

MATERIAL TRANSFER AGREEMENT

THIS AGREEMENT is made the \_\_\_ day of \_\_\_\_\_\_ 20\_\_ between

BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST of Duckworth Lane, Bradford, West Yorkshire BD9 6RJ, (“BTHFT”), acting through BORN IN BRADFORD of the Bradford Institute for Health Research, Temple Bank House, Bradford Royal Infirmary, Duckworth Lane, Bradford BD9 6RJ.

and

…………………………… of ……………………………………………….. (referred to as “the Recipient”)

Hereafter referred to collectively as “Parties” and individually as “Party”.

BACKGROUND:-

BTHFT, through the Born in Bradford study (the “Study”), has collected and owns certain biological research material provided by participants in the Study (“Study Participants”). The investigator(s), named in Appendix 1 (“Investigator”), wish(es) to use certain material held by BTHFT as set out in Appendix 1 (“Material”). The Material will be transferred to the Recipient named in Appendix 1 (“Recipient”) and will be processed by the Recipient as described in Appendix 1 (“Assay”). The results of the Assay (“the Results”) will be used by the Investigator in the research as set out in Appendix 1 (“Research”) as agreed by the Study’s Executive Committee. BTHFT is willing to supply the Recipient with the Material for a period of one (1) year to conduct the Assay under the terms and conditions of this Agreement.

Ethical approval for the storage and subsequent use of Born in Bradford samples was granted by Bradford Research Ethics Committee (Ref 07/H1302/112).

[Delete if not needed] Ethical approval for storage and subsequent use of ALL IN samples was granted by the Bradford Research Ethics Committee (08/H1302/21).

NOW IT IS AGREED by the Parties as follows:-

1. That the Investigator and other relevant researchers at the Recipient involved in the Research have read and will abide by the Born in Bradford Guidance for Collaborators (see Appendix 2). All future correspondence pertaining to the Material and the Research should be addressed to Born in Bradford at BTHFT.

2. The Material remains the property of BTHFT. There is no transfer or licence or implied transfer or licence of rights in the Material from BTHFT to the Recipient including all intellectual property rights. This Agreement does not restrict the rights of BTHFT to distribute the Material to other institutions or to publish its own information relating to the Material.

3. The Recipient will use the Material in accordance with good standards of laboratory practice and shall ensure compliance with all applicable laws, regulations pertaining to the Research.

4. The Recipient will retain the Material in a secure location on its premises and will not permit the Material or any part of it to come into the possession or control of any other organisation or any individual other than those researchers who are involved in the Research described in Appendix 1 under direct supervision of the Recipient. The Recipient will not transfer the Material in whole or in part to third parties without the relevant third party entering into a separate Material Transfer Agreement with BTHFT.

5. The Recipient will use the Material only to carry out the Research described in Appendix 1 of this Agreement. The Recipient will not use the Material or any parts thereof for any commercial purpose or any purpose that is subject to consulting or licensing obligations to third parties.

6. The Recipient will not use the Material in any experiments involving humans and will not use the Material in contact with any cells or other materials to be infused into humans. If animal studies have been proposed, Investigator has considered *in vitro* approaches to the research and has followed the applicable guidelines for animal experimentation regarding such work.

7. The Recipient will use all reasonable endeavours to ensure that the Material in its possession or under its control is returned as soon as reasonably practicable or destroyed upon (i) the reasonable request of BTHFT; or (ii) on termination of this agreement; or (iii) in the event that either Party is in breach of any of the conditions of this Agreement; or (iv) the consent of the relevant Study Participant is withdrawn. If the Recipient is required to destroy the Materials then it will ensure that this is done in compliance with all applicable laws and regulations and upon BTHFT’s request will confirm in writing to BTHFT that the Materials have been destroyed.

8. The Recipient will return all Material not used in the Research (“Residual”) to BTHFT or to the Bristol Bioresource Laboratory, whichever is the originating laboratory, within 6 months of the completion of the Research.

9. The Recipient will inform the Born in Bradford Chief Investigator in confidence of the results of the Research (“Results”). All Results generated by the Research shall be the property of the Recipient save that the Recipient grants to BTHFT a royalty-free, non-exclusive right to use such Results for internal non-commercial research and teaching. The Recipient will provide the Born in Bradford Chief Investigator in confidence with a fully documented electronic copy of the Results before publication in any form or within 6 months of the completion of the Research whichever is the sooner.

10. The Recipient will acknowledge Born in Bradford and acknowledge or include as authors those BTHFT employees identified by the Born in Bradford Executive Committee who have played a key scientific role in the generation of the Material in all publications relating to the Research and Results in accordance with standard academic practice. The Born in Bradford Executive Committee will be provided in confidence and will be given the opportunity to review any papers intended for publication at least 14 days prior to submission.

11. The Recipient will keep any data relating to the Materials provided by BTHFT or by the Bristol Bioresource Laboratory confidential and will not try to identify Study Participants.

12. The Recipient will not try to link any data provided by BTHFT or by the Bristol Bioresource Laboratory to other Born in Bradford data held by different recipients or by the same Recipient for different projects.

13. The Materials are supplied without cost but the Recipient shall reimburse BTHFT or the Bristol Bioresource Laboratory, whichever is the originating laboratory, for any reasonable costs that may be incurred when preparing and sending the Materials to the Recipient.

14. BTHFT accepts no liability in connection with the Recipients use of the Material. BTHFT does not represent that (i) the Materials are of satisfactory quality or fit for any particular purpose; or (ii) use of the Material is free from infringement of third party rights, including intellectual property rights.

15. The Recipient will neither assign, transfer, mortgage, charge nor part with any of its rights or obligations under this Agreement.

16. This Agreement will be governed by the laws of England and shall be subject to the jurisdiction of the English Courts. This clause shall not prevent a party from seeking interim relief in any court of competent jurisdiction.

AGREED BY THE PARTIES through their authorised signatories

SIGNED for and on behalf of BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST:

…………………………………………………………………………………………………………...

Name: ………………………………………………. Date: ……………………………………

SIGNED for and on behalf of RECIPIENT:

(1) Authorised signatory of Recipient ……………………………………………………………

Name: …………………………………………………………… Date: …………………….

Although I am not a party to this agreement I have read and understood its terms.

(2) Signature of Investigator: ………………………………………………………………..

Name: …………………………………………………………….. Date: ……………………

**Add further signature lines as required**

**We require two signed original copies (not photocopies) one for our records and the other we will return to you.**

# Appendix 1 – Study and sample details

Project number:

Investigator:

Recipient:

Description of Research:

Description of Assay:

Description of Material:

# Appendix 2 – 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.v4i2.22