

G0 biological sample collection participant information sheets and consent forms pre HT Act

Please note

- 'The consent requirements of the HT Act are not retrospective. This means that legally it is not necessary to seek consent under the HT Act to store or use an 'existing holding' for a scheduled purpose. An existing holding is material from the living or deceased that was already held at the time the HT Act came into force on 1 September 2006.'¹ The samples outlined in this document are classified as existing holdings and are therefore exempt from the HT Act consent provisions.
- Other versions of the documentation provided may have been used during sample collection
- The request for donation of specific sample types may have changed throughout the course of the collection timepoint

¹paragraph 56 of the HTA Code of Practice and Standards, [Code E: Research](#)

Table of samples collected for G0 pre HT Act and their corresponding consent form and participant information sheet

cohort	collection	sample collection dates	sample type	non HTA relevant material	HTA relevant material existing holdings	HTA relevant material post HTAct	copy of PIS provided	copy of consent form provided
G0 mother	Antenatal	1990-08 to 1992-11	whole blood, blood derivatives, urine	Y	Y		1. Joining in 'Children of the Nineties' (pg. 1)	1. Consent form -Children of the Nineties (pg. 3)
G0 mother/G1	Birth	1991-01 to 1993-01	blood derivatives, placenta, cord, DNA	Y	Y		1. Joining in 'Children of the Nineties' (pg. 1)	1. Consent form -Children of the Nineties (pg. 3)
G0 mother/father	Nov-93	1993-11	hair, nails	Y			1. Newsletter Summer 1993 (pg. 4) 2. Hair and Nail letter (pg. 6)	1. Implied Consent (pg. 8)
G0 mother/father	Carer *	2005-02 to 2008-06	whole blood, blood derivatives, cell line, DNA	Y	Y	Y	1. We're changing the world (pg. 9) 2. DNA, Genes and Cell-Lines (pg. 14)	1. TeenFocus2 Parent Blood Consent (pg. 13) 2. TeenFocus2 Parent Cell line Consent (pg. 16)

NB: Page numbers in table are those labelled as 'G0 participant sample documentation pre HTAct page' in document. * The collection includes samples donated pre and post HT Act.

JOINING IN 'CHILDREN OF THE NINETIES'

QUESTIONS AND ANSWERS

What will I have to do?

Nothing unless you want to. As a mother you have the right to say 'no' at any point. You can decide to do some things but not others. Of course, we hope you will want to do every-thing as the more mothers who join in the better.

How can I help?

We will be sending you a number of questionnaires to fill in at various times. These will ask about you and your feelings, your home and how you live, your likes and dislikes. We hope you will enjoy filling them in.

What about my partner?

If you are living with a husband or partner, we would very much like to include them in the research. Partners can be an important influence on the health and development of a child. If you agree we will give you a questionnaire to pass on to him. His answers will, like yours, be confidential and he will be asked to return his questionnaire directly to us. The decision to include your partner in the study, however, will be yours.

How do you measure health?

We will know how your pregnancy progresses from the hospital records, and details of your baby and how he or she develops from the child health records. These will not give us enough information on you and your baby though, and we will be sending you questionnaires asking for details of how you are feeling and any problems you may have with the baby.

Does the study involve anything else?

We are not conscious of many of the things that are happening around us. We won't be aware, for example, of the amount of lead we are breathing in from car exhausts or the magnetic fields that result from electrical equipment.

Researchers can work out some of these things using chemical tests on blood and urine samples. In order to do this we will be keeping some of the blood and urine that is routinely taken from you during your pregnancy. We will keep the placenta (the afterbirth) once the baby is born. We may also ask for a lock of your hair. With the blood we will be able to find out whether you have an allergy, and whether your genes affect the health of your baby.

We won't do any of these tasks unless you give us your permission to do so.

Some of you will be asked if you would like to take part in special studies, (with additional measurements made in your home).

This will only be done if you are happy about it.

What if I don't want to fill in questionnaires?

If for any reason you do not wish to fill in the questionnaires yourself, you might prefer to be visited by one of our Children of the Nineties assistants. They can ask you the questions and fill in the form for you while you are busy with the baby or doing housework or just putting your feet up.

What if I miscarry?

Please let us know as soon as you can. We do not want to upset you by sending more questionnaires about your pregnancy, but we would like to ask you some questions about how you are.

What about privacy and confidentiality?

This is very important. The forms will only have a number on. A very complicated set of procedures will ensure that no one will be able to link the information you give us with your name. If you want to know more about this, please let us know, and we will send you an information sheet.

How long will the study go on?

It is starting during pregnancy. For some parents it will stop when the baby is born and for others it will continue until your child is at school.

A lot of the Children of the Nineties study will be interesting and fun. We hope you will want to take part. There will be newsletters letting you know the results of the study, and birthday cards for your child.

What happens next?

Please send back the enclosed card, and then we will send you a questionnaire in a few days time. Other questionnaires will follow in the next few months.

Further information

If you want to discuss any details please ring the Children of the Nineties hotline (Bristol 256260) during office hours, or write to the address below.

Dr. Jean Golding, Children of the Nineties - ALSPAC, Institute of Child Health, 24 Tyndall Avenue, Bristol. BS8 1BR.

Telephone: Children of the Nineties hotline - (Bristol) 256260.



**The Avon Longitudinal Study of Pregnancy & Childhood
(ALSPAC)**



Children of the Nineties

24 Tyndall Avenue
Bristol BS8 1TQ

Tel: Hotline (0117) 928 5007

Direct: (0117) 928 ____

Fax: (0117) 928 5010

Ref: (3)D:\usr\jean\consent.fm1

Consent Form - Children of the Nineties

I have now considered the proposal that various samples of blood and urine from me, and the placenta, may be kept by the Children of the Nineties project and used for research purposes.

I understand that the results of all analyses will be kept as highly confidential, that the samples will be stored with only a number on them, and that there will be no way of identifying either me or my child from these samples.

I confirm that I will be happy for these samples, including the baby's placenta, to be stored and used for research purposes.

I also understand that if I should change my mind at any point will be allowed to do so

Signed:

Date: 19

Name in full

Your date of birth: 19...

If you do not wish some or all of these samples to be used for research, please say so below and sign your name:



Newsletter

SUMMER 1993

CHILDREN IN FOCUS

You may think that with all the questionnaires you fill in, and the blood and urine samples and placentas, we have enough information to answer every conceivable question. Almost true, but for some studies it is necessary actually to meet, measure, and test some children at regular intervals to find out the answers.

For this reason we have picked out a thousand babies at random, and invited their mothers to bring them in to the clinic at 4 months and, if they are willing, again at 8, 12 and 18 months. At 4 months we measure growth accurately, look at vision and at the way the babies recognise pictures. At 8 months our staff again measure growth, and look at vision. They also look at the way the eardrum moves and take a small blood sample if the mother is happy with this. The mother is also asked to fill in a dietary diary of everything the baby has eaten and drunk, including medicines, over 3 days.

The feedback from parents about the clinics has been very positive, and most have enjoyed the experience and are willing to return. For our staff it has been a delight actually to meet mothers and babies instead of just dealing with names, numbers and piles of questionnaires.

One benefit of this part of our study will be to help the health service planners decide whether health visitors and GPs should examine all babies in different ways than they do at present. For example, should they be looking for anaemia or glue ear in the first year of life?



4 month old baby having his arm circumference measured

Our 1000th Child In Focus

(Left) baby Ross and his mother Sue Collins at the 4 month clinic. Ross has two big sisters, Michelle, 9, and Danielle, 7, who thoroughly enjoy their baby brother.

Sue says the age gap has allowed her more time and energy for him too. She feels that the study is very worthwhile and she enjoyed the tests at the clinic.



SHALL WE HAVE A PARTY?

One mother suggested how nice it would be to put on a party for parents who have taken part in Children of the Nineties. She wanted to meet Professor Golding and other mothers and babies to share experiences. What a lovely idea! The only problem is that there are more than 14,000 mothers, and nearly as many fathers taking part, plus babies and other children. We were somewhat overawed by the idea of a party on that scale. Any ideas?

BABIES' SLEEPING PATTERNS

At 6 months you are asked about your baby's sleeping patterns. Our preliminary analysis of the first 6 month questionnaires sheds light on sleeping behaviour at that age.

Whether a baby sleeps through the night or not is a subject of intense interest to you, the parents, (and also to us). The conflict between your needs and expectations and the baby's behaviour may drive you to seek help from your health visitor or G.P.

For some parents, knowing that the baby is well and that the sleep pattern can be considered as 'normal', or at least that it is shared by many babies of a similar age, may be sufficient help for them to be able to cope with the situation.

So what is the normal range of sleep patterns? The

hours the baby slept each night ranged from 1 to 15 with 12 being most common. For 16% of babies there was no regular sleeping pattern.

Only 16% never woke at night at 6 months. 50% woke occasionally, 9% woke most nights, 5% once every night and a further 17% woke more than once per night with the number of times ranging from 2 to 8.

What parents do when their baby wakes is shown below. The strategies which are most frequently used are presumably those which work most often for most babies. By 6 months more than half the babies (61%) were put to sleep in their own rooms, on their own, although almost 1 in seven was moved during the night. Twenty eight percent slept in their parents' bedroom.

When your baby wakes at night what do you do?

		Always	Usually	Sometimes	Never
a	feed him/her milk	16%	13%	23%	48%
b	give other drink (including water)	2%	5%	27%	66%
c	rock or cuddle	23%	16%	33%	28%
d	give him/her a dummy	16%	14%	10%	60%
e	bring him/her into your bed	8%	7%	34%	51%
f	change his/her nappy	7%	8%	49%	36%

POINTS FROM THE OFFICE

You may have been thinking that it was a long time since you heard from us. As you see we have not forgotten you. It's just that the gap between questionnaires widens as the baby grows. The sequence for the first two years is 4 weeks, 8 weeks, 6 months, 8, 15, 18, 21, 24 months.

With the wider gap between questionnaires, it becomes easier to lose you, so please don't forget to let us know if you move or change your phone number.

UPDATE

Dannielle, the little girl with Turner's Syndrome whose story was featured in the Spring '92 newsletter, is doing very well. At 18 months she began walking and now, almost 2, she runs everywhere. She's eating and drinking normally and starting to put sentences together. With the treatment she receives she is growing fast, and her mother Sarah is constantly finding longer clothes for her.

Sarah and another mother of a child with T.S. are setting up a support group in Avon. They can be contacted through our hotline, 0272 256260.

CAN WE HELP?

Having a young family means busy days and nights. If filling in one of our questionnaires is the last straw for you and keeps going to the bottom of the pile - do ask for help! We are very happy to come out and go through it with you. If you have several children - a job - a sick child, or alternatively if our questionnaires seem totally inappropriate for you or your child Please call us on Bristol 256260 and ask for Pam.

HAIR AND NAIL SAMPLES

Many trace elements like aluminium and mercury occur naturally in small quantities in our bodies. We would like to examine hair and nail samples of children in our study to see what their current levels are, and whether there are any problems connected with higher or lower levels.

Sometime soon we may ask you if you could send us some of your baby's nail clippings and a small sample of hair. Using these we will be able to estimate levels of trace elements in the body. This is done by vaporising the samples with a laser and measuring the energy emitted. Different trace elements give off energy at different characteristic frequencies and up to 20 different trace elements can be measured from one sample.

The Avon Longitudinal Study of Pregnancy and Childhood (ALSPAC)



11 APR 1994

Children of the Nineties
Institute of Child Health
University of Bristol
24 Tyndall Avenue
Bristol, BS2 8BJ
Tel: Hotline (0272) 256260

ref: hair.nai

8.3.1995
KT

Dear Mother,

Thank you again for all you are doing to help. This is enabling the study to continue to be the best ever.

There are just a few things we would like to ask you now:

1. We would like to put your study child's name in our files so that we can send birthday cards directly to him or her:

My study child's full name is

2. We are also anxious to bring our records up to date.

Is your name and address above correct? PLEASE WRITE ANY CHANGES BELOW.
Include any new telephone number.

.....
.....

TEL. NO.....

Thank you

HAIR	NAILS	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	CHILD
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	MOTHER
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	FATHER

NOW PLEASE TURN OVER →

Steering Committee:
Professor J. D. Baum, Professor G. M. Stirrat,
Professor M. Pembrey, Professor C. Peckham, Professor J. Golding,
Professor M. Rutter, Professor J. Berry, Dr. C. Pennock, Dr. J. I. Pollock.

AND NOW FOR SOMETHING COMPLETELY DIFFERENT

HAIR AND NAILS

In order to look at the ways in which the air we breathe, the water we drink and the food we eat may influence our health, we would like to have some hair and toe nails from you, your study child and your partner if you have one. We will be using these to look at levels of things like mercury and lead.

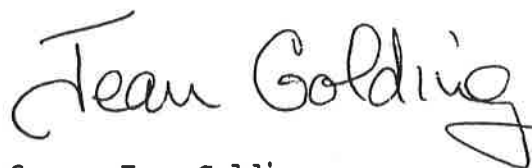
If you are happy to do this WE HAVE ENCLOSED 6 BAGS AND 6 LABELS. Two for YOU, two for your CHILD and two for your PARTNER.

1. Please peel off the labels and put one on each bag.
2. Hair should be cut from the back (nape) of the neck as close to the scalp as you can manage. We would like whatever you can give us, (the more the better) from each of you. PLEASE PUT THE SAMPLES IN THE APPROPRIATE LABELLED BAGS MARKED 'HAIR'.
3. Cut several toe nails and put them in the appropriate bags marked 'nails'.
4. Make sure the bags are sealed tightly and post back to us together with this piece of paper when completed.
5. Please answer the following questions for each of the persons for whom hair has been enclosed:

	Study child	Mother	Partner
a) Please list the types of shampoo (and conditioner) used in the past month
b) List anything else that has been used on the hair in the past 6 months (e.g. dye)

N.B. We are cutting costs by not sending a reminder - so please don't wait. Send this back as soon as you can. Many thanks for all your help.

Yours sincerely,



Professor Jean Golding

P.S. If this has come at around the same time as one of your regular questionnaires, we do apologise. This mailing is in fact going to everyone at roughly the same time.

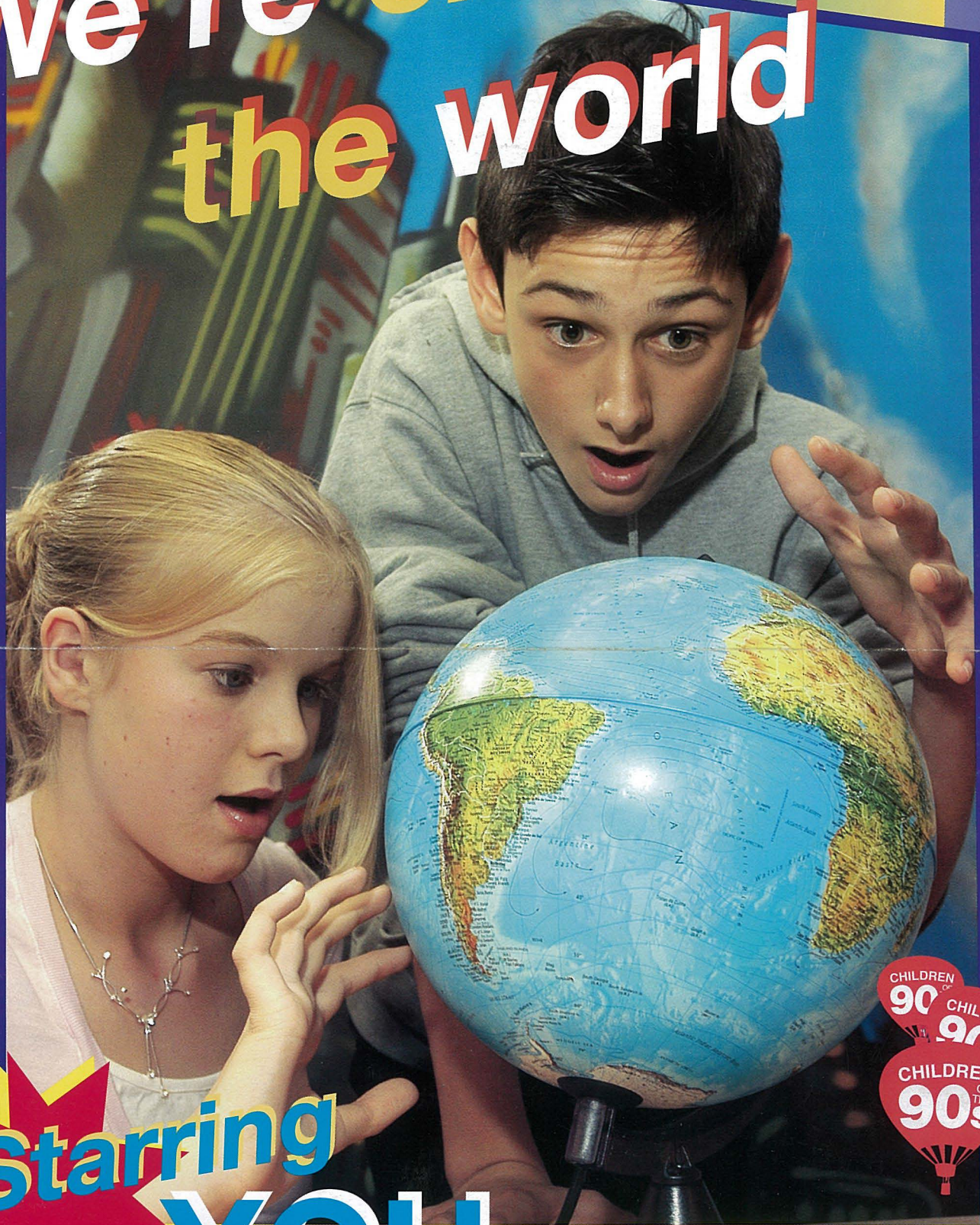
IMPLIED CONSENT

The consent for the hair and nail collection was not formally documented. However, as these samples were collected by the participants at home and posted to ALSPAC consent is implied.

CARERS SAMPLES

Biological samples were collected from a parent/guardian when the G1 participant attended one of the Teen Focus Clinics. If the parent/guardian accompanied the G1 participant at multiple Teen Focus timepoints samples were only collected from the parent/guardian at one timepoint. An example of the information given for the collection of carers samples is provided.

We're changing the world



CHILDREN
OF THE
90s

CHILDREN
OF THE
90s

CHILDREN
OF THE
90s

Starring
YOU

and a cast of thousands....

at **STARBURST**

Reception area:
Battle the aliens on our new space invaders machine.

Day in the life

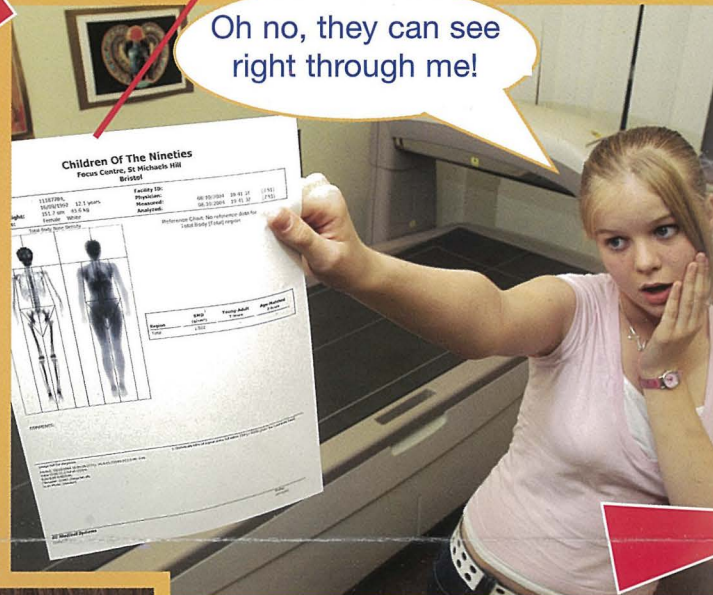
As soon as they arrive, Reuben and Kez can see that Focus is going to be fun



Hmmm.... it's looking good!!!

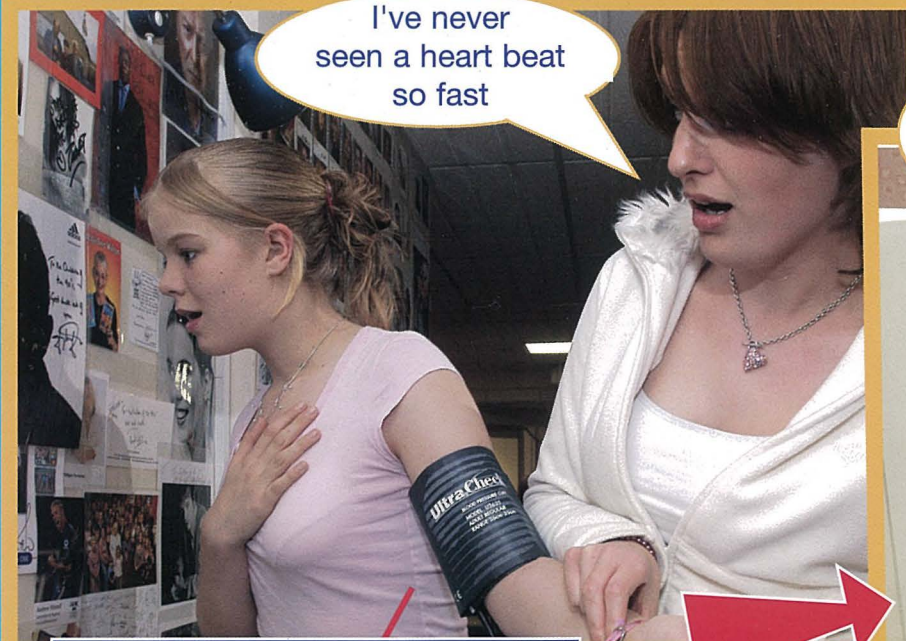
Measuring: You will be able to see how your skeleton is. Also, for the first time we will also be looking at...

Kez sees herself in a totally new way



Oh no, they can see right through me!

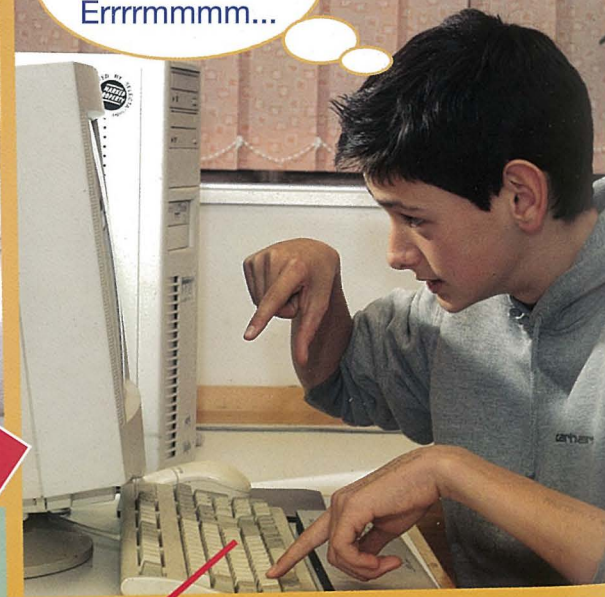
I've never seen a heart beat so fast



but Kez has spotted her heart-throb on the Wall of Fame

It asks, "Are you decisive?" Errrrmmmm...

Reuben is determined to beat the computer



Blood pressure:
We'd like to check your blood pressure to see if it is changing as you get older.

Computer sessions:
We will be asking about your life and about your friends on the computer. There are some games to play too.

Diet:
How has what you eat since you were 10+? The forms you fill in help us to do a survey of 13-14 year olds' diets

of TEENFOCUS2

Fitness:
We want to see how fit you are and whether this has changed since you were 9+.

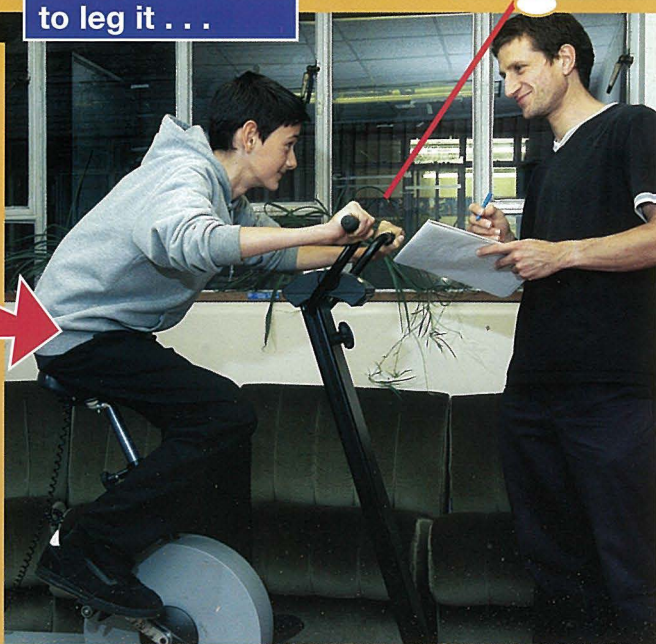
is developing again with our special low dose scanner.
flexible some of your joints are.

Then things get even weirder . . .

Are we going round the bend?

Reuben decides to leg it . . .

This guy should go in for the Olympics!

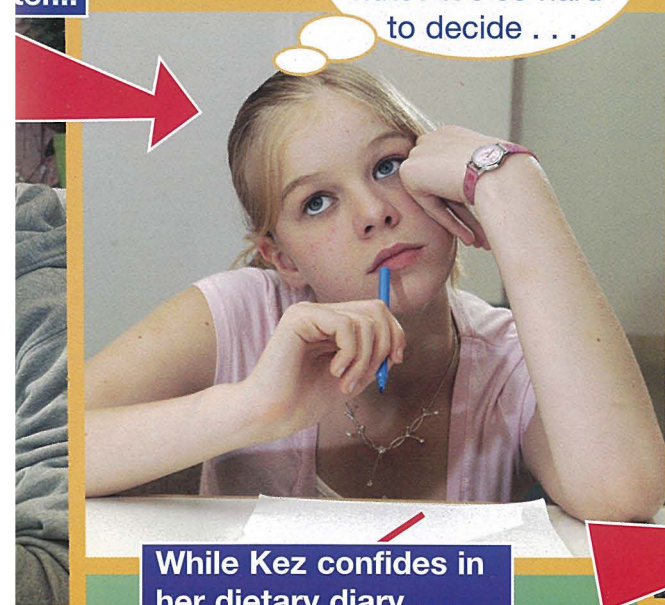


I've had enough excitement for one day

Carrot stick or 6-pack of doughnuts? It's so hard to decide . . .

Better not over-do it . . .

ned
ter...



While Kez confides in her dietary diary . . .

. . . and they both test out their activity monitors

Activity monitors:

The monitors that you wore at 11+ are producing excellent information in relation to diet, blood pressure, height, weight and so on. We need to see how these things change as you get older.

NOW! Turn the page

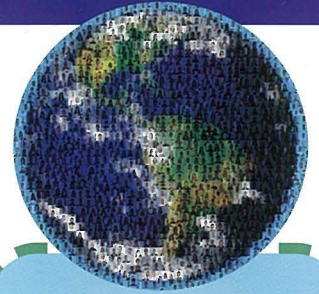
to find out more...

and drink changed dietary diaries over what we like today.



WHAT YOU CAN EXPECT AT...

TeenFocus2



You may feel that lots of things are changing in your life - at school, with your friendships, tastes and attitudes, abilities and interests. We want to monitor those changes and describe, in scientific papers, what it means to be growing towards adulthood in the first decade of the 21st Century.

That's why your visit and the information you give are so important. It's also why some of the

measures and questions are apparently the same as before. The results may be very different this time, because you are older.

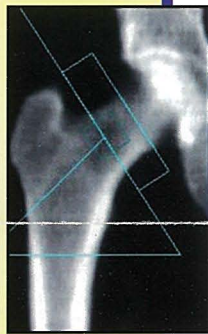
You can say no, or stop if there is anything you don't want to do or answer. All the information you give us is stored anonymously. We are sorry that we can't feed back to you all your own results, but we can give you height, weight, and blood pressure measurements.

You're changing the world!

Because of you and all the children of the 90s, people across the globe can look forward to happier and healthier lives. So, as a symbol, we're creating a picture of the world, made up of your faces which will become a poster for the Focus Centre. We'll be sure to have a magnifying glass on hand too so that you can spot your friends.

Measuring

Are you happy for us to measure your height, weight, arm and hip circumferences and the straightness of your back? If so please wear clothes you're happy to be measured in. We'll be doing an additional scan of one hip (see picture). This is something that is usually done when people have a scan of their whole body.



● To contact
TeenFocus2

call: 0117-928 8266

Interview and Computer session

We want to see how things in your life are changing as you get older. We are interested in the moods and feelings that you have and what sort of person you think you are.

Blood pressure and sample

Would you like to give blood and saliva samples this time? We know we ask you frequently but these samples are so valuable. They answer so many questions especially about things like hormones and antibodies to infection which change over time. Like everything at the visit it's entirely voluntary so you can always say no.

Fitness

To test your fitness, we may ask you to do a basketball task instead of cycling, (pictured).



Parents

Don't feel left out! You often tell us that you want to be involved and we plan to ask if you would be willing to give us a blood sample and if time to have your height, weight and blood pressure measured. As always at these visits everything is voluntary and if you can help us with these things it is a bonus. As you can see from the picture here we had a bit of fun 'sizing up' a 6ft 5in study dad!



... and if you have time to spare at TeenFocus2 there's the Exploratory to explore again - you may find some different things there this time!

◆ Log on to your Children of the 90s website for the latest competitions, games and news
www.alspac.bris.ac.uk/discovery



CONSENT FOR EMLA (if applicable)

Have you ever had a bad reaction to local anaesthetics? Y/N

Have you recently used or been given a local anaesthetic? Y/N

Are you taking any medication containing sulphonamides? Y/N

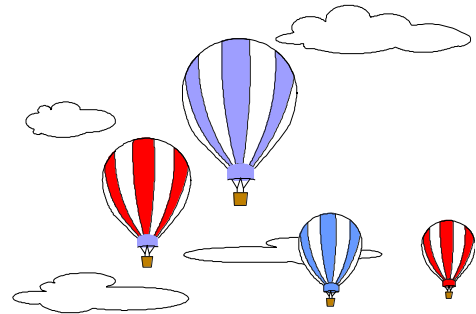
.....
Are you anaemic? Y/N

Do you suffer from any clotting or bleeding disorders ? Y/N

Signed.....

Date.....

CHILDREN OF THE 90s



TeenFocus2
24 Tyndall Avenue

Bristol BS8 1TQ
(correspondence only)

Tel: 0117 928 8266 There is an answer phone on this line.
e-mail: focus-admin@bristol.ac.uk

Permission to use blood samples

After the sample below has been taken, you will be informed if it shows that your Haemoglobin is low (below 9g/dl). After that analysis the name will be taken off the blood sample. It will be stored for future analyses. The blood sample will have no name attached to it. Results will be used for statistical purposes only and not linked to named people.

CONSENT

The purposes and possible risks in having blood taken have been explained to me. I understand that donated blood will be considered a gift but I will have the right to withdraw permission for analysis.

I agree to having a sample taken for biochemical analyses by/on behalf of the 'Children of the 90s' study:

Signed:

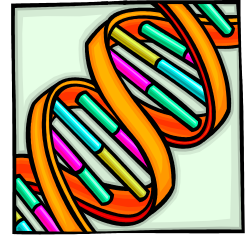
Date:

Name (PLEASE PRINT).....

The University of Bristol holds legal liability insurance in the event that any participant is injured due to any negligence on the part of the University.

DNA, GENES, and CELL-LINES.....

Our genes are important in making us more or less likely to develop many common diseases. We all have a slightly different set of genes in our bodies. DNA from a child's parents (mothers, fathers, partners) can help us in various ways to look at the effects of these differences.



We are therefore asking parents/carers visiting the clinics with their children if they would be prepared to provide a small blood sample which can be treated so that it provides a never-ending supply of cells which can in turn be used to provide DNA and which can also be studied to provide a more detailed description of how some parts of the body work. We would also take the opportunity to save some of the blood so that we could measure other things, like cholesterol.

Question: What are genes? **Answer:** Genes are the instructions which determine growth and development of all living organisms.

Question: What is DNA?

Answer: DNA is the chemical language in which genes are written.

Question: Why do you want to study my DNA?

Answer: Although we all have essentially the same genes as each other, there are many small differences which some of us have and others do not. These different versions of our genes make us more likely or less likely to develop many common diseases, such as allergies (like asthma), or diabetes or heart disease and can affect our character and behaviour.

Question: Is it just genes that cause disease?

Answer: No. We already know that many of our problems are partly caused by genes and partly by our environments.

Question: How will my DNA help?

Answer: Your child's genes are a mixture of your genes and the child's father's genes. By having DNA to study parent's genes we can work out which gene variants are responsible for the way in which your child grows and develops. We will also be able to find out how gene variants have affected parents and compare this with affects on the children.

Question: Why do you need more DNA?

Answer: We each have about 30,000 genes. With your permission, we want to study many of these genes in parents. The DNA we have extracted from blood samples taken during mothers' pregnancies will run out before we can complete this work. This time we would like to collect a blood sample and treat the cells from the sample so that they can be stored indefinitely as 'immortalised' cell-lines. These cells can be used to make more DNA whenever it is needed.

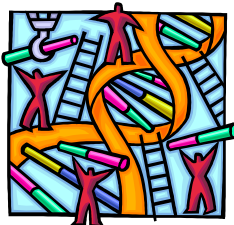
Question: What are *immortalised* cell lines?

Answer: Cells are the building blocks of the body. Skin, muscle, bones, blood, and all the other parts of our body, are made up of millions of cells. Each cell has a copy of all our genes. If we take cells from our bodies we can only keep them alive for a limited time. However if cells are treated with a virus they can be kept alive indefinitely - they become *immortalised*.



Question: Do *immortalised* cell-lines have other uses?

Answer: Yes, our study is unique in its detailed descriptions of its participants gathered over many years (as you have probably realised!). One of the ways in which we may be able to add further important information is by studying *immortalised* cell lines. Cells from cell-lines retain some of the basic features, as well as the DNA, of the people from whom they were derived. For example, cell-lines from people with raised blood pressure grow faster than those from people with normal blood pressure. Studying cells in this way may provide important stepping-stones that will help bridge the gap between genes and people and improve our understanding of how the two are linked.



Question: Will anyone be able to connect the results of tests to me

Answer: No. All the information in the 'Children of the 90s' study is kept separate from your name. No-one who works with samples or answers to questionnaires is allowed to know who they came from. This means that the study is completely confidential.

Question: Would you ever sell my DNA or cell-lines?

Answer: No, we would never sell these, or any of the information you have given us.

Question: If the 'Children of the 90s' study makes cell-lines from my blood, can I be sure they will not be used for cloning?

Answer: Yes, you can be sure. The use of human tissues, including cell-lines, is strictly controlled. Charities and government organisations which give money for research, Bristol University, and the Children of the 90s study ethics committee, which includes parents of study children, would not allow human cloning.

Question: If I change my mind later and don't want you to keep my DNA or cells, what should I do?

Answer: You can change your mind at any time. Write to us and say you don't want us to keep your DNA or cells. We will remove them and destroy them.

If you would like to know more about the problems we may be able to solve by having parents' DNA, there is a more detailed document available. For more information, Please phone 0117 928 8900, or ask the clinic staff. They will be able to help you, or put you in touch with someone who can.

