

1. General.

- 1.1 The Volunteer Physician will act on behalf of the Study Site, and will Process Personal Data in accordance with the study Protocol for the Project entitled 'The Health and Occupational Research Network (THOR).
- 1.2 By acknowledging to these terms, the Volunteer Physician on behalf of the Study Site agree that it will adhere to and is governed by and subject to the national laws and regulations of the Study Site.

2. Confidentiality and Data Protection

Confidentiality

- 2.1 The Study Site agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality).
- 2.2 The STUDY SITE 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 University of Manchester and The University of Manchester agrees to treat Personal Data and confidential patient information as Confidential Information.

Data Processing Terms

- 2.3 For the purposes of the relevant data protection legislation, The University of Manchester is the Controller and the STUDY SITE is the 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 Controllorship of The University of Manchester, that would not have taken place but for this Agreement regardless where that Processing takes place.
- 2.4 The Study Site acknowledges that whereas The University of Manchester is the Controller, the Study Site is also a 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 Controllorships of The University of Manchester and STUDY SITE.
- 2.5 Where the STUDY SITE is The University of Manchester's Processor and thus where the Processing is undertaken by the STUDY SITE for the purposes of the Study, Clauses 2.6 to 2.10 below will apply. For the avoidance of doubt, such Clauses do not apply where the STUDY SITE is Processing the Participant Personal Data as a Controller.
- 2.6 The STUDY SITE agrees only to Process Personal Data for and on behalf of The University of Manchester in accordance with the instructions of The University of Manchester and for the purpose of the Study and to ensure The University of Manchester's compliance with the Data Protection Legislation.

- 2.7 The STUDY SITE agrees to comply with the obligations applicable to Processors described by Article 28 GDPR including, but not limited to, the following:
- 2.7.1 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);
 - 2.7.2 to not engage another Processor without the prior written authorisation of The University of Manchester (GDPR Article 28(2));
 - 2.7.3 to Process the Personal Data only on documented instructions from the The University of Manchester unless required to do otherwise by legislation, in which case the STUDY SITE shall notify The University of Manchester 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));
 - 2.7.4 to ensure that personnel authorised to Process Personal Data are under confidentiality obligations (GDPR Article 28(3)(b));
 - 2.7.5 to take all measures required by GDPR Article 32 in relation to the security of processing (GDPR Article 28(3)(c));
 - 2.7.6 to respect the conditions described in GDPR Article 28(2) and (4) for engaging another Processor (GDPR Article 28(3)(d));
 - 2.7.7 to, taking into account the nature of the Processing, assist The University of Manchester, 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));
 - 2.7.8 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 STUDY SITE (GDPR Article 28(3)(f));
 - 2.7.9 to, at the choice of The University of Manchester, destroy or return all Personal Data to The University of Manchester 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 STUDY SITE as Controller for the purpose of clinical care or other legal purposes; and
 - 2.7.10 to maintain a record of Processing activities as required by GDPR Article 30(2).
- 2.8 The STUDY SITE shall ensure that:
- 2.8.1 its Agents do not Process Personal Data except in accordance with these terms (and in particular the Protocol);

- 2.8.2 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:
- a. are aware and comply with the STUDY SITE's duties under this clause;
 - b. 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
 - c. 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.

2.9 The STUDY SITE agrees to:

- 2.9.1 allow The University of Manchester(s) or another auditor appointed by The University of Manchester(s) to audit the STUDY SITE'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 University of Manchester complying with all relevant health and safety and security policies of the STUDY SITE and/or to provide The University of Manchester with evidence of its compliance with the obligations set out in this Agreement; and
- 2.9.2 obtain prior agreement of The University of Manchester to store or Process Personal Data outside of the UK and the European Economic Area.

Data Sharing Terms

- 2.10 Personal Data shall not be disclosed to The University of Manchester by the STUDY SITE, 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.
- 2.11 The University of Manchester agrees to comply with the obligations placed on a Controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to Processing of Personal Data (GDPR Article 5).
- 2.12 The University of Manchester agrees to ensure persons processing Personal Data under this Agreement are equipped to do so respectfully and safely. In particular:

- 2.12.1 to ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the STUDY SITE) 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;
 - 2.12.2 to ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the STUDY SITE) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
- 2.13 The University of Manchester agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular to:
- 2.13.1 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;
 - 2.13.2 ensure all access to Personal Data on IT systems processed for Study purposes can be attributed to individuals;
 - 2.13.3 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;
 - 2.13.4 adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;
 - 2.13.5 take action immediately following a data breach or near miss.
- 2.14 The University of Manchester agrees to ensure data are processed using secure and up to date technology. In particular, to:
- 2.14.1 ensure no unsupported operating systems, software or internet browsers are used to support the processing of Personal Data for the purposes of the Study;
 - 2.14.2 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;
 - 2.14.3 ensure IT suppliers are held accountable via contracts for protecting Personal Data they Process and for meetings all relevant information governance requirements.