

Collaboration and Information Sharing Agreement between Bradford Teaching Hospitals NHS Foundation Trust and [Investigator institution] (“The Investigator’s Institution”) in relation to Born in Bradford approved study [study number] (“The Study”).

**i. Background to the Agreement:**

Born in Bradford is a longitudinal multi-ethnic birth cohort study aiming to examine the impact of environmental, psychological and genetic factors on maternal and child health and wellbeing. Bradford is a city in the North of England with high levels of socio-economic deprivation and ethnic diversity. Women were recruited at the Bradford Royal Infirmary at 26-28 weeks gestation. For those consenting, a baseline questionnaire was completed. The full BiB cohort recruited 12,453 women comprising 13,776 pregnancies between March 2007 and December 2010 and the cohort is broadly characteristic of the city’s maternal population. Researchers are looking at the links between the circumstances of a child’s birth, the context in which they grow up, their health and well-being and their educational progress. Ethical approval for the data collection was granted by Bradford Research Ethics Committee (Ref 07/H1302/112).

It is critical to the success of the Born in Bradford approved study [study number] [study title] (“The Study”) that the information to which this agreement relates is handled within the appropriate legislative and regulatory environment, in particular the Data Protection Act 1998.

This agreement sets out the roles of each party to the agreement in relation to the information shared and their responsibilities therein.

**1. Parties to the Agreement:**

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| Details be included for all agencies which are party to the Agreement:   1. **Professor John Wright, Director of Research**   **Bradford Teaching Hospitals NHS Foundation Trust**  **Bradford Royal Infirmary**  **Duckworth Lane**  **Bradford**  **BD9 6RJ**   1. **“The Investigator”**   **[Investigator individual]**  **“The Investigator’s Institution”**  **[Investigator institution]** |

**2. Purposes of the Agreement:**

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| This agreement is in place to ensure the protection and security of data shared between Bradford Teaching Hospitals NHS Foundation Trust (BTHFT) and The Investigator’s Institution for the purposes of The Study. |

**3. Information to be shared**

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| Research data from Born in Bradford cohort participants will be shared between the parties. Only data necessary for the Investigator to carry out the Study will be shared (“The Data”), and this will be determined by the Born in Bradford Executive Group. Person identifiable data will not be shared. The Data will be pseudonymised. |

**4. Methods used for sharing:**

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| The Data will be transferred from BTHFT to The Investigator at The Investigator’s Institution using the IronPort encrypted email service or the Kiteworks secure filesharing service. If the file size is too big for Ironport or Kiteworks, or there are other barriers to accessing these at The Investigator’s Institution, one of two transfer methods will be used:   1. A secure sftp or secure https connection will be provided by The Investigator’s Institution to allow BTHFT to upload The Data. The folder to which The Data is uploaded will only be accessible by The Investigator. 2. The Data will be downloaded to a SafeXs encrypted memory stick and transferred physically to The Investigator at The Investigator’s Institution by a member of BTHFT staff. |

**5. Need to know**

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| For BTHFT:  Prof John Wright, Director of Research, BTHFT  BTHFT staff members in the Born in Bradford Data Team involved in processing The Data.  For The Investigator’s Institution:  The Investigator. |

**6. Supporting processes:**

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| The Investigator has read and will abide by the “Guidance for BiB Collaborators” set out in Appendix 1.  The Investigator has read and will abide by the “Terms and Conditions for Data Transfers” set out in Appendix 2. |

**7. Information retention issues:**

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| The Investigator will retain all information for as long as necessary to complete The Study. The Investigator will delete The Data and any data items derived from The Data from the Investigator’s Institution’s information systems at the request of BTHFT or upon completion of The Study, whichever is earlier.  Participant data will be held in accordance with the relevant legislation (in particular the Data Protection Act 1998); Records Management: NHS Code of Practice and each agency’s relevant policies and procedures. |

**8. Staff development issues:**

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| Both parties to this agreement will ensure that their staff carry out information governance training appropriate to their role.  All staff at BTHFT complete annual mandatory training in Information Governance procedures. Staff are made aware of their responsibilities under the Data Protection and Freedom of Information Acts, which are laid out in the Trust’s DPA and FOI policies and procedures. |

**9. Consent from service users:**

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| Every pregnant woman attending Bradford Royal Infirmary antenatal clinic between March 2007 and December 2010 was invited to take part in the Born in Bradford Cohort Study. Consenting women signed a consent form. The consent form made clear that they can withdraw their consent at any time by contacting the Born in Bradford office, at which point a member of the Born in Bradford team follows a standard operating procedure to action the withdrawal. |

**10. Incident Reporting**

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| Incidents are to be reported immediately and in writing to the Director of Research, BTHFT |

**11. Any other relevant issues**

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| Further information in relation to the Born in Bradford Cohort Study can be obtained by contacting the project office on +441274 364474  This agreement to be reviewed annually. |

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**Approved by (PRINT NAME):**

**Signature:**

**Institution:**

**Date:**

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**Approved by (PRINT NAME):**

**Signature:**

**Institution:**

**Date:**

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**Copies of this Agreement should be retained by the named persons above and be made available for inspection on request.**

**A copy should be sent to the DP Officer of each party.**

# Appendix 1 – Guidance for BiB Collaborators

**Use of existing data or existing biological samples**

1. Requests for existing data and biological samples will be reviewed, prioritised and authorised by the BiB Executive Group. The Investigator should complete an outline proforma available on the Born in Bradford website ([www.borninbradford.nhs.uk](http://www.borninbradford.nhs.uk)) and submit to the BiB Director.
2. Any new data derived from the BiB cohort (interview, physical measurements, new variables derived from existing data) must be lodged with the BiB database at the end of the project (or at any time at the request of the BiB Director). The nested study Principal Investigator must supply adequate documentation concerning new variables (including statistical programs) to permit their use in future analyses of the data.
3. The Investigator must notify the BiB Director of any potential errors discovered whilst using BiB data or biological samples.
4. Any residues of biological samples or excess materials must be returned to BTHFT or to the Bristol Bioresource Laboratory, whichever is the originating laboratory, within 6 months of the completion of the research. The expense of transferring both from and back to the BiB site must be met by the applicants.

**Collection of new data or new biological samples**

In addition to the Guidance for existing data or samples, Investigators collecting new data or samples are expected to adhere to the following Guidance:

1. Full proposals *must* be reviewed by the BiB Executive Group *prior to submission for funding*. The Investigator should complete an outline proforma available on the Born in Bradford website ([www.borninbradford.nhs.uk](http://www.borninbradford.nhs.uk)) and submit to the BiB Director.
2. The Investigator should ensure that there is genuine local research partnership and where appropriate a strong link to practitioners to promote translation of findings into practice.
3. The Investigator will be required to meet additional costs (administrative, data management, laboratory etc) that are incurred by the Born in Bradford programme for new data and sample collection. Where a new grant will be submitted to fund the study, the final copy of the grant including the finances must be sent to the BiB Director for approval at least two weeks before the submission date.
4. Researchers working on new studies will be employed wherever possible by the Born in Bradford programme in order to promote efficient integration, good research governance and research capacity-building locally.
5. In addition to the review by an appropriate ethics committee, researchers will be expected to obtain review and advice from relevant patient/public involvement groups, including Born in Bradford’s parent governors group. Please contact the BiB Community Engagement Officer for advice on the most appropriate form of PPI (borninbradford@bthft.nhs.uk).
6. The Born in Bradford Executive Group will act as data guardians and provide peer review for the scientific merit of research ideas and the use of the collected data and biological samples.

**Governance and intellectual property**

1. The BiB Director will be responsible for the design and conduct of the Born in Bradford platform study, ethical approval and compliance with research governance requirements. The Investigators will be responsible for the governance of their specific study.
2. Bradford Teaching Hospitals Foundation Trust is the Sponsor of the project.
3. Intellectual Property developed from the Born in Bradford platform study will be owned by Bradford Teaching Hospitals Foundation Trust. We will consider dividing intellectual property rights where collaborators will be making a particular contribution. Any such division must be considered and agreed before the collaboration starts.

**Publications and reports**

1. We would like to have all work linked to Born in Bradford to be easily identified, including in electronic searches. We encourage collaborators to include Born in Bradford in article titles e.g. Obesity in a bi-ethnic population: a Born in Bradford study. If this is not possible then authors should include Born in Bradford as a keyword and in the abstract. A protocol and cohort description of the study [1, 2] and BiB 1000 study [3] have been published and should be referred to in all methods sections
2. Authorship on papers must follow standard practice that all authors must have made a substantial contribution to the conception and design of the study, or analysis and interpretation of data, and drafting the paper. In a long running study such as Born in Bradford there are likely to be a number of people whose work makes production of a paper possible but who may not meet authorship criteria. In such cases we encourage the use of the contributorship (see BMJ guidelines).
3. The Investigator should agree authorship guidelines with their team and collaborators at the start of any new research project to avoid later disputes. Studies where new data or biological samples will be collected should have a local (Bradford) investigator in the study team.
4. The following acknowledgement must be included in all papers using BiB data:

*“Born in Bradford is only possible because of the enthusiasm and commitment of the Children and Parents in BiB. We are grateful to all the participants, health professionals and researchers who have made Born in Bradford happen.”*

For papers using Born in Bradford GP primary care data, the following additional acknowledgement must be included:

*“We gratefully acknowledge the contribution of TPP and the TPP ResearchOne team in completing study participant matching to GP primary care records and in providing ongoing informatics support.”*

1. When a paper or abstract is ready to be submitted authors will be required to submit a copy (in confidence) to the BiB Director for review by the BiB Executive Group. All papers will be reviewed within two weeks of receipt to check confidentiality is protected; to ensure that the paper will not bring the study into disrepute; to try to identify overlap with other papers published or in preparation. Advice and feedback will be offered to authors where we feel this may be helpful.
2. Born in Bradford is committed to the translation of research into practice. All authors are required to send the BiB Director a summary of key policy and commissioning implications from their analysis upon conclusion of their project.
3. Collaborators must send copies of the final submitted draft and an electronic copy of the final published version to the BiB Director. All press releases on research arising from the study must be approved by the BiB Director.

**Contact**

Please send all enquiries via email to the Born in Bradford Programme Director ([rosie.mceachan@bthft.nhs.uk](mailto:rosie.mceachan@bthft.nhs.uk)).

**Reference**

1. Born in Bradford Collaborative Group. Born in Bradford, a cohort study of babies born in Bradford and their parents: protocol for recruitment phase. BMC Public Health 2008; 8:327 doi:10.1186/1471-2458-8-327
2. Wright, J., Small, N., Raynor, P., Tuffnell, D., Bhopal, R., Cameron, N., Fairley, L., Lawlor, D.A., Parslow, R., Petherick, E.S., Pickett, K.E., Waiblinger, D., & West, J, on behalf of the Born in Bradford Scientific Collaborators Group (2012). Cohort profile: The Born in Bradford multi-ethnic family cohort study. International Journal of Epidemiology. 2012; 1-14 doi:10.1093/ije/dys112
3. Bryant M, Santorelli G, Fairley L, West J, Lawlor DA, Bhopal R, Petherick E, Sahota P, Hill A, Cameron N, Small N, Wright J. Design and characteristics of a new birth cohort, to study the early origins and ethnic variation of childhood obesity: the BiB1000 study Longitudinal and Life Course Studies 2013 4(2) 119-135 doi:10.14301/llcs.v4i2.221

# Appendix 2 – Terms and Conditions for Data Transfers

1. The Investigator and other relevant employees of The Investigator’s Institution involved in the research have read and will abide by the “Guidance for BiB Collaborators” given in Appendix 1 of this Agremeent.

2. The data remains the property of the Born in Bradford study. This agreement does not restrict the rights of Born in Bradford to distribute the data to other institutions or to publish any document relating to the data.

3. The Investigator will retain The Data in a secure location at The Investigator’s Institution and will not permit The Data or any part of it to come into the possession or control of any other organisation or any individual other than those employees of The Investigator’s Institution who are involved in The Study under direct supervision of The Investigator.

4. The Investigator will not transfer The Data in whole or in part to third parties without the relevant third party entering into a separate Information Sharing Agreement with Born in Bradford.

5. The Investigator will use the data only to carry out the research described in the proforma relating to The Study as approved by the Born in Bradford Executive Group (“The Proforma”), and only for research that has appropriate ethnical approval. The Investigator will not use The Data or any parts thereof for any commercial purposes or any purpose that is subject to consulting or licensing obligations to third parties.

6. The Investigator will use all reasonable endeavours to ensure that The Data and any data items derived from The Data shall as soon as possible be returned or destroyed upon (i) the request of BTHFT, (ii) on termination of this agreement, (iii) in the event that The Investigator or The Investigator’s Institution are in breach of any of the conditions of this agreement or (iv) the withdrawal of consent of a relevant study participant. If The Investigator is required to destroy The Data then it will confirm in writing to the Director of Research, BTHFT that The Data has been destroyed and no further copies of the data are held by The Investigator or The Investigator’s Institution.

7. All data and information (including the results of chemical and biological analyses and cleaned or derived variables) relating directly to study participants will be returned to BTHFT upon the request of BTHFT or within 6 months of the completion of The Study, whichever is sooner, for incorporation into the Born in Bradford data warehouse and shall be owned by BTHFT.

8. The Investigator will provide the Director of Research, BTHFT with a fully documented electronic copy of the full results of The Study before its publication in any form or within 6 months of the completion of The Study whichever is sooner.

9. The Investigator will keep the data confidential and will not attempt to identify study participants.

10. The Investigator will not attempt to link The Data to other Born in Bradford data held by different individuals or by The Investigator for different projects.

11. The Investigator will not try to link The Data to data from other sources other than those that may be set out in The Proforma.