of clinical care or other legal purposes; and
	10. to maintain a record of Processing activities as required by Article 30(2) GDPR.
7. The Participating NHS / HSC Organisation 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 Participating NHS / HSC Organisation’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.
8. The Participating NHS / HSC Organisation agrees to:
	1. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Participating NHS / HSC Organisation’s compliance with the obligations described by this Agreement, Data Protection Legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the Participating NHS / HSC Organisation and / or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and
	2. obtain prior agreement of the Sponsor to store or Process Personal Data outside the UK and European Economic Area.
9. Where the Participating NHS / HSC Organisation 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.
10. In this Agreement the following words shall 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 or equivalent individual, any nurse or other health professional), any such person’s principal employer in the event it is not the Participating NHS / HSC Organisation 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;
* **Controller**
shall have the meaning set out in the Data Protection Legislation (and "Controllership” shall be construed accordingly);
* **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;
* **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 refer to those recruited by or under the care of the Participating NHS / HSC Organisation for the purpose of 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 the Data Protection Legislation and which relates to any actual or potential Participant or their treatment or medical history;
* **Process**
as defined in the Data Protection Legislation (and "Processing" and "Processed" shall be construed accordingly);
* **Processor**
shall have the meaning set out in the Data Protection Legislation;
* **Protocol**
the full description of the Study, together with any amendments thereto in line with Clause 1 of this Agreement, and incorporated into this Agreement by reference;
* **Pseudonymised Data**
individual-level data relating to a Participant (as opposed to aggregated data) who is made no longer identified or identifiable to the recipient of 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;
* **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) Party to this Agreement, that takes responsibility for the initiation, management and financing (or arranging the financing) of the Study;
* **Study**
the research project that is the subject of this Agreement;
1. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

**Authorisation**

**Authorised on behalf of Sponsor by:**

|  |  |
| --- | --- |
| **Name** | Enter name |
| **Job Title** | Enter job title |
| **Organisation Name** | Enter organisation name |
| **Date** | Enter date |

**Authorised on behalf of Participating NHS / HSC Organisation by:**

|  |  |
| --- | --- |
| **Name** | Enter name |
| **Job Title** | Enter job title |
| **Organisation Name** | Enter organisation name |
| **Date** | Enter date |