

...helping to understand children's coughs, colds and ear infections

This leaflet provides information for parents and carers

We would like to invite you and your child to take part in our research study.

Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please read the following information carefully and feel free to talk to others about the study if you wish.

Please don't hesitate to ask us if anything is unclear or if you would like more information, and take your time deciding whether or not you wish to take part.

What is the purpose of the study?

We are interested in the normal coughs, colds, sore throats, chest infections and ear infections that most children develop. These are collectively called **respiratory tract infections**. We know a good deal from previous research into these infections in children who are taken to the doctor. We know far less about how these symptoms develop out in the community (especially in children who do not go to the doctor with their symptoms).

We want to collect information about the symptoms of these illnesses going round in the local community and how long they last. We also want to try to find out what the actual bugs are by looking at nasal and saliva swabs taken from the children when they are ill and comparing these with swabs taken when they are well.

One main point of doing this work is to see if it would be possible to roll this out on a bigger scale to feed the information on illnesses going around in the community into an online resource. This type of 'real-time' illness information could help parents and GPs know what common bugs are going round in the area and how best to manage them – with a special interest in:

- helping parents know whether to take their child to the doctor, and
- helping GPs give antibiotics only to children who really need them

Study Contact Details

Abhi Vora Study Administrator	Tel: 0117 3314598 Email: eepris-kids@bristol.ac.uk Website: http://www.bristol.ac.uk/eepris
Emma Anderson Study Manager	Address: School of Social and Community Medicine, University of Bristol, Canyne Hall, 39 Whatley Road, Bristol BS8 2PS
Professor Alastair Hay Principal Investigator	

Why have my child and I been invited to take part?

You have been invited to take part in this study because your child is aged between 3 months and 15 years (and has no known condition affecting the immune system). This invitation to take part in our research has come from your GP surgery because it is one of several surgeries in Bristol who have agreed to invite their patients into our study. We at the University of Bristol have no access to your contact details or anything about you until you contact us directly yourself.

We are hoping to recruit nearly 500 parents (or about 800 children) to take part in our study to track normal respiratory infections (coughs, colds, sore throats, chest and ear infections).

How long will we be involved if we take part?

If you decide to take part, you will be in the study for just a few weeks (minimum) or up to a few months (maximum), depending on when (or if) your child develops a respiratory infection – and whether you carry on in the study after they get better. In other words:

- Minimum duration is from your enrolment in until your child has one episode of illness (cough, cold, sore throat, chest or ear infection) through to recovery.
 - Maximum duration is from your enrolment until we finish collecting data in May/June 2016.
- Most children are expected to pick up at least one respiratory infection over this period. You can opt out of the study at any time.

What are the advantages of taking part?

You will be making a valuable contribution to research on the illnesses that affect most children in our country. The wider aims of this research are to improve the understanding, diagnosis and management of respiratory illnesses which could benefit your child and many other children in future. Ultimately we would like to set up a website that provides real-time information on the illnesses circulating in the community. This could help doctors make decisions about treatment, and help parents feel more confident in managing their children's health.

Will I be compensated for taking part in the study?

If your child develops a respiratory illness during the study (and it is likely that they will), and you complete our surveys and research nurse visit, we will give you a £15 high street voucher as a thank you gift for your time. If you also take part in the interview study, you will receive an extra £5 shopping voucher.

Are there any disadvantages in taking part?

The only disadvantage in taking part is the time taken – to answer research questions and to have a research nurse visit. There are no real risks in taking part, as we are simply collecting information about naturally occurring illnesses. Taking nasal and saliva swabs are simple procedures and are not uncomfortable for the child.

Will my taking part in this study be kept confidential?

Yes, all information collected about you and your child in this study will be kept strictly confidential in accordance with the Data Protection Act. Even your GP will not see your answers to the survey. Your name will not appear on any papers or reports. To keep your information confidential all survey answers will be identified by a code only, and stored on password protected computers in locked buildings which are alarmed when staff are not there. The computer based systems have secure encryption to ensure confidentiality for any data collected or sent over the internet.

Only staff on the research team or from regulatory authorities (University of Bristol, NHS R&D offices, and regulatory inspectors), who check the quality of the research, will be given access to the
Parent Information Leaflet EEPRIS Study Version 5 (2016-02-11)

page 2 of 6

data, and only on an as-needed basis. A monitoring authority may also want to cross check the research data we collect with NHS medical notes for a small sample of our participants. Your identifiable details will only be available to the immediate study team who need it. Data records which cannot be linked to you or your child in any way will be kept securely for twenty years in line with University of Bristol policies.

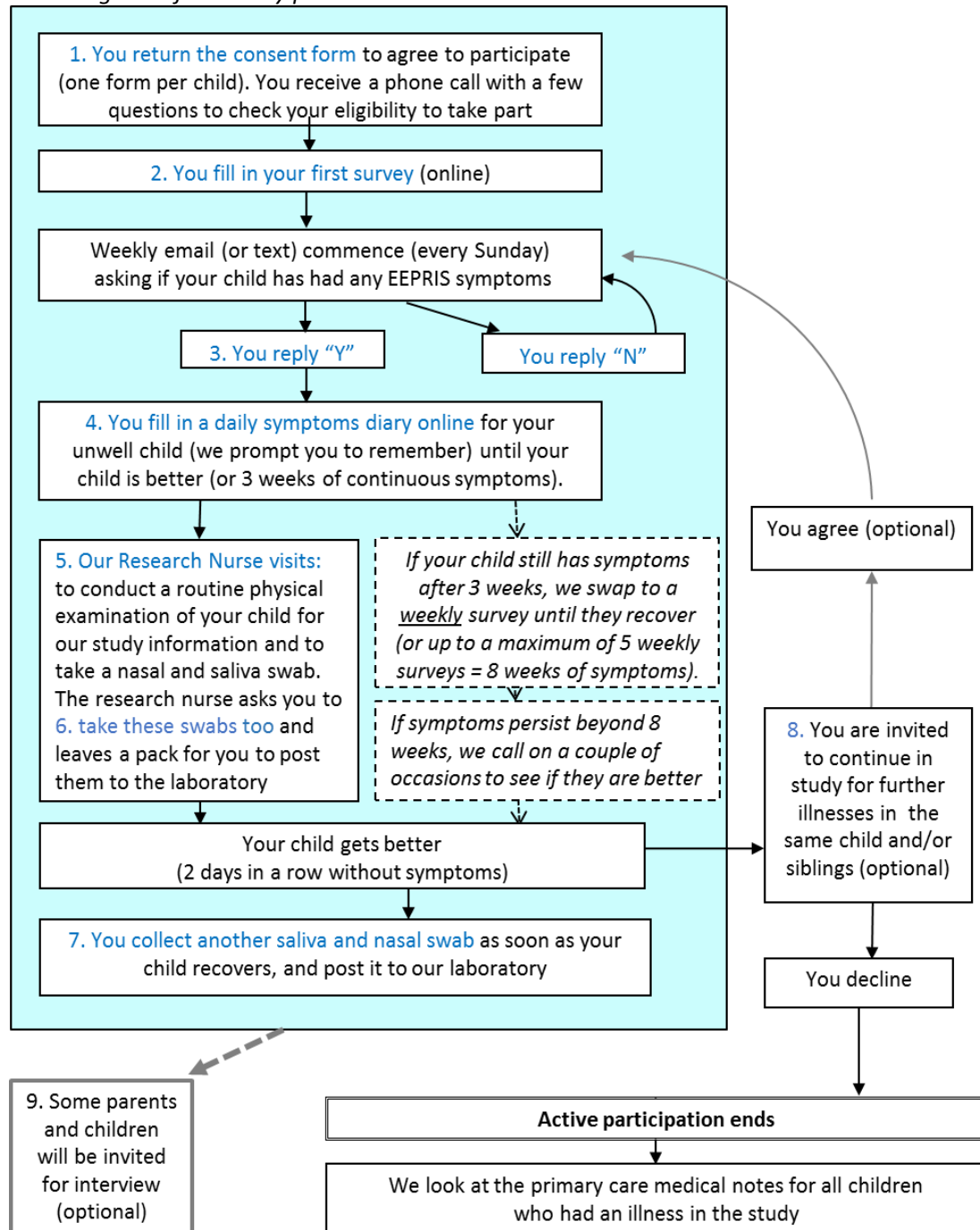
If we take part, what does it involve for me and my child?

1. Once you send back your complete consent form – one for each child – we will call you to check that you understand everything about the study and that you and your child are eligible to take part. If you are, we will welcome you to the study and send you an email with a link to fill in a brief online survey to start you in the study. Please note – there is a separate starter survey to complete for each child you enrol, but you will have just the one welcome phone call even if you have more than one child in the study.
2. Once you have filled in the survey, you will start to receive a weekly email every Sunday to ask if your child has developed any EEPRIS symptoms (cough, cold, sore throat, chesty symptoms or ear ache/discharge) in the last week. We ask that you respond (simple Yes/No) to each one. Please note – you will receive a separate email for each child you enrol.
3. When you reply Y (to tell us your child has developed any of the EEPRIS symptoms) we will email a link to complete a daily symptoms survey online (via phone, tablet or desktop).
4. We ask you to complete the daily survey (prompted by email reminders every two days) until your child feels better. We will call you if you forget to fill these in for a few days.
5. A research nurse will arrange to visit while your child is ill to take a record information on their physical symptoms for the study and collect a swab of saliva and a swab from just inside the child's nostril.
6. During the visit you will be asked to collect the same samples yourself which the research nurse will ask you to put in a post box to send to the laboratory (pre-paid postal packaging provided). This is because we want to compare swabs taken by a nurse with the swabs that parents can use and put in the post, to see if the posted ones will be good enough to use on a wider scale in future.
7. We ask you to collect one more set of saliva and nasal swabs (on your own at home using a kit provided by the research nurse) as soon as your child is better and post these to our laboratory.
8. Once you have provided information and swabs for one complete infection, you can opt to carry on in the study with the same child (and/or any other children in your household) or finish. If you opt to carry on, the weekly emails will resume for any children you consent to carry on with. No weekly emails checking for new symptoms will be sent after the end of our data collection phase (May/June 2016)

OPTIONAL:

9. We will invite a selection of parents and children to take part in one audio-recorded interview, of about 45 minutes, at your home (or location of choice). This is to find out parents' and children's experiences of taking part in the study, and to gather opinions on a possible future online resource of 'real-time' illness information. You do not have to agree to be interviewed to take part in the study.

Flow diagram of the study process:



Additional information

At the end of the active data collection period we will collect some information from the medical records of each child who had a respiratory infection in the study. We will check to see if they saw the GP or another healthcare professional when they were ill, and if antibiotics or other medications were prescribed.

We will also collect information from your child's medical records about any vaccines they have had and any major long-term conditions, as these can make a difference to how likely a child is to become ill. We will check for antibiotics prescribed in the 12 months before they were recruited to

the study, and for any consultations in that time to do with respiratory infections. Only staff on the research team or clinical staff will be allowed to collect this information.

What will happen if we don't want to carry on with the study?

You and your child can leave the study at any time, without giving a reason. This will not affect the care your family receives now or in the future. If you do decide to leave the study, we will use the information we have collected up to that time, unless you tell us otherwise.

What will happen to my samples?

The samples will be sent to a laboratory to test what bugs (viruses and bacteria) they contain. Neither parents nor GPs will receive feedback on the findings from individual children's swabs.

We would also like to ask your permission to keep any left-over material from samples at the end of the study, rather than throw them away. This will allow us and/or other researchers to do further work on them in the future. Some of this could include genetic analysis (like DNA mapping) of the bacteria and viruses in the samples to gain more detailed information about them, with a potential for genetic analysis of your child's cells also (only to look for genes relating to risk factors for infection). You can separately decline for genetic analysis of samples. No information that could be used to identify you will be given to anyone using the samples. Neither the samples nor anything in them or any information related to them will be sold or used to make money. You will be able to say on the consent form whether you would be happy for your samples to be kept and used in this way or not, and you do not need to agree to any of this in order to take part in this study.

Who can take part?

You and your child (aged over 3 months and under 15 years) can take part if you:

- have legal responsibility for the child
- have access to the internet (preferably daily)
- are happy to give a brief (Y/N) response to a weekly email while in the study
- are willing to provide information online (via phone, tablet or desktop) if/when your child develops symptoms of a respiratory infection during the course of the study
- are willing to have a research nurse visit to do a basic physical examination to collect information for our study (e.g. listen to your child's chest, check oxygen levels, like doctor or nurse would in the NHS) collect saliva and nasal swabs from your child, and to take these swabs yourself as well.

Do we have to take part?

No, it is up to you whether or not you want your child to take part. Deciding not to take part will not affect the care you or your child receive from your doctor or nurse now or in the future. You have been given this information to read now, and the study team can discuss it with you in more detail if you would like to get in touch (contact details are at the beginning of this leaflet). A child-friendly copy of this information sheet is provided for your child to read, or for you to read to your child so that he or she can understand what is being asked and why.

For children in year 3 (aged 7/8 and over): If they are happy to be included then they will need to sign to say they agree to take part – on the child assent form (found on the back of the main consent form). This is as well as your consent. We have to make sure that any child who is unhappy about taking part knows they don't have to and it is OK for them to refuse. This form means that if your child can understand what is being explained but doesn't want to take part or sign the form, we will not include them.

What will happen to the results of the research study?

A report of the study results will be completed for the funding body. Results will also be published in scientific journals and presented at scientific conferences. You or your child will not be identified in any report, publication or presentation; all results will be completely anonymous.

We will send you a newsletter with a summary of the main results of the study, and we will update our website with links to study publications when they become available. It is a fairly lengthy process to publish results, so the final results of this study will not be available for at least a year.

What if relevant new information becomes available?

Sometimes we get new information about the illness being studied but this is unlikely to happen during the time you are involved in this study. If the study is stopped for any other reason, we will tell you and the care of your child by your doctor or nurse will continue as normal.

What if something goes wrong?

If you have complaints or concerns about the study, please get in touch with the study team in the first instance. Taking part in this study will not affect your normal rights to pursue any complaint about your medical treatment within the NHS in the normal way.

Remember, this is a research study, not medical care. If you have any concerns about your child's health or your own, please seek advice from your doctor (not the study team) as usual.

Who is organising and funding the study?

The research is run by the University of Bristol working with NHS GP surgeries in the Bristol area. Our research team is based in the School of Social and Community Medicine, which has a reputation for high quality research and experience with working with NHS patients, GPs and the public.

The study is funded by the National Institute for Health Research (NIHR), Health Protection Research Unit (HPRU). The HPRU is a partnership between universities across England and Public Health England (PHE) which supports high quality research to protect our health.

Who has reviewed the study?

All research is looked at by an independent group of people, called a Research Ethics Committee to protect your child's safety, rights, wellbeing and dignity. This study has been given a favourable opinion by the South West Frenchay Bristol Research Ethics Committee (reference: 15/SW/0264).

How do I enrol in the study?

If you have decided that you would like to take part, please:

- **Fill in the consent form (and ask your child to sign assent if in school year 3 or older)**
- **Post it back to the research team in the Freepost envelope provided.**

Once we receive this we will call you to check that you understand everything about the study and that you and your child are eligible to take part.

If you are, we will welcome you into the study, email you a copy of your consent information and the link to a survey to start you in the study, and send you a welcome pack in the post.

Thank you for reading this and considering taking part in this study