

LIFE
STUDY

Understanding lives –
now and for the future

Barking, Havering and Redbridge
University Hospitals



NHS Trust

ABOUT



STUDY

PARTICIPANT INFORMATION FOR MOTHERS WITH BABIES

THE BOOKLETS 'PARTICIPANT INFORMATION FOR PREGNANT WOMEN' AND 'PARTICIPANT INFORMATION FOR FATHERS AND PARTNERS' TELL YOU ABOUT THE FIRST STAGES OF LIFE STUDY.

NOW WE'D LIKE TO TELL YOU ABOUT THE NEXT STUDY CENTRE VISITS FOR YOU AND YOUR BABY.

BEFORE YOU DECIDE WHETHER OR NOT TO TAKE PART IN THE BABY VISITS, IT IS IMPORTANT FOR YOU TO UNDERSTAND WHAT TAKING PART WILL MEAN FOR YOUR BABY.

PLEASE TAKE TIME TO READ THE FOLLOWING INFORMATION CAREFULLY. DISCUSS IT WITH OTHERS IF YOU WISH.

ASK US IF THERE IS ANYTHING THAT IS NOT CLEAR.

IT IS YOUR CHOICE WHETHER OR NOT YOU WANT YOUR BABY TO PARTICIPATE.

Contact details

Phone: 0800 953 6655

Email: midwife@lifestudy.ac.uk

Website: www.lifestudy.ac.uk

ABOUT LIFE STUDY

Life Study is a new and very important research study that will involve more than 80,000 babies born between 2014 and 2018 – and their families – from across the UK.

Life Study will collect information about these babies over their early lives and childhoods and into adult life. This will help us understand how early life experiences shape health and wellbeing later on.

Life Study will support a wide range of research designed to understand how to give every child the best possible start in life.

In the UK, there have been several major research studies similar to Life Study beginning in 1946 and most recently in 2000. Between them these studies have recorded the childhoods and adult lives of different generations growing up in Britain. Babies in the earliest study are now well into their sixties and they continue to help researchers understand the importance of childhood experiences and how making a difference to children's lives today makes a difference to their future lives as adults.

Life Study will focus on the lives of a new generation. It is also different to previous studies in some important ways. Unlike most other studies, Life Study will start in pregnancy creating an exciting new opportunity to understand how babies grow and develop from as early as possible. It is also the largest study of its kind so far, which means that we will be able to answer some research questions we haven't been able to before now using other smaller studies.

From the information, measures and samples we collect from Life Study babies and their families, researchers may be able to understand:

- why some babies develop asthma, eczema and food allergies while others do not
- how children get ready for learning at school during their preschool years
- how fathers influence their children's development

Birth cohort studies

Life Study is a special type of research study known as a birth cohort study – it starts with babies born over a certain period and then continues to study the same babies throughout their lives. The babies in the first UK birth cohort study have been seen more than 17 times and are now over 60 years old!



Pollutants

A pollutant is a substance put into the environment that may have bad effects either very soon or after a longer time. The metal lead is an example of a pollutant that can have a bad effect on children's development. It was taken out of petrol in the 1990s in the UK to protect children's health.



Did you know...

From blood samples we can look at things like antibodies that are produced when your body tries to defend itself against an infection. A certain type of antibody is produced in allergic reactions so doing a test for those antibodies would give us information about things like food allergies, and hay fever or pollen allergies and others. We can also look at vitamin levels and deficiencies, which are related to our changing food nutrients.



- the impact of air and chemical pollutants in early life
- which parental leave policies are best for parents with young children.

The time is right for a new study. Life in the UK is changing all the time and babies born today will have very different lives to ours and will live longer than their parents – one in five will live to be at least 100 years old! By making sure we involve all different families, from different communities, cultures and backgrounds, whether in good health or not, Life Study will not only reflect the rich social and cultural mix of the UK today but also help us understand how to give all children the best possible start in life.

By taking part in Life Study you could make a difference to the lives of your children, your children's children and many generations to come.

WHAT WILL HAPPEN IF I TAKE PART?

If you agree to take part, we will ask you to:

1 Visit our Life Study Centre at King George Hospital

We will ask you to visit us three times: once during the last four months of your pregnancy and then two more times during your baby's first year. The visits may last up to two hours each.

At each visit you will be asked to answer some questions, have your weight and height measured and eyes tested, and give a small amount of blood and urine. Your baby will have similar measurements and will also be given some tasks and games to play – some of them with you. We will watch while they do these and film them. We would like to collect a small amount of their urine, saliva and poo. We will not take any blood from your baby or carry out any tests that are painful or uncomfortable for them.

2 Give some biological samples

We will ask you to give some samples around the time of birth. Some of these might otherwise be thrown away. These include:

- placenta (afterbirth) and some blood left in the umbilical cord
- blood samples left over from routine blood tests at your antenatal clinic visits
- blood samples left over from your baby's newborn screening bloodspot (heel prick test).

We would also ask you and your baby to give a sample of stool (poo) and urine and would like you to give a vaginal swab.

3 Agree to be contacted again by Life Study in future – we may wish to contact you and your baby again at some time in the future to answer other questions or attend for more visits. It is your choice whether to take part in these when you are contacted.

4 Agree Life Study can request information that the NHS and other organisations already hold about you to allow us to understand about your and your baby's future health and wellbeing.

This will help researchers get a more complete picture of how the information Life Study collects directly from you may be related to other events in your and your baby's life. This would only be done with your permission.

If you take part in Life Study you will be agreeing to have the anonymised samples and information you and your baby have provided stored by Life Study and used by researchers for many years to come.

This booklet is about the visits to the Life Study centre after your baby is born – when they are about six months and 12 months old – and information linkage for your child.

DO I HAVE TO AGREE TO EVERYTHING?

No. If you feel uncomfortable about answering some questions then you do not need to answer them. If you are unable to have some measurements or do not want to have them, you can still take part without doing these.

We do need you to agree to us getting some information from your health records, and to using birth and health records to track when your baby is born. If you do not wish to agree to this, then you will not be able to join Life Study.

Ideally, we would like a blood sample from you and a saliva sample from your baby. If you are worried about giving these samples, then please talk to the Life Study staff or midwife about this.

Find out more

Find out more about information linkage and your child on pages 18 – 22.

You can also visit our website www.lifestudy.ac.uk for more information.



Did you know...

Previous research based on studies like Life Study has improved children's health and lives. For example, studies like this led to changes to make it easier for parents who want to stay in hospital with their sick child.



THE LIFE STUDY JOURNEY



At the 20 week scan

At your scan appointment, our Life Study midwife will give you some more information and ask you if you would like to take part in the study.

You will be able to ask questions and discuss anything you need to know or are unsure about.

You don't have to decide straightaway. You can think about it and contact us later.



After 20 weeks

Your first Life Study appointment at your local study centre:

King George Hospital

It should be about two hours long.

With your permission, we will ask you some questions, take some measurements and collect some small samples of your blood and urine.

We would like to see dads or partners at the pregnancy visit and you can come along together.



Birth

With your permission, we will collect some samples from you and your baby around the time you give birth.

Some samples would normally be thrown away after birth, such as placenta (afterbirth). We will not take any blood from your baby.

The samples include:

- placenta, umbilical cord and cord blood
- Blood left over from routine blood tests
- vaginal swab
- stool (poo)
- urine
- saliva
- throat swab



Baby 6 months

Your second Life Study appointment at your local centre:

King George Hospital

It should be about two hours long.

With your permission, we will ask you some questions, take some measurements and collect some samples from your baby: urine, saliva and stool (poo).

We would also like to watch or record your baby doing some tasks and games together with you.



Baby 12 months

Your third Life Study appointment at your local centre:

King George Hospital

It should be about two hours long.

With your permission, we will ask you some questions, take some measurements, and collect some samples from both you and your baby.

You: blood and urine

Baby: urine, saliva, stool (poo).

We would also like to watch or record your baby doing some tasks and games together with you.

THE 6 MONTH VISIT

Red book

The personal child health record (or 'red book') contains information about things like your child's immunisations and may help in answering some of the questions at the visit.



Did you know...

From saliva, we can test for food allergies.

In stool (poo), we can measure the number and type of different microbes (bugs like bacteria and viruses). We are interested in the types of microbes that live in different parts of the body. These microbes may have an important role to play in deciding whether children get allergies or other illnesses.



WHAT HAPPENS BEFORE THE VISIT?

Before you come, we will confirm your appointment in a letter and ask you to fill in a short form with details like your NHS number and your baby's details.

We will also ask you to complete a short questionnaire about your baby's development, sleeping patterns, eating behaviours and the activities you do with your baby.

You will need to bring the completed form, questionnaire and your baby's red book with you to the visit.

WHAT HAPPENS DURING THE 6 MONTH VISIT?

When you arrive, the Life Study team will tell you more about the visit and answer any questions you may have. You can then decide whether to continue. If you wish to continue, you will be asked to sign a consent form for your baby to take part. You can let the Life Study team know if you wish to skip any questions, measurements or samples.

During the visit, we will ask you to:

- answer questions, for example about your baby's birth, health, your health, work, lifestyle, neighbourhood and childcare arrangements

During the visit, we would like your baby to:

- have some measurements
- give small samples of urine (by putting a cotton wool ball or filter paper in your baby's nappy), saliva (using a small sponge) and stool (from nappies). The samples will only be tested once they have been anonymised so they cannot be linked back to you or your baby.
- take part in some child development tests with you, including:
 - the 'gap task' – tracking your baby's eye movements
 - asking you to put your baby in a car seat
 - watching you and your baby doing activities together.

MEASUREMENTS AT THE 6 MONTH VISIT

LENGTH

Your baby's length will be measured lying down on a measuring table.

WEIGHT

Your baby's weight will be measured by sitting or lying your baby on electronic baby scales. You will be asked to undress your baby for weighing.

HEAD SIZE

Your baby's head size will be measured with a measuring tape.

SKINFOLD THICKNESS

Skinfold thickness will be measured on your baby's back and arm. A staff member gently holds the skin and fat up (not the muscle) then measures the thickness with calipers.

The calipers are used often in clinical practice and research. They are safe for use at all ages and are not painful.

ARM SIZE (MID-UPPER ARM CIRCUMFERENCE)

The circumference of your baby's mid-upper arm will be measured using a flexible measuring tape.

GAP TASK

In the gap task, your baby will sit on your knee and will watch some cartoons on a screen. An eye-tracking monitor within the computer screen is able to tell exactly where your baby is looking. This test will find out how quickly your baby responds to images, what kind of pictures interest your baby and for how long. It is called the 'gap task' because it is looking at the gaps in your child's interest or attention. The recordings will be used by child psychologists trying to understand baby's attention and behaviours.

CHILD DEVELOPMENT OBSERVATIONS

Your child will take part in some child development tests with you. We will ask you to play some games with your baby and strap your baby in a car seat. We will also ask you to show your baby some pictures.

A staff member will watch you and your baby and film you doing these activities together.



THE 12 MONTH VISIT

WHAT HAPPENS BEFORE THE VISIT?

Before you come, we will confirm your appointment in a letter and ask you to fill in a short form with details like your NHS number and your baby's details.

We will also ask you to complete a short questionnaire about your baby's development, sleeping patterns, eating behaviours, activities you do with your baby and toys they have.

You will need to bring the completed form, questionnaire and your baby's red book with you to the visit.

WHAT HAPPENS DURING THE 12 MONTH VISIT?

When you arrive, the Life Study team will tell you more about the visit and answer any questions you may have. You can then decide whether to continue. You can let the Life Study team know if you wish to skip any questions, measurements or samples.

During the visit, we will ask you to:

- answer questions, for example about your baby's birth, health, your health, work, lifestyle, neighbourhood and childcare arrangements
- have some measurements taken, including weight, body fat, waist circumference, skinfold thickness, mid upper arm circumference, and activity (using an activity monitor)
- give a sample of blood of 40-50ml (around three tablespoons) just like you gave in the pregnancy visit
- give small samples of urine.

During the visit, we would like your baby to:

- have some measurements
- give small samples of urine (by putting a cotton wool ball or filter paper in your baby's nappy), saliva (using a small sponge) and stool (to be collected at home and brought to the study centre). The samples will only be tested once they have been anonymised so they cannot be linked back to you or your baby.
- take part in some child development tests with you, including:
 - the 'gap task' – tracking your baby's eye movements
 - asking you to put your baby in a high chair
 - watching you and your baby doing activities and looking at pictures together.

MEASUREMENTS AT THE 12 MONTH VISIT



At the 12 month visit, we will repeat some measurements from the 6 month visit, such as:

- length
- weight
- head size
- skinfold thickness
- arm size
- gap task.

We will also do some new measurements of child development and eye tests.

CHILD DEVELOPMENT OBSERVATIONS

We will ask you to play some games with your baby and strap your baby in a high chair. We will also show you and your baby some pictures together. A staff member will watch you and your baby and make a film recording of you and your baby doing these activities together.



PLUSOPTIX EYE TEST: TO CHECK FOR A SQUINT

The Plusoptix is used to screen for squint (lazy eye) in children and babies. A staff member will ask you to sit your baby on your lap with baby looking at the machine they are holding and then a reading will be taken.

If the Plusoptix does not give a reading, we will ask to take a photograph of your baby's eyes and a specialist will look at this later.

FRISBY EYE TEST: TO CHECK HOW BOTH EYES WORK TOGETHER (STEREOVISION)

The Frisby screening stereotest is used regularly by eye specialists. It checks if both eyes work together – but it doesn't test how good your baby's eyesight is. Your baby will be shown a glass plate with four squares. A baby who has stereovision will look more often at one square because it looks different.

ACTIVITY MONITOR: TO MEASURE PHYSICAL ACTIVITY AND SLEEP

We may also ask you and your baby to each wear an activity monitor for eight days. The activity monitor is like a watch and it measures the amount of physical activity a person does. It doesn't need to be taken off at all during the eight days as it is waterproof, so it can be worn in the bath or shower, or swimming pool. The activity monitor will record how much time you, or your baby, are moving around or are asleep.

After eight days, you can post it back to us in a special prepaid envelope.

GENERAL INFORMATION ABOUT THE VISITS

WILL I GET ANY RESULTS AT THE VISIT?

The visit is not a health check and blood, urine and other samples will not be analysed immediately so we cannot give you or your GP any results. We will give you some readings of measurements (for example of your baby's size). If any measurements are outside of expected limits you would be advised to take them to discuss with your GP but we would not contact your GP directly. Life Study staff are trained to collect and record research information.

WILL MY GENERAL PRACTITIONER (GP) KNOW I AM TAKING PART?

If you agree, we will send a letter to your GP to say that you are taking part in Life Study.

We will NOT tell your GP anything about the information that you provide or the results of measurements or tests carried out during the visit. You may tell your GP about these if you wish.

If during the visit Life Study staff become concerned about keeping your baby safe from serious harm, they will follow child protection guidance. They may consider it necessary to contact your GP or healthcare professional.



WHAT IF I DON'T WANT TO CARRY ON WITH LIFE STUDY?

You can withdraw from Life Study at any point.

During the visit, you can withdraw by telling one of the staff.

After the visit, you can withdraw by telephoning 0800 953 6655 or by emailing midwife@lifestudy.ac.uk.

WHAT HAPPENS ONCE I HAVE STOPPED BEING PART OF LIFE STUDY?

This depends on what you have told us you want to happen. There are three options open to you. You can ask Life Study for: "no further contact" or "no further access" or "no further use". These are explained below and more details are also on the Life Study website.

'No further contact': This means that Life Study would not contact you again, but would have your permission to keep and use information and samples that you have already given and to request further information from your health and other records in the future.

'No further access': This means that Life Study would not contact you again and would not request information from your health and other records in the future. Life Study would still have



your permission to keep and use the information and samples you have already given us.

'No further use': This means that Life Study would no longer contact you and would not request information from your health and other records in the future AND any information and samples already collected would no longer be given to researchers.

Under all of these options Life Study would keep some of your information: for example, the consent form and withdrawal form would be kept as a record of your wishes and some

information would be retained to ensure you are not contacted again. Your information would not be used for new research, but it would not be possible to remove your information from research already completed. Depending on your preference, Life Study would destroy your samples that are still in storage. Your samples would not be given out for new research but it may not be possible to trace and destroy the remains of any anonymised samples that have already been given out.

Details of how to withdraw are on the Life Study website www.lifestudy.ac.uk.

CHOOSING TO WITHDRAW FROM LIFE STUDY

OPTION 1 NO FURTHER CONTACT

- ! Life Study will not contact you again.
- ➔ Life Study can request further information from your health and other records in the future.
- ➔ Life Study has your permission to keep and use information and samples that you have already given.

OPTION 2 NO FURTHER ACCESS

- ! Life Study will not contact you again.
- ! Life Study will not request information from your health and other records in the future.
- ➔ Life Study has your permission to keep and use information and samples that you have already given.

OPTION 3 NO FURTHER USE

- ! Life Study will not contact you again.
- ! Life Study will not request information from your health and other records in the future.
- ! Any information and samples already collected by Life Study will no longer be given to researchers.

WHAT WILL HAPPEN TO MY BABY'S SAMPLES?

Your baby's samples will be stored securely for future research studies, the same as for your samples. Any researcher who uses the samples will not know your personal details or be able to identify you or your baby. All research using the samples will have to be approved by an ethics committee.

We will not be testing the samples immediately. This means that we will not be able to give you any results from them.

HOW WILL MY CHILD'S INFORMATION BE USED?

Results from any questionnaires, measurements or from tests carried out on samples will be used by approved researchers. These researchers will use the information collected on all Life Study participants to understand how early life circumstances influence children's lives as they grow up. They include researchers who are working in the UK or other countries, in universities or for commercial companies looking at new treatments or diagnostic tests.

Your name and address are kept separately and Life Study will never pass on information with these personal details to researchers. Information that is given to researchers will be anonymised so they will not

be able to identify you or your baby. Researchers using the Life Study information will not know it was you who gave us that information or those samples.

Life Study will not sell your information to anyone.

Life Study will not pass on your personal information or results to insurance companies or employers. Life Study will not allow access to personal information or results by the police, security services, relatives or lawyers, unless legally forced to do so by the courts.

HOW WILL LIFE STUDY KEEP MY CHILD'S INFORMATION CONFIDENTIAL AND SECURE?

We're very careful to keep all of your child's information confidential and secure as this is very important to us.

Information or samples will be stored separately from your child's personal details (such as name and address) to protect their identity. Only the Life Study staff who need to contact you and your child will know your name and contact details.

We will store your child's information securely. We use a number of methods, such as encryption and secure computer systems, to prevent unauthorised access to your personal

information. All possible precautions will be taken to prevent unauthorised access and we do not expect this to ever happen. However, in the extremely unlikely event of unauthorised access, you and your child could not be identified. This is because when we collect your information or your child's information, or obtain further information from records, we remove personal details and replace them with a unique identification number (code).

WHAT WILL HAPPEN TO THE RESULTS OF LIFE STUDY RESEARCH?

Researchers will be expected to make the results of research based on Life Study publicly available so that other researchers and the public can obtain full benefit from it.

WHERE CAN I FIND OUT THE RESULTS OF LIFE STUDY RESEARCH?

Summaries of the results of Life Study research will be put on the Life Study website at www.lifestudy.ac.uk. For further information about the study, please contact us using the details in this booklet.



MORE ABOUT INFORMATION LINKAGE AND YOUR CHILD

Did you know...

Linking information about how children develop in the preschool years to their school record later on has been used before in studies like Life Study. This can help us understand how children become 'ready to learn' before they actually start school.



WHY DO YOU NEED TO LOOK AT MY CHILD'S RECORDS?

This is a good way to obtain information that you might not be able to remember easily. For example, GPs record details about the name or dose of medicines such as antibiotics or asthma inhalers that you or your baby may have been prescribed and this will give a better understanding of these important illnesses and treatments.

In Life Study, we are interested in linking to information from records which are related to a child's health and wellbeing and the wider circumstances of their family and community. Examples of these are records from GPs, hospitals, fertility treatment, dentists and opticians, and also education and school records, employment and benefit records and the Census which describes your neighbourhood area.

HOW DO YOU LINK TO MY CHILD'S INFORMATION?

We will ask for permission to access information from your child's routine records in the same way as we ask for permission to access your information. We can only ask for information from a child's records if we have consent from a parent or legal guardian. Some examples of information from your baby's records that we would like to request are:

- Birth information (including information from any admissions to special or intensive care if your baby has needed this care)
- Child Health Records (which record your baby's development checks and immunisations)
- Screening test results (such as the newborn hearing test)
- School information (once she or he starts attending school)



WHICH RECORDS WILL LIFE STUDY REQUEST INFORMATION FROM?

Details of the types of records containing information related to your child's health and wellbeing are in the table over the page. We would like your permission to ask for this information.

This may include information about physical and mental health, progress at school, or any special needs a child may have.

We also provide names of the organisations or departments who currently hold the records which contain this information. Sometimes these organisations or departments change. Where this could happen, we have included a more general statement in the consent form saying that you agree to us asking for information from 'the relevant department holding this information'.



Type of information	Why?	Where from?	What do you want to know about?	What sort of questions could Life Study help to answer?
 Health	<p>We may be able to understand how your child's health is affected by other areas of your lives and has an impact on later health and wellbeing.</p>	<p>Routine medical and other health records:</p> <ul style="list-style-type: none"> • NHS • family doctors or GPs • other healthcare organisations or providers, such as dentists or opticians • NHS registration records (currently held by the NHS Central Register and Personal Demographic Service) • public birth and death registrations (currently held by the National Records for Scotland, Office for National Statistics and General Register Office in Northern Ireland) • health-related records held by the UK Departments of Health • disease or other health-related registers, such as national cancer registers 	<ul style="list-style-type: none"> • visits to your family doctor or other health professional (for example, midwife) • admissions or attendances at hospital • prescriptions and treatment health status, and records of specific conditions such as diabetes 	<p>Does anything in pregnancy or early life make a child more likely to have asthma or food allergies later in life? Can we find a way to prevent that?</p>
 Education	<p>Your child's experiences at school are likely to be an important influence on their own lifelong health, development and wellbeing.</p>	<p>Different organisations, such as:</p> <ul style="list-style-type: none"> • school • college • university • work-based training or apprenticeships 	<ul style="list-style-type: none"> • exam results, for example SATS and GCSEs in England, Wales and Northern Ireland and Standard Grades in Scotland • information about disability, special educational needs (SEN), religion, looked after child or children in need status • information from the National Pupil Database • information about the school • courses/training records • higher education records 	<p>Does the age of a child when they start school make a difference to how well they do overall at school? Should children start school earlier or later than they do now?</p>



HOW OFTEN WILL LIFE STUDY ASK FOR INFORMATION FROM MY CHILD'S RECORDS?

This will depend on the type of record and how often it changes. We may request some information, for example from medical records, at regular intervals so we can look at any new information and keep up to date with events in your and your baby's lives. Other records such as school records may not change so often, and so we may ask for information from these once or twice. We may want to ask for information about your baby more regularly as this may change more often.

DO I HAVE TO AGREE TO INFORMATION LINKAGE FOR MY CHILD?

We will ask you to agree to obtaining some information from your child's routine health records as without this permission we cannot, for example, find out about your baby's birth, or trace you and your baby as you both grow older. *If you do not wish to agree to this linkage, then you will not be able to join Life Study.*

Education records are helpful to build a complete picture of the wider environment and life of children in our study but these are optional. We would



like to have your permission to request this information but you can still take part in Life Study if you choose not to let us use information from all the records suggested. On the consent form, you will be asked to indicate which records you will allow us to request your child's information from.

CAN I WITHDRAW OR STOP INFORMATION LINKAGE FOR MY CHILD?

You are free to tell us to stop requesting information from some or all of your child's records at any time without giving a reason.

We will continue using your child's information until you tell us that you wish to withdraw your consent or stop taking part.

OTHER INFORMATION

WHO IS ORGANISING AND FUNDING THE STUDY?

Life Study is funded by the Economic and Social Research Council (ESRC), Medical Research Council (MRC), University College London (UCL) and the Wellcome Trust. The Life Study team is based at UCL and collaborates with scientists, researchers and academics from all over the UK. NHS maternity units throughout the UK are also working with us to help make the study a success.

WHO HAS REVIEWED THE STUDY?

The plans for Life Study were reviewed by an independent group of international scientists before it was given funding. There has also been a UK-wide consultation with academics and researchers about the design of the questionnaires, measurements and sample collection. Participant representatives and members of the public have been involved in various ways, including focus groups and a study pilot, to give us their feedback on the study.

The study has been approved by the NHS London – City and East Research Ethics Committee (REC reference 12/LO/1492).

If you or someone you know would like this information provided in a different format or language, please visit our website www.lifestudy.ac.uk for more information.