

## Life Study: a summary

### 1. Introduction

The overarching vision for Life Study is to develop a UK wide large scale cohort study which will provide information relevant to the improvement of the lives, health and well-being of children, both now and in the future. This cohort will provide a rich and internationally unique longitudinal resource of data, environmental and biological samples that can be used to address future questions and hypotheses regarding early life origins of disease, health, well-being and development. We will collect information on more than 80,000 children across England, Scotland, Wales and Northern Ireland. Women and their partners will be invited to take part during pregnancy, or soon after birth, and they and their new baby will be seen either at specially commissioned Life Study Centres on three occasions during pregnancy and the first year of the baby's life, or in their own homes when the baby is about 6 months old with a further contact at 12 months by web or phone. Although funding currently enables follow up to 12 months of age, the intention is have further contact with children and their families throughout childhood and into adult life as with previous UK birth cohort studies.

### 2. What are the aims of Life Study?

The aim of Life Study is to understand how the family, social and physical environment in very early life influences child development, health and wellbeing.

Five major research themes will be explored through the cohort:

- Inequalities, diversity and social mobility
- Early life antecedents of school readiness and later educational performance
- Developmental origins of health and ill-health in childhood
- Social, emotional and behavioural development: the interplay between infant and parent
- Neighbourhoods and environment: effects on child and family

The multi-disciplinary design and the scale of this study will also allow exploration, for the contemporary UK population, of cross cutting issues such as intergenerational influences on child outcomes, and issues relating to diversity arising from, for example, different family structures, ethnic groups, early life experiences, and prematurity. The study offers an opportunity to develop and test our understanding of social and biological mechanisms operating through the life course, and to identify opportunities to inform health and social policy. The study is innovative in design and its size means it will have enough statistical power to examine the interplay between biology, behaviour and environment (including by ethnic groups).

### **3. Overview of the study design**

As mentioned previously, there are two components to Life Study– a pregnancy component of more than 60,000 mothers and their partners recruited during pregnancy through maternity units participating in Life Study, and a birth component comprising a nationally representative sample of 20,000 babies recruited through the birth register. The larger component of pregnant mothers is geographically clustered. The maternity units have been selected to represent births to mothers from a range of ethnic and social backgrounds, with over-representation of births to mothers from black and minority ethnic groups.

Mothers and their nominated partners will be invited to attend a specially commissioned Life Study centre local to selected maternity units on one occasion around the 28th week of pregnancy. Mothers will be invited to attend the same centre with their baby when their baby is aged 6 and 12 months. Attendance at a Life Study centre will enable a richer assessment of the child’s development than is possible in the home.

At the same time a nationally representative sample of approximately 20,000 UK births will be recruited based on a clustered sample survey design from England, Northern Ireland, Scotland and Wales. Mothers, and their partners, will be visited at home when the child is 6 months old. Mothers will have a further assessment using computer assisted web or telephone interviews when the baby is 12 months of age. No biomedical measures or biological samples will be collected in this group.

Babies recruited through the pregnancy and birth components will be born over the same time period as far as is possible and the study design ensures that data from both sources can be combined using appropriate statistical methods. Recruitment to both components will take place over a four year period from 2014-18 with one year follow up of last recruits completed in 2019. Data will be made available to researchers through the UK Data Service in an anonymised form to protect participant confidentiality, with stricter controls on access to sensitive data. Research ethics approval has been given by London – City and East Research Ethics Committee and Life Study is registered under the Data Protection Act.

### **4. What does taking part in Life Study involve?**

The pregnancy component involves three visits for mothers: the first, in pregnancy, includes an invitation to her nominated partner while the second and third made when the baby is 6 and 12 months old respectively, involve just her and her baby. These visits comprise a mixture of interviews, questionnaires, measurements and taking of blood and urine samples. The birth component involves a questionnaire for the mother and the father/partner at a household visit made when the baby is six months old and a telephone or web-enabled questionnaire with the mother only at 12 months. In all instances participants will be given information about the Study ahead of the visit and informed consent obtained. We are currently piloting some work with fathers/partners which may lead to one further contact with fathers/partners at around 12 months.

### **5. What information is collected?**

The information collected through questionnaires and interviews is divided into three broad, over-arching topic groupings, namely: Parents and Families, Infants, and Neighbourhoods and Environment.

Topic areas include:

### *Parents and Families*

Demographics, identity, parental and family health, parental mental health, infections and immunity, behaviour and lifestyle, education, employment, financial situation, pregnancy and birth, parenting, family relationships, and social networks and support.

### *Infants*

Child health, child development, sleeping and crying, diet and nutrition, and childcare.

### *Neighbourhoods and Environment*

Housing, neighbourhoods, and environment.

Other measures to be collected at the Life Study Centre visits include assessments of child neurodevelopment and of body size and composition on mothers and partners (height, weight, body fat and skin folds) and on babies (weight, length, head girth, skin folds and mid upper arm circumference). These measures are not collected from participants in the birth component.

No blood will be taken from the babies. Blood and urine samples will be collected from the mothers and their partners, and urine and saliva from the babies at the Centre visits. A sample of placenta and umbilical cord will be collected from the maternity units at delivery and other samples (principally cord blood and faecal samples) relevant to assessment of infection and immunity are being piloted. In addition, leftover dried blood spots and maternal serum collected for new-born and antenatal screening respectively will be collected. Samples will be processed and stored in a central biorepository. No biological samples are collected from participants in the birth component.

## **6. Linkage to information from routine health and administrative records**

All participants will be asked to consent to linkage to information derived from their routine health and administrative records. This enables long term follow up of participants. Administrative data sources include school data held by the Department of Education as well as income and benefits data held HMRC and the DWP. Life Study has liaised with government and regulatory authorities to ensure consent forms meet their requirements.

As with previous cohort studies, it will be important to link to a range of other variables relating to the neighbourhoods in which participants reside. By linking to postcodes, it will be possible to access and derive a number of these variables, for example about the area that participants live including measures of air and water quality as well as of the built environment.

Participants have been asked to consent to linkage to the following records all of which have been used in other research studies. These include: primary care and hospital health records; health-related demographic registers used to trace participants in and to identify future migrations or death; benefits and employment records; education records; mobile phone records; assisted conception records; and maternity and child health datasets; and cancer registries.

## **7. Follow-up and future data collection after the first year of age**

It is intended that parents and children participating in Life Study will be re-contacted at later ages with further questionnaires and biomedical follow up. These would allow assessment of changes to family circumstances, measurement of child growth and development, and ascertainment of key outcomes such as health and educational outcomes in the child. Follow up of cohort members would include linkage to routine records as described above.