

BRADFORD INSTITUTE FOR HEALTH RESEARCH:

DATA SHARING CONTRACT

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| **Providing Organisation** | Bradford Institute for Health Research  Bradford Teaching Hospitals NHS Foundation Trust  Bradford Royal Infirmary  Duckworth Lane  Bradford  BD9 6RJ |
| **Receiving Organisation** | Organisation name and address |

Each a “Partner Organisation” and collectively the “Partner Organisations”.

## Purpose of Contract

This Data Sharing Contract (either “the Contract” or “the Data Sharing Contract”) establishes an undertaking by the above-named Receiving Organisation to abide by a code of conduct regarding the management of any patient or other person Data shared or received by the organisation in pursuance of research projects or other approved programmes that are supported by the Bradford Institute for Health Research based at Bradford Teaching Hospitals NHS Foundation Trust (the Providing Organisation).

Each data sharing arrangement will require a separate Data Sharing Agreement which describes the data to be shared under the terms and conditions of this Data Sharing Contract (the “Data”) and other Data specific details and controls as described at clause 9 below.

The purpose of this Contract is to:

* Clarify the responsibilities of the Partner Organisations in relation to the Data
* Ensure that confidentiality and privacy of the Data are respected appropriately
* Ensure that the Receiving Organisation follows legislation and good practice in relation to data protection
* Set out arrangements for termination of the Contract

## General Terms

1. This Contract does not supersede any other data sharing arrangements operating between the Partner Organisations, it is relevant only to data sharing for the purposes of research projects or other approved programmes that are supported by the Bradford Institute for Health Research (BIHR) based at Bradford Teaching Hospitals NHS Foundation Trust (BTHFT).
2. It is intended that this Contract is valid for a five year period from the date the Receiving Organisation signs, at which point it may be renewed or terminated by the Providing Organisation in consultation with the Receiving Organisation.
3. The Contract shall be reviewed every 2 years or as a result of changes to relevant legislation or national policy. Any changes to the terms of the Contract during the five year period shall be provided in writing and signed as an amendment to the Data Sharing Contract by each Partner Organisation.
4. The Receiving Organisation is responsible for ensuring that their organisation has implemented appropriate policies, procedures and processes to safeguard the Data.
5. Nothing in this Contract shall:
   1. impose an obligation on any Partner Organisation to disclose any personal, health or sensitive Data to the other; or
   2. require any Partner Organisation to act in a manner which conflicts with its legal obligations, legal functions or duties, or internal governance arrangements.
6. The Partner Organisations undertake to ensure that each of its employees, including students, contractors, and locums, have undertaken appropriate information governance training and recognises and understands their responsibilities when sharing or receiving patient or other person Data under this Data Sharing Contract and the relevant Data Sharing Agreement.
7. Failure to comply with the terms of this Data Sharing Contract may lead to the withdrawal of the Receiving Organisation’s right to participate in the Contract and access to any Data supplied under the Data Sharing Contract or linked Data Sharing Agreement being withdrawn.
8. This Data Sharing Contract alone does not facilitate data sharing. No Data shall be transferred or shared until a separate Data Sharing Agreement has been completed and signed by each participating organisation in respect of the proposed data flow or data sharing arrangement.
9. A specific Data Sharing Agreement between the Receiving Organisation and the Providing Organisation shall provide details for each individual data sharing arrangement including:
   1. The Data to be shared including frequency: See section 4 of the Data Sharing Agreement
   2. The purpose the Data is to be used for: See section 4 of the Data Sharing Agreement
   3. The method of transfer / details of how the Data will be shared: See section 4 of the Data Sharing Agreement

A copy of the Data Sharing Agreement template can be found at <https://borninbradford.nhs.uk/wp-content/uploads/BIHR-Data-Sharing-Agreement.docx>

1. Each Data Sharing Agreement shall be governed by the terms and conditions of this Data Sharing Contract. Data to be shared under this Contract may be anonymised (including through de-identification or pseudonymisation with appropriate controls in place) or Personal Data. Personal Data means information relating to an identified or identifiable natural person.

## Termination

1. Either Partner Organisation may terminate this Contract and the Data Sharing Agreements governed by it before it is due to expire by giving written notice of their intention to terminate not less than one month before the intended termination date if the departing Partner Organisation has taken all reasonable steps to ensure that withdrawal does not place the other Partner Organisation in breach of any third party contractual agreements to perform a research project or other programme.
2. If the Providing Organisation has reason to believe that the Receiving Organisation is in breach of the terms of this Contract or of a Data Sharing Agreement governed by this Contract then Providing Organisation will report this to the Receiving Organisation and shall have the right to suspend data sharing arrangements until the potential breach has been investigated and it has been confirmed that there was no breach or that the breach has been remedied.
3. Either Partner Organisation may terminate this Contract with immediate effect in writing if:
   1. The other organisation is in material breach of the terms of the Contract and or a specific Data Sharing Agreement governed by the Contract and the organisation fails to or cannot remedy the breach within 30 days of notice of the breach
   2. The other organisation ceases to operate as a legal entity for example through closure or merger with another organisation.
   3. The other organisation no longer has the lawful power to perform any of the obligations contained within this Contract.
4. Termination of the Data Sharing Contract for a Partner Organisation automatically terminates any Data Sharing Agreements governed by the Contract that have resulted in Data being shared with the Partner Organisation.
5. On termination of the Contract, or sooner at the termination of the specific Data Sharing Agreement, unless otherwise agreed in writing between the Partners Organisations the Data held by the Receiving Organisation under the governance of the Contract shall be securely and permanently destroyed and confirmation in the form of a destruction certificate (which may be in the form of a letter) shall be provided to the Providing Organisation.

## Intellectual Property Rights

1. Ownership of the Data (including copyright and related rights, database rights and sui generis database rights) shall vest in the Providing Organisation.
2. The Receiving Organisation shall provide the Providing Organisation with a complete electronic copy of any Derived Data generated from access to and use of the Data within a period of 6 months of the termination of the specific Data Sharing Agreement. Derived Data is defined as follows:

a) Derived Data: individual-level data generated by the Receiving Organisation from analyses or functional combinations of the Data. An example of a Derived Data variable includes Body Mass Index (BMI), being a function of height and weight or a diagnostic indicator based on analysis of clinical codes. The Providing Organisation retains ownership of these Derived Data and these data, with their explanatory documentation, must be returned to the Providing Organisation to feed back into the data resource. The Receiving Organisation is only permitted to keep the Derived Data until the end of the specific Data Sharing Agreement. The syntax or methodology documentation used to create the Derived Data is the property of the Receiving Organisation, but the Providing Organisation shall be granted a non-exclusive royalty free and perpetual license to access, use and distribute this for research, teaching and other non-commercial purposes.

1. Analyses and results (if any) derived from access to and use of the Data shall be owned by the Receiving Organisation with the exception of Derived Data. The Receiving Organisation grants to the Providing Organisation an irrevocable, perpetual, worldwide, transferrable, royalty-free license to use all Receiving Organisation analyses and results for research, teaching and other non-commercial purposes.

## Publications

1. The Receiving Organisation will provide any potential publications to the Director of Research at the Providing Organisation (see Notices) at least one (1) month prior to submission of the publication to ensure that the data presented is not in breach of ethical approvals and to ensure appropriate acknowledgements are included. If the Receiving Organisation doesn’t receive communication back within 14 days of issuing such notice, then the Receiving Organisation shall be entitled to pursue the publication as submitted.
2. The Receiving Organisation will acknowledge the Providing Organisation in all publications and presentations arising from use of the Data in the form specified in guidance for collaborators published on the Providing Organisation website: <https://borninbradford.nhs.uk/research/guidance-for-collaborators/>.

## Data Controller Responsibilities

1. Where the shared Data is Personal Data the Receiving Organisation shall be considered to become the Data Controller unless otherwise set out in the specific Data Sharing Agreement.
2. The Receiving Organisation shall ensure that Data are processed lawfully and in accordance with all applicable laws and regulatory standards, including secure storage and transfer.
3. The Receiving Organisation will inform the Providing Organisation when a subject access request is made by a patient and will respond to the patient as required by the Data Protection Act.
4. Where the shared Data is not Personal Data but becomes Personal Data through processing undertaken by the Receiving Organisation, the organisation shall become the Data Controller. As Data Controller, the organisation shall be responsible for notifying the Providing Organisation; identifying whether the action constitutes a data breach; and establishing a lawful basis for continuing to hold or destroy the Personal Data as appropriate.

## Terms and Conditions for Data Sharing

1. As a Data Controller, the Providing Organisation is not under any obligation to transfer or share access to their Data under this Contract unless they are satisfied that it is appropriate to do so.
2. As the Data Controller for the Data to be shared or accessed it is the Providing Organisation’s responsibility to ensure that:
   1. There is an appropriate lawful basis for providing the Data and that this is set out in the specific Data Sharing Agreement.
   2. Appropriate information has been provided to all affected patients. The Receiving Organisation shall provide material to assist the Providing Organisation with patient information, fair processing and informed consent where appropriate.
   3. All patient objections to data sharing (or where applicable withdrawal of consent) are honoured and Personal Data for these patients is not shared.
3. If the Providing Organisation receives a request to disclose health Data under this Contract which they do not intend to comply with they must inform the applicant of its decision in writing and provide reasons for the rejection of the request.
4. The Providing Organisation shall supply Data in the form and format agreed within the specific Data Sharing Agreement.
5. The Providing Organisation shall transfer the Data to the Receiving Organisation using an appropriately secure method as agreed and specified in the Data Sharing Agreement.
6. The Receiving Organisation shall ensure that the Data is only accessed by those employees, agents, students and contractors that are named in the specific Data Sharing Agreement and where appropriate shall use role based access controls to limit that access.
7. The Receiving Organisation shall ensure that all its employees, agents, students and contractors shall only use any Data received under the terms of this Contract for the purpose detailed in the specific Data Sharing Agreement.
8. The Receiving Organisation shall not pass any Data received under a Data Sharing Agreement to any third party unless otherwise set out within the specific Data Sharing Agreement or with prior written consent of the Providing Organisation.
9. The Receiving Organisation shall ensure the Data is stored on hardware located in secure environments (locked locations in locked buildings). The hardware used to store the Data must be encrypted to the AES-256bit standard (or the latest encryption standard outlined in the Data Security and Protection Toolkit) and accessible using strong passwords (at least 12 characters using a mix of letters, cases, numbers and symbols).
10. Should the Data need to be transported, the Receiving Organisation shall ensure the Data is transported in an encrypted format using encryption to the AES-256bit standard and strong passwords (at least 12 characters using a mix of letters, cases, numbers and symbols). Where the Data is being transported physically then the device must also be encrypted to AES-256bit standard. Encryption keys must be held securely and not transported using the same mechanism as the Data.
11. The Receiving Organisation is responsible for ensuring their electronic file infrastructure is fit for purpose and it is secured through the implementation of access control mechanisms; regular patching of software and hardware; use of current anti-virus software; the conducting of penetration testing and swift resolution of any vulnerabilities found.
12. The Receiving Organisation shall not combine or link the Data received under the terms of this Contract with any other Data held by the Receiving Organisation unless otherwise specified in the specific Data Sharing Agreement.
13. For patient level Data that has been anonymised the Receiving Organisation shall not use or manipulate the Data in any way that re-identifies any individual from that Data.
14. The Receiving Organisation shall notify the Providing Organisation of any Data Breach (or suspected Data Breach) as soon as is practicable. A Data Breach is a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, data which is the subject of a Data Sharing Agreement. Data Breaches should be recorded according to local incident management procedures but must be assessed to establish whether an incident is reportable (as defined in the DSP Toolkit). Use of the DSP Incident Reporting reporting system will automatically notify the Information Commissioners Office for incidents that are required to be notified. Further guidance is available at the following: <https://www.dsptoolkit.nhs.uk/Help/29>
15. Before publishing any Data, or analyses or results derived from Data, received under a Data Sharing Agreement the Receiving Organisation shall ensure that all steps necessary have been taken to render the Data anonymous to a level sufficient to be compliant with the Information Commissioner’s Office code of practice: <https://ico.org.uk/media/1061/anonymisation-code.pdf>
16. The Receiving Organisation shall not transfer Personal Data received under the terms of this Contract outside the UK or the European Economic Area without the prior written consent of the Providing Organisation and only where such transfer is permitted under and complies with the Data Protection Act 2018 and the General Data Protection Regulations (UK or EU where applicable).
17. The Receiving Organisation shall notify the Providing Organisation if a request is received regarding the Data under the Freedom of Information Act 2000 prior to the release of any Data and shall use its best endeavours to involve the Providing Organisation in producing the response to such a request.
18. The Receiving Organisation shall adhere to the Guidance for Collaborators: <https://borninbradford.nhs.uk/research/guidance-for-collaborators/>

## Notices

1. The Parties’ representatives for the purpose of receiving reports and other notices shall until further notice be:
   1. Providing Organisation:
      1. Director of Research – Professor John Wright ([john.wright@bthft.nhs.uk](mailto:john.wright@bthft.nhs.uk))

b. Receiving Organisation: Receiving Organisation contact for Notices

# Signature Page

## Parties to the Data Sharing Contract

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| Signed for and on behalf of Receiving Organisation | Receiving Organisation name and address |
| Name |  |
| Role / Job Title |  |
| Signature |  |
| Date |  |

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| Signed for and on behalf of Providing Organisation | Bradford Teaching Hospitals NHS Foundation Trust  Bradford Royal Infirmary  Duckworth Lane  Bradford  BD9 6RJ |
| Name | Professor John Wright |
| Role / Job Title | Director of Research |
| Signature |  |
| Date |  |