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# DATA SHARING AGREEMENT

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## Between

THE UNIVERSITY OF BIRMINGHAM

## and

## **THE UNIVERSITY OF BIRMINGHAM**

 **DATA SHARING AGREEMENT**

**THIS DATA SHARING AGREEMENT** is made the       day of            2019 between

1. **THE UNIVERSITY OF BIRMINGHAM**, established by Royal Charter No: RC000645, having its principal office at Edgbaston, Birmingham B15 2TT, (the “University”); and
2. , having offices at       (the “Collaborating Institution”)

**WHEREAS,**

1. The Collaborating Institution has agreed to transfer and grant the University access to the Data as detailed in Schedule 1 for the purpose of collaborative research and publication upon the terms and conditions.

**NOW, THEREFORE,** it is hereby agreed as follows:

1. **DEFINITIONS**

**Agreement** means this agreement, its schedules and any other documents attached to, or referred to as forming part of this Agreement;

**Confidential Information** Means all and any information, documents, data and opinions disclosed by a Party to the other Party (or otherwise acquired by one Party pursuant to this Agreement) including without limitation commercial, financial or proprietary material, pricing information, inventions, formulations, compositions of matter, data, know-how, formulae, algorithms, processes, operating methods and procedures, results, designs, drawings, specifications, industrial and or intellectual property, computer programmes or other software and any other information relating to the Study whether in oral, written, electronic, graphic or digitised format; or disclosed pursuant to discussions with any of the officers, employees, students, honorary members of staff, agents, advisors or consultants of a Party and whether or not marked or indicated as confidential; information of whatever nature relating to the Study or business or properties of a Party obtained by observation during visits to its premises or those of any third party instructed, engaged, or retained in any way whatsoever by a Party; and analyses, compilations, studies and other documents prepared by the Parties, their officers, employees, students, honorary members of staff, agents, advisors or consultants which contain or otherwise reflect or are generated from the information specified in this clause; and samples, prototypes or models relating to the Study;

**Effective Date** Means the date of which the last signature is obtained;

**ESCP collaborators** Means all hospital site personnel taking part in the ESCP 2019 MASC audit;

ESCP Committee Means European Society of Coloproctology Audit Committee;

**Intellectual Property Rights** Means patents, inventions, registered designs, copyrights, database rights, domain names, design rights, copyright, rights affording equivalent protection to copyright, database rights, design rights, topography rights, trademarks, service marks, business names, trade names, moral rights, registration of or an application to register any of the aforesaid items, and rights in the nature of any of the aforesaid items in any country, rights in the nature of unfair competition rights and rights to sue for passing off;

**Privacy Laws** means all privacy laws applicable to the parties, including the Data Protection Act 2018 and the Privacy and Electronic Communications (EC Directive) Regulations 2003, together with all subordinate legislation, directions of any competent privacy regulator, common law decisions, relevant regulatory guidance and codes of practice, or re-enactment thereof and the equivalent of any of the foregoing in any relevant jurisdiction;

**Processed Data** means any derivatives of the Collaborating Institution’s Data including but not limited to results of the Study;

**REDCap**  REDCap is a secure web application for building and managing online surveys and databases hosted by the University of Birmingham for the Birmingham Surgical Trials Consortium;

**Study** European Society of Coloproctology 2019 Audit - Management of Acute Severe Ulcerative Colitis (MASC);

**Data** means any information, personal data and data provided by the Collaborating Institution to the University for the Study set out in Schedule 1 as amended from time to time by the Collaborating Institution and any modifications, deletions or expansions approved in writing by the Collaborating Institution.

1. **COMMENCEMENT**

This Agreement shall commence on the Effective date and continue for a period of 24 (twenty-four) months, (Duration Period) subject to clause 9.

1. **DATA PROTECTION**

 Should either party share personal data, Parties agree to comply with its obligations as set out in Schedule 2 (Data Protection) of this Agreement.

1. **COLLABORATING INSTITUTION OBLIGATIONS**

4.1 The Collaborating Institution shall provide the University with Data together with such information as the University may reasonably need for the purpose of carrying out the analysis anticipated under the Study as set out in Schedule 1.

4.2 The Collaborating Institution confirms that the Data has been collected with necessary informed consents of patients, or their representatives where applicable, and in accordance with all privacy laws.

4.3The Collaborating Institution confirms that the Data has been anonymised and necessary precautions are taken when inputting the data.

**5. UNIVERSITY OBLIGATIONS**

5.1 The University shall ensure that any employees, students, consultants, collaborators, sub-contractors or agents (together referred to as Personnel) that may process the Data shall;

5.1.1 process the Data solely for the Study in accordance with this Agreement and written instructions as given reasonably by the Collaborating Institution from time to time;

5.1.2 comply with all applicable laws and regulations, as amended form time to time, with the respect to the collection, use, storage and disclosure of any Data;

5.1.3 not to disclose Data to any third party without the prior written consent of the Collaborating Institution (excluding ESCP collaborators and the ESCP Committee).

5.2 Where anonymized data is transferred to the University under this Agreement, no effort will be made to de-anonymise the data set; no attempt will be made to learn the identity of, or other identifying information about the patients who provided data and no effort will be made to re-identify data that are de-identified.

5.3 The University shall ensure that only those Personnel who are required to access the Data in order to meet its obligation under this Agreement will have access to the Data and that those Personnel have undertaken appropriate training regarding and comply with Privacy Laws.

**6. CONFIDENTIALITY**

6.1 Each party shall treat as confidential the terms of this Agreement, the Data and either party’s Confidential Information which it may receive or derive as a result of this Agreement and shall not disclose to any person, or allow any other person to use, such information other than as permitted by this Agreement.

6.2 Each party shall be entitled to disclose the information referred to in this Confidentiality clause to its professional advisers strictly on a 'need to know' basis and provided such professional advisers are under a binding duty of confidence.

6.3 The obligations of this Confidentiality clause shall not apply to information which:

6.3.1 is in the public domain other than as a result of breach of this Agreement; or

6.3.2 is proved by documentary evidence to the satisfaction of the disclosing party as being at the time of the Agreement already lawfully in the possession of the receiving party; or

6.3.3 is properly received by the receiving party from a third party who is rightfully in possession of such Confidential Information and who is not bound by any obligation of confidence or secrecy; or

6.3.4 is proved by contemporaneous documentary evidence as having been independently developed by the receiving party with no knowledge of the Confidential Information; or

6.3.5 is required to be disclosed by law, court order or a government agency.

PROVIDED THAT clauses 6.3.1 to 6.3.4 shall not apply to Data.

6.4 If a Party receives a request under the Freedom of Information Act 2000 or the Environmental Information Regulations 2004 to disclose any of the other Party's Confidential Information, it will send a notice to the other Party together with a copy of the statutory request. The other Party will respond within ten (10) days after receiving such notice as to whether it considers that a statutory exemption applies to the statutory request. If that Party does state that an exemption applies the recipient party shall use its reasonable endeavours to ensure that such exemption does apply to the Confidential Information requested.

6.5 The obligations of the Parties under this Agreement shall continue in force, for a period of 5 years from the termination date.

**7. LIABILITY**

7.1 No Party makes any representation or warranty that advice or information given by any of its employees, students, agents or appointees who work on the Study, or the content or use of any materials, works or information provided in connection with the Study, will not constitute or result in infringement of third-party rights.

7.2 No Party accepts any responsibility for any use which may be made of any work carried out under or pursuant to this Agreement, or of the results of the Study, nor for any reliance which may be placed on such work or results, nor for advice or information given in connection with them.

7.3 The liability of any Party for any breach of this Agreement, or arising in any other way out of the subject-matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.

7.4 The Parties acknowledge that damages will not normally be an adequate remedy for breach of any of the terms set out in this Agreement and that the Disclosing Party should be entitled to apply for equitable relief including injunctions in respect of any breach by the Receiving Party.

**8. INTELLECTUAL PROPERTY**

8.1 To the extent that the Collaborating Institution is permitted to grant such rights, and subject to clause 7.1 and 7.2, the Collaborating Institution grants to the University a non-exclusive, non-transferable licence to use the Data for non-commercial research as specifically described within Schedule 1 for the Duration Period.

8.2 This Agreement does not affect the ownership of any Intellectual Property Rights in the Data and the Intellectual Property Rights in them will remain the property of the Collaborating Institution. No licence to use any intellectual property is granted or implied by this Agreement except the rights expressly granted in this Agreement.

**9. PUBLICATION**

9.1 The University and the ESCP Committee having jointly agreed the conclusions of the Study shall be permitted to publish the results of the Study, which they have undertaken in accordance with normal academic practice. Authorship shall be in accordance with usual practice for ESCP audits as set out in section M of the Study, attached as Schedule 1 of this agreement.

**10. TERMINATION**

10.1 In the event that any Party shall commit any breach of or default in any terms or conditions of this Agreement, the non-defaulting Party may terminate this Agreement by giving ninety (90) days’ written notice to the other Party of its intention to terminate the defaulting Party in addition to any other remedies which they may have at law or equity. The notice shall include a detailed statement describing the nature of the breach. If the breach is capable of being remedied and is remedied within the ninety day period, then the termination shall not take effect. If the breach is of a nature that it can be fully remedied but not within the ninety days period then termination shall not be effective if the defaulting Party begins to remedy the breach within the notice period and continues diligently to remedy it until it is fully remedied. If the breach is incapable of remedy then the notice shall take effect at the end of the ninety day period in any event.

10.2 If any Party passes a resolution for its winding-up; or if a court of competent jurisdiction makes an order for that Party’s winding-up or dissolution; or makes an administration order in relation to that Party; or if any Party appoints a receiver over, or an encumbrancer takes possession of or sells an asset of, that Party; or makes an arrangement or composition with its creditors generally; or makes an application to a court of competent jurisdiction for protection from its creditors generally; this Agreement will terminate forthwith.

10.3 On termination or expiry of this Agreement howsoever caused, the University shall immediately expunge the Data from their computer systems and shall destroy any written records with regard to the Data such the University no longer hold any records with regard to the Data whether written, computerised or in any other form whatsoever.

**11. MISCELLANEOUS**

11.1 No failure to exercise or delay in the exercise of any right or remedy which any Party may have under or in connection with this Agreement shall operate as a waiver thereof, and nor shall any single or partial exercise of any such right or remedy prevent any further or other exercise thereof or any other such right or remedy.

11.2 This Agreement is personal to the Parties and neither Party shall assign, charge or otherwise transfer any rights or obligations under this Agreement, without the prior written consent of the other Party.

11.3 A person who is not a party to this Agreement shall not be entitled to benefit or have any rights to enforce any of its provisions and the Contracts (Rights of Third Parties) Act 1999 shall not apply.

11.4 Any notice to be given under this Agreement shall be in writing and shall be sent by first class mail or air mail to the relevant address of the relevant Party as set out below, or such other address as that Party may from time to time notify to the other Party in accordance with this Clause. Notices sent as above shall be deemed to have been received three working days after the day of posting (in the case of inland first class mail), or seven working days after the date of posting (in the case of air mail).

In the case of notices to the University, send to:

Director of Research Support Services,

University of Birmingham

Edgbaston

Birmingham

B15 2TT

United Kingdom

In the case of notices to the Collaborating Institution send to:

…………… ……………………………………

11.5 References to any statutory provision, enactment, order, regulation or other similar instrument shall be construed as a reference to the statutory provision, enactment, order, regulation or instrument (including any EU instrument) as amended, replaced, consolidated or re–enacted from time to time and shall include any orders, regulations, codes of practice, instruments or other subordinate legislation made under it. 11.6 To the extent a provision or section of this Agreement is invalid, unenforceable whether in whole or in part, the remaining provisions or sections of this Agreement shall remain unaffected.

11.7 If any dispute arises in connection with this Agreement it shall be notified in writing by one Party to the other. An initial meeting between such senior officers each Party nominates shall be held within 30 days of receipt of notice solely in order to negotiate in good faith to resolve the matter in dispute. If the dispute cannot be settled by the nominated senior officers, the Vice Chancellor of the University and the Vice Chancellor of the Collaborating Institution, with the authority to settle the matter, shall meet promptly to try and resolve the dispute

11.8 The construction, validity and performance of this Agreement shall be governed by English Law and the Parties submit to the exclusive jurisdiction of the courts of England.

**IN WITNESS WHEREOF the parties have executed this agreement the day and year first written above.**

For and on behalf of **THE UNIVERSITY OF BIRMINGHAM**

Signature: ...............................................................................................

Name: .....................................................................................................

Title: .......................................................................................................

Date: .......................................................................................................

For and on behalf of

Signature: ...............................................................................................

Name: .....................................................................................................

Title: .......................................................................................................

Date: .......................................................................................................

**SCHEDULE 1**

MASC Study Protocol



**SCHEDULE 2**

1. DATA PROTECTION

1. DEFINITIONS

In this Schedule 2 the following definitions shall apply:

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| --- | --- |
| **"Controller", "Processor" "Data Subject" and "Data Protection Officer"** | shall have the meaning given to those terms in the applicable Data Protection Laws; |
| **"Data Protection Laws"** | means (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the Processing of Personal Data to which a Party is subject, including the Data Protection Act 2018 ("**DPA**") and EC Directive 95/46/EC (the "**DP** **Directive**") (up to and including 24 May 2018) and on and from 25 May 2018, the GDPR and all legislation enacted in the UK in respect of the protection of personal data; and (b) any code of practice or guidance published by the ICO (or equivalent regulatory body) from time to time; |
| "**Data Processing Particulars**" | means, in relation to any Processing under this Agreement:(a) the subject matter and duration of the Processing;(b) the nature and purpose of the Processing;(c) the type of Personal Data being Processed; and(d) the categories of Data Subjects;as set out in Appendix A.  |
| **"Data Subject Request"** | means an actual or purported request or notice or complaint from or on behalf of a Data Subject exercising his rights under the Data Protection Laws in relation to Personal Data including without limitation: the right of access by the Data Subject, the right to rectification, the right to erasure, the right to restriction of processing, the right to data portability and the right to object; |
| **"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 repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119/1, 4.5.2016; |
| "**ICO**" | means the UK Information Commissioner's Office, or any successor or replacement body from time to time;  |
| "**ICO Correspondence**" | means any correspondence or communication (whether written or verbal) from the ICO in relation to the Processing of Personal Data;  |
| **"Losses"** | means all losses, fines, penalties, liabilities, damages, costs, charges, claims, amounts paid in settlement and expenses (including legal fees (on a solicitor/client basis), disbursements, costs of investigation (including forensic investigation), litigation, settlement (including ex gratia payments), judgment, interest and penalties), other professional charges and expenses, disbursements, cost of breach notification including notifications to the data subject, cost of complaints handling (including providing data subjects with credit reference checks, setting up contact centres (e.g. call centres) and making ex gratia payments), all whether arising in contract, tort (including negligence), breach of statutory duty or otherwise; |
| **"Personal Data"** | means any personal data (as defined in the Data Protection Laws) Processed by either Party in connection with this Agreement, and for the purposes of this Agreement includes Sensitive Personal Data (as such Personal Data is more particularly described in Appendix A (*Data Processing Particulars*)); |
| **"Personal Data Breach"** | has the meaning set out in the Data Protection Laws and for the avoidance of doubt, includes a breach of Paragraph (c); |
| **"Processing"** | has the meaning set out in the Data Protection Laws (and "**Process**" and "**Processed**" shall be construed accordingly); |
| "**Security Requirements**" | means the requirements regarding the security of Personal Data, as set out in the Data Protection Laws (including, in particular, the seventh data protection principle of the DPA and/ or the measures set out in Article 32(1) of the GDPR (taking due account of the matters described in Article 32(2) of the GDPR)) as applicable; |
| **"Sensitive Personal Data"** | means Personal Data that reveals such special categories of data as are listed in Article 9(1) of the GDPR; and |
| "**Third Party Request**" | means a written request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by law or regulation.  |

2. DATA PROTECTION

2.1Nature of the Processing

2.1.1 The Parties acknowledge that the factual arrangements between them dictate the role of each Party in respect of the Data Protection Laws. Notwithstanding the foregoing, each Party agrees that the nature of the Processing under this Agreement will be as follows:

1. the Parties shall each Process the Personal Data;
2. each Party shall act as a Controller in respect of the Processing of the Personal Data on its own behalf and in particular each shall be a Controller of the Personal Data acting individually and in common, as follows:
3. The University shall be a Controller where it is Processing Personal Data of patients from REDCap or the purpose set out in Schedule 1 (MASC Protocol)and
4. The Collaborating Institute shall be a Controller where it is Processing Personal Data of patients onto REDCap for the purpose set out in Schedule 1.
5. Notwithstanding Paragraph 2.1.1, if either Party is deemed to be a joint Controller with the other in relation to the Personal Data, the Parties agree that they shall be jointly responsible for the compliance obligations imposed on a Controller by the Data Protection Laws, and the Parties shall cooperate to do all necessary things to enable performance of such compliance obligations, except that each Party shall be responsible, without limitation, for compliance with its data security obligations set out in Paragraph 2.2.2(e) where Personal Data has been transmitted by it, or while Personal Data is in its possession or control.

2.1.2 Each of the Parties acknowledges and agrees that Appendix A (*Data Processing Particulars*) to this Agreement is an accurate description of the Data Processing Particulars.

**2.2Data Controller Obligations**

2.2.1 Each Party shall in relation to the Processing of the Personal Data comply with its respective obligations under the Data Protection Laws.

2.2.2 Without limiting the generality of the obligation set out in Paragraph 0, in particular, each Party shall:

* + - 1. where required to do so make due notification to the ICO;
			2. ensure it is not subject to any prohibition or restriction which would:
				1. prevent or restrict it from disclosing or transferring the Personal Data to the other Party as required under this Agreement;
				2. prevent or restrict it from granting the other Party access to the Personal Data as required under this Agreement; or
				3. prevent or restrict either Party from Processing the Personal Data, as envisaged under this Agreement;
			3. ensure that appropriate technical and organisational security measures are in place sufficient to comply with obligations imposed on the Controller by the Security Requirements.

and where requested provide to the University evidence of its compliance with such requirements promptly, and in any event within forty-eight (48) hours of the request;

* + - 1. use reasonable endeavours to notify the other Party if it is obliged to make a disclosure of any of the Personal Data under any statutory requirement, such notification to be made in advance of such disclosure or immediately thereafter unless prohibited by law;
			2. notify the other Party in writing without undue delay and, in any event, within twenty-four (24) hours of it becoming aware of any actual or suspected Personal Data Breach in relation to the Personal Data received from the other Party and shall, within such timescale to be agreed by the Parties (acting reasonably and in good faith):
				1. implement any measures necessary to restore the security of compromised Personal Data; and
				2. support the other Party to make any required notifications to the ICO and/or other equivalent relevant Regulator and affected Data Subjects;
			3. take reasonable steps to ensure the reliability of any of its personnel who have access to the Personal Data;
1. **INDEMNITY**

3.1 Both Parties shall indemnify on demand and keep indemnified the other Party from and against all and any Losses that are sustained, suffered or incurred by, awarded against or agreed to be paid by the other Party to the extent arising from the first Party's breach of its obligations under this Schedule 2 (Data Protection) and/or failure to comply with the Data Protection Laws, including, in particular all Losses resulting from:

3.1.1 any monetary penalties or fines levied by the ICO on the other Party;

3.1.2 the costs of an investigative, corrective or compensatory action required by the ICO, or the defence of a proposed or actual enforcement taken by the ICO;

3.1.3 any Losses suffered or incurred by, awarded against, or agreed to be paid by the other Party pursuant to a claim, action or challenge made by a third party to or against the other Party (including by a Data Subject); and

3.1.4 except to the extent covered by Paragraphs  3.1.1 or 3.1.2 3.1.3, any Losses suffered or incurred, awarded against or agreed to be paid by the other Party.

3.2 Nothing in this Agreement shall exclude or limit a Party's liability under this Paragraph 3.

Appendix A

Data Protection Particulars

|  |  |
| --- | --- |
| **The subject matter and duration of the Processing** | Subject matter: The Processing of Personal Data including Clinical data, Diagnostic procedures, Medical treatment, Progress details, Operative details and Endpoint variables.Duration: 24 (Twenty four) months from the effective date. |
| **The nature and purpose of the Processing** | The primary objective is to explore differences in patients, diagnostic procedures, medical treatment, surgical techniques and outcomes across non-operated and operated patients with ASUC to identify areas of practice variability resulting in apparent differences in outcome warranting further study.Patient Data will be collected using REDCap electronic data capture tools on the Birmingham Surgical Trials Consortium (BiSTC) REDCap system hosted at the University of Birmingham. Collaborating Institutions will have individual password-protected access to their unit’s data entered on to REDCap. During the running of the audit, only local data will be visible to investigators; other sites’ data will not be accessible.In order to facilitate entry of follow-up data, investigators will need a way to link REDCap records to patient records. This can be achieved by keeping a password protected spreadsheet containing a look-up table. |
| **The type of Personal Data being Processed** | Collaborating Institutions to provide anonymised data. Data uploaded onto REDCap by Collaborating Institutions may contain: demographic details, clinical data, diagnostic procedures, medical treatment, progress details, and operative detailsData received by the University is anonymised |
| **The categories of Data Subjects** | The Personal Data concerns Data Subjects who are adults hospitalized for severe acute ulcerative colitis classified, of any sex. |

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