# The PCV15/PCV20 Study

Dear Parent/Guardian,

The University of Nottingham Health Service (Cripps Health Centre) would like to invite you and your child to take part in a study designed to guide decisions on changes to the UK immunisation schedule. This would involve your child potentially receiving a new pneumococcal vaccine, which offers protection against a wider range of bacteria which cause invasive pneumococcal disease. Your child will furthermore receive remaining vaccines as per the UK current scheduled vaccination.

**What is the study about?**

* PCV13 vaccine is currently routinely given at 3 and 12 months of age.
* There are currently two new vaccines against pneumococcal disease, called PCV15 and PCV20. They are both licensed in the UK for older adults and PCV15 is also licensed for paediatric use.
* The study will evaluate the protection provided by PCV15 and PCV20.

**What happens in the study?**

* This study is enrolling children who have not yet had their 2-month vaccines.
* Children will be randomised into a group to receive two doses of either PCV15, PCV20, or PCV13, or three doses of PCV20
* The study involves up to six study visits depending on group allocation over a period of 11 months.
* The PCV vaccines will be given at specific time points group dependent (3 and 12 months of age or 2, 4 and 12 months of age)
* Children will also receive all routine vaccines as part of the current UK immunization schedule at 2,3, 4 and 12 months of age and will not have to attend their designated GP surgery to receive them. (In the event that your child leaves the study early, you will have to contact your GP surgery to complete your child’s immunization schedule).
* If receiving two doses of either PCV15, PCV20, or PCV13 blood samples will be taken at two visits (at ages 4 and 13 months). If receiving three doses of PCV20, blood samples will be taken at two visits (at ages 5 and 13 months). Local anaesthetic cream will be used to numb the area before blood tests.
* If receiving two doses of either PCV15, PCV20, or PCV13 nasal samples will be taken at three visits (at 3, 4 and 13 months). If receiving three doses of PCV20, nasal samples will be taken at four visits (at 2, 3, 5 and 13 months). A nasal strip will be used to collect samples from the nasal mucosa, holding the strip for 60 seconds. This procedure is painless but participant might feel some tickle.
* Which PCV vaccine is given at each age will be decided at random, with an equal chance of either vaccine. The study will be open label, which means that the parents will be informed which PCV vaccines their child will be receiving.
* The study visits will be conducted in at The University of Nottingham Health Service (Cripps Health Centre)

You and your child have been approached because your child is within the age range for the study and lives in an area where the study is being carried out; we apologise if this invitation is not relevant to you.

Taking part in this study is voluntary. If you would like to know more, please read the Participant Information Sheet (attached)

If you are interested, please register your interest by completing the online pre-screening questionnaire <https://www.ovg.ox.ac.uk/studies/pcv/unhs>*.*

Alternatively, you may contact us by phone: **0115 8227979 or**

 email **nnicb-nn.research@nhs.net**

The research team is happy to discuss the study with you and answer any questions you may have.

Thank you for considering taking part in this study.

Yours sincerely,

Dr David Turner, Email: nnicb-nn.research@nhs.net, Tel: 0115 822 7979

If you are interested in participating in this study:

***You can complete the online pre-screening questionnaire*** *https://www.ovg.ox.ac.uk/studies/pcv/unhs.*

**Accessing data for research mailouts:**

We do not have your personal details unless you have specifically provided us with these. For more information about how we approach and invite individuals to take part in our research please visit: <https://www.unhs.co.uk/info.aspx?p=9>. If you wish to complain about any aspect of the way you have been approached to take part in this study, please contact the University of Nottingham Health Service on 0115 8227979 or email nnicb-nn.research@nhs.net . You can also contact the University of Oxford, Research Governance, Ethics and Assurance (RGEA) office on 01865 616480 or email RGEA at rgea.complaints@admin.ox.ac.uk

Some study sites will send invitation letters from their hospital birth records and clinic lists. These letters will be sent via hospitals clinical teams not via the research team.

**[For NHS database extracts or using GP surgeries as PIC sites include:]**

Please note: you have been approached because your child is within the age range for the study and you live in one of the areas in which the study is being conducted. If you have received this invitation through the post, this has either been mailed to you by the Child Health Information Service (CHIS), another equivalent NHS database, or by your GP surgery. If you do not wish the NHS to use your health records for the purposes of supporting any health-related research, please visit: https://www.nhs.uk/your-nhs-data-matters/manage-your-choice to make your choice.

NHS England holds information from the records that health and social care providers in England keep about the care and treatment they give. The data they hold can be used to plan and improve health.

NHS England was requested by the **Oxford Vaccine Group, University of Oxford (as study Sponsor)** to run an electronic search to identify potential participants who may be eligible for this study, in order to invite them to participate. NHS England arranged for this invitation to be sent out on our behalf by an external mailing company to preserve the confidentiality of potential participants. **The [INSERT SITE NAME and] Oxford Vaccine Group have no access to this data.** The database extracts and mailouts do not involve NHS resources or money. Should the details be incorrect please get in touch with your GP surgery.

The Health Research Authority, on advice from the Confidentiality Advisory Group, has provided the legal permission for the Oxford Vaccine Group, University of Oxford (as study Sponsor) to use your data under section 251 of the National Health Service Act 2006 – this includes permission for NHS England to identify and invite you on behalf of the study team. The Confidentiality Advisory Group, is an independent body which provides expert advice on the use of confidential patient information in England and Wales.

The National Data Opt out has been applied prior to sending this invitation. If you do not wish the NHS to use your health records for the purposes of supporting any health related research in the future, please visit: <https://www.nhs.uk/your-nhs-data-matters/manage-your-choice> to make your choice.

Taking part is voluntary and you do not have to take part in this study. If we do not hear from you we will assume that you do not want to take part in the study. However, you are welcome to contact us by any of the above means to inform us and provide feedback if you wish.

For more information on how we identify participants and process data for our studies, please see the below privacy notices:

**Privacy notices:**

NHS England:

<https://www.england.nhs.uk/contact-us/privacy-notice/how-the-nhs-and-care-services-use-your-information-the-national-opt-out/>