Participant Information Sheet for Parents/Caregivers

Study Title: Elevated Childhood Lead Interagency Prevalence Study (ECLIPS)

We would like to invite you and your child to take part in a research study about lead exposure in children. Before you decide, you need to understand why the research is being done and what it would involve for you and your child. Please read the following information carefully. Talk to others about the study if you wish and take your time to decide if you want to take part. Please ask us if there is anything that is not clear or if you would like more information.

What is the study about?

Lead is a metal commonly found in our environment due to past use in paint, plumbing, and petrol. Despite being a controlled substance, it is still commonly found in our everyday environments, mainly through failing lead paint, lead flashing on buildings, some consumer products and many other sources. Lead can contaminate our air, water, soil, dust and food.

Lead exposure can have a wide range of long-term health effects, so it is important to detect and minimise contact with it. Children are more at risk from the effects of lead because of their growing and developing brains. Currently in the UK, we do not have a good understanding of how many children are exposed to lead or at what levels.

The ECLIPS study aims to develop and test methods for screening the amount of lead in children's blood collected through a simple at-home finger-prick test. We are also interested in how different methods of communication influence families' willingness to take part. This information will help us plan other larger studies in the future which will inform public health policies to reduce children's exposure to lead in homes and communities across the UK.

Who is running the study?

ECLIPS is led by Northumbria University in partnership with the UK Health Security Agency, Leeds Teaching Hospitals NHS Trust, University of Bristol, University of Oxford, University of Warwick, and the Health & Safety Executive, Synnovis and the Lead Exposure and Poisoning Prevention (LEAPP) Alliance. Our team includes experts in environmental science, health, epidemiology, and economics.

Who is eligible to take part?

We are inviting families with children aged 1-6 years who live in Leeds to take part. If your child meets these criteria, you may be eligible to take part in the study.

Children who are under 12 months, or are older than 6 years, or who have a brother or sister already involved in the study cannot participate. Children who have a bleeding disorder or are taking blood thinning medication are not eligible to take part.

What does taking part involve?

If you decide to take part, we will ask you to do some or all the following:

1. **Complete three online surveys:**
   - a short survey to express your interest in joining the study. This will take about 5 minutes to complete.
   - a questionnaire about your child, your home, and lifestyle factors that might affect lead exposure. This will take about 20 minutes to complete.
   - a short survey on the use of the blood spot sampling kit, and any feedback you may have on the study. This will take about 5 minutes to complete.
2. **Collect a blood spot sample:** We will send you a finger-prick blood spot sampling kit for you to get a small blood sample (two or three drops) from your child. The sampling kit will include detailed instructions, a lancet (pin prick) device, sterile wipes, sticking plaster, a special blood spot collection card, and return postage-paid envelope. Collecting the sample will take about 20 minutes including time for preparation and packing up.
3. **Collect and send us soil and dust from your home environment:** We would like to measure lead in a sample of household dust collected by your vacuum cleaner, and soil from your garden and/or backyard if you have one.

What will happen to my child's blood sample?

After posting the blood spot sample in the pre-paid envelope, your child's sample will arrive at the Health and Safety Executive's (HSE) Laboratory in Buxton where the Capillary Capitainer Blood Lead Concentration (CC-BLC) will be measured. The sample will not include your address details, just your child's participant identification number, their name and date of birth.

How will I hear about the results?

You will receive the results of your child's blood lead test in a letter prepared by our qualified health team along with an educational guide on how to reduce lead exposure. If any follow-up is needed, we will guide you through the next steps.

If we are concerned about a significant risk of harm to your child or yourself and others from exposure to lead, we have a duty of care to report this to the relevant health authorities (such as the local Health Protection Team) and we will work with you and the required professionals.

Do I have to take part?

No. Participation in this study is completely voluntary and choosing not to take part will not affect you or your child's medical care in any way.

What are the possible benefits of taking part?

- *For your family:* You will receive the results of your child's blood lead test, which will give you information about their exposure to lead. You will have peace of mind knowing that in the unlikely event that a lead exposure is identified you will be supported by local health practitioners to access any follow-up required.
- *For your community and wider society:* Potential lead exposure risks in your community can be identified. Developing better methods for monitoring lead exposure in children will allow a better understanding of lead exposure in UK children. This will lead to better policies and programs to reduce lead exposure in homes and communities, helping children develop to their full potential by reducing harmful lead exposure.
- *Compensation:* As a token of appreciation for your participation you will be eligible to receive shopping vouchers at different points in the study: £5 for the initial short survey, £25 upon receipt of the blood sample, £10 for the second questionnaire and £10 for the feedback questionnaire. We use vouchers to avoid any negative impact on family benefits.

What are the possible disadvantages or risks of taking part?

- *Discomfort from finger prick:* Your child may experience brief discomfort from the finger prick. We will provide detailed instructions to make this process as comfortable as possible.
- *Risk of infection:* This risk is minimal as the lancet device is sterile, automatically retracts after use, and we provide sterile wipes and plasters.
- *Anxiety about results:* Some parents may feel anxious about receiving their child's blood lead results. We will share results as they become available, provide clear information about what the results mean and what steps to take if needed. Where we recommend follow-up, our clinical partner will also make direct contact with your child's nominated medical practitioner/Dr to support your access to follow-up healthcare and advice.
- *Breach of confidentiality:* We need to hold some personal data on you and your child (such as your home address and your child's name) so that we can carry

out the study but we take extensive measures to protect your confidentiality as detailed below. We only keep this personal information for a limited period of time.

Will my taking part be kept confidential?

All information collected about you and your child during the research will be kept strictly confidential, in line with the Data Protection Act 2018 and General Data Protection Regulations. You and your child will be assigned a unique partcipant ID number, and the key linking this number to your personal details will be stored separately from your research data. All electronic data will be stored on secure, password-protected university servers. Only authorised members of the research team will have access to your identifiable information. Personal identifiable information will be deleted 3 years after the completion of the study.

What will happen to the data collected?

As a publicly funded organisation, Northumbria University must ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research (and for children we ensure consent has been provided by the parent/guardian/caregiver). This means that when you agree to take part in this study, we will use your data only in the ways needed to conduct and analyse the data as part of the research study.

Northumbria University will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The University will keep identifiable information about you for 3 years after the study has finished. Research data will be pseudonymised as quickly as possible after data collection. This means all personal identifiers will be removed from the research data and will be replaced with a participant ID number. The key to you and your child's personal details will be stored separately and securely to safeguard your identity and only used in communications back to you or your assigned health care professionals.

What if I change my mind and want to withdraw from the study?

You can change your mind and exit the study at any time without giving a reason. If you want to withdraw from the study or want to see a copy of the personal data we are holding on you and your child, please email us as **pb@aware@northumbria.ac.uk** .

If you want to withdraw from the study we will process the data according to your wishes, either retain, or delete it from our records. However, please note it is not possible to delete pseudonymised data once analysed and published, but we will remove you and your child's details from our participant identifier database.

Data Sharing

Your pseudonymised data will be shared between the partner organisations listed at the beginning of this handout (see 'Who is running the study') for the purposes of this research study. All data shared will be transferred securely and in accordance with data protection regulations.

Specific data sharing agreements will be in place between relevant partners where the sharing of your personal details is required to conduct aspects of the study and to allow us to fulfil our duty of care and to enable timely response to any blood lead levels of concern.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. The University has in place policies and procedures to keep your data safe.

Your pseudonymised data may also be used for future research (for example, as a publicly funded study, the final dataset will be placed in a data repository for use by others in the future), including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

For further information, please refer to the Northumbria University Research Participant Privacy Notice.

How are we informing and engaging with the public?

We will write up the findings of this study to share with all interested parties. We are committed to ensuring that the voices of the local community are heard throughout this study. A group of community advisers, hosted by the Lead Exposure and Poisoning Prevention (LEAPP) Alliance, is guiding the project. Once we gather all data, we will share easy-to-understand reports and infographics, including information on how to reduce lead exposure at home. We will present our findings at scientific conferences and through research publications. These outputs will be shared on the project website and help to inform future public housing and health policies and interventions.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Northumbria University Research Ethics Committee: [NU Ethics No. 10258].

What happens next?

If you would like to participate, please register online and provide consent for you and your child to take part, then take the first online survey using the link provided. If you have not received a participation link, but wish to take part please email us at pb_aware@northumbria.ac.uk

Upon registration and completion of the first online survey, you will be eligible to receive your first thank-you voucher. If you are one of the approximately 500 selected to receive the blood sampling kit, more information on the following steps will be provided.

Who should I contact if I want further information?

For more information about the study, please go to our website: leadsafefutures.org

Or contact us at our project email pb_aware@northumbria.ac.uk

Who should I contact if I wish to make a complaint?

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter:
dp.officer@northumbria.ac.uk

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered please address your complaint to:

Chair of Northumbria University Research Ethics Committee
Prof Louise Bracken, Pro Vice Chancellor for Research and Knowledge Exchange, Northumbria University, Newcastle upon Tyne, NE1 2SU.
Email: louise.bracken@northumbria.ac.uk

Thank you for taking the time to read this Participant Information Sheet