



**All about the HELIX study**

(The **H**uman **E**arly-Life **E**xposome)  
Please read this information carefully

Invitation to take part

## **We would like to invite you and your child to take part in this research study**

HELIX is one of the first studies to look at the effects of various environmental exposures, such as pollution, on child health across Europe. HELIX will work together with 200 BiB families and families from five similar projects across Europe to collect information from 6 to 7 year old children. In total 1200 families across Europe will be included in this project.

### **Why are we carrying out the HELIX Project?**

Cohort studies, like BiB, can provide a wealth of information on environmental exposures and help to explain what role they play in children's health. There are an increasing number of childhood diseases that are related to pollution in the environment. Exposure to certain chemicals during pregnancy and early childhood may explain some of the developmental changes of the nervous, immune, and reproductive systems in children. The data collected for this study will be analysed by researchers and will lead to the development of strategies to create healthier and safer environments for present and future generations.

### **Do I have to take part?**

Whether you decide to take part in this project is entirely up to you. If you decide you want to, but later change your mind, you can withdraw at any time. Whatever you decide your child's



medical care will not be affected in any way and participation in BiB is also not affected. All GP surgeries in Bradford will receive information about this new study.

### **What will happen to me and my child if we take part?**

If you agree to take part in this study after reading this information, we will ask you to complete a consent form. We will arrange an appointment out of school hours for you and your child to come to the Clinical Research Facility at the Bradford Royal Infirmary (BRI) for a detailed assessment.

### **What do you need to do before the appointment?**

– Before the appointment we will give you two containers

to collect urine (one to be collected from your child the night before, and a second to be collected in the morning on the day of your appointment). We will ask you to place the urine samples in a cool box, which we will provide and to place this cool box in your fridge until you come to attend the appointment.

- We will give you a brief questionnaire to complete before the appointment which will ask you about your child's behaviour and your address history in the last few years, which will give us a better understanding of the environment you have been living in. You will need to bring this questionnaire with you to the appointment.



### What will happen at the appointment?

- We will provide you with free transport for a return journey from your home to the Clinical Research Facility.
- Two Community Researchers will look after you during your visit. There are different parts to the appointment:
- We would like you to complete a computerised questionnaire with the help of the Community Researcher. Ideally questions are answered by the mother and this will take approximately one hour.
- During that time the second Community Researcher will ask your child to ‘play’ some ‘game-style’ memory and attention tests on a computer.
- We would also like you to

complete a very short memory test on a computer, similar to the ‘game-style’ test of the child.

- We would like to carry out a test to see how well your child’s lungs are working. This is done by blowing forcefully into a tube connected to a computer (Spirometry).
- We would like to carry out a clinical examination of your child which will include:
  - Blood pressure measurement
  - Height and weight measurement, also waist and head circumference
  - Skinfold thickness measurement on the upper arm and the thigh and on the back and waist, as well as a brief electronic and pain free test of body composition (Bioimpedence).
- At the end of the visit we would like to collect a blood sample from your child’s arm for different tests. We will apply a local anaesthetic to numb the skin. The blood sampling is carried out by our Community Researchers who are highly skilled in taking blood from children. The whole visit will take approximately 1½ to 2 hours.

### What will happen to the information we collect?

All the information we collect will be stored in strict confidence, as required by the Data Protection Act. The information will be used by researchers from BiB and our by research partners from HELIX who are based both,

inside and outside the European Economic Area. Some of these countries do not have the same data protection laws as in the United Kingdom; however any information we send will be anonymised using a unique study number. Only certain members of the BiB study team will be able to link you to the information we have collected about you.

### What will happen to the samples we collect?

The samples will be used to determine the levels of a wide range of environmental pollutants including metals and chemicals such as pesticides and plasticizers. We will also analyse your child’s genes and biological processes such as their metabolism. Initially the samples will be processed and stored at our laboratory at the BRI. All samples will be anonymised and only certain members of the BiB study team will be able to link them to you or your child. We will send anonymised samples to our partners in Spain and other specialised laboratories within and outside of Europe. Any samples which are not used will be returned to us and stored for future use. We are not able to give individual feedback from the results of the tests.

### Are there any possible advantages to taking part in the project?

In the short-term it is unlikely that you will receive direct medical benefits. However, the main advantage is that you will

- ▶ be helping us in our efforts to understand more about the health of people living in our communities, and how this might be improved for future generations.

### **What are the costs of the study?**

There are no costs to you participating in the study. You will receive a compensation of £20 to show our appreciation for your and your child's involvement and commitment.

### **How will I find out the results of the study?**

The findings from the study will be published in scientific journals. We will also make sure that those taking part will hear about the results through public meetings, Children's Centre groups and through our BiB website and newsletter. None of these publications or presentations will identify individual participants.

### **Who is organising and funding the research?**

The study is funded by the European Union and co-ordinated by our partners in Spain CREAL (Centre for Research in Environmental Epidemiology) in Spain. Dr Rosie McEachan is overseeing the study here in Bradford. **The Yorkshire & The Humber (Bradford-Leeds)**



### **Research Ethics Committee,**

established by the Health Research Authority, and the Research and Development Department at Bradford Teaching Hospitals NHS Foundation Trust have approved the project. HELIX is locally co-ordinated by Dagmar Waiblinger and Julia Blackburn at the BRI and other Born in Bradford staff are also involved. If you wish to take part or have any questions about the project or just want to know more about the work we are conducting please

contact the Born in Bradford community office on 01274 383454.

You can also visit our website: [www.borninbradford.nhs.uk](http://www.borninbradford.nhs.uk) or [www.projecthelix.eu](http://www.projecthelix.eu), if you want to know more about HELIX. We will also phone you to find out how you feel about the study.

Thank you for taking the time to read this information sheet.