[Insert Local Headers]

LION MenB

earLy protectIOn agaiNst **Men**ingococcal **B** disease in infants

INFORMATION SHEET FOR PARENTS

[Site name] would like to invite you and your baby to take part in a study of a new schedule of Men B vaccination, which may provide infants earlier protection against meningitis.

The information in this document is designed to help you decide whether you would like your child to take part in this study. Please take time to read the following carefully and discuss it with others if you wish. We will go through the information sheet with you and answer any questions you have.

Why is this study being performed?

In 2015, the United Kingdom became the first country in the world to introduce the meningococcal group B (Men B) vaccine into its routine schedule for infants. This vaccine has proved to be very effective in protecting against meningitis (infection of the lining of the brain) and septicaemia (blood poisoning) caused by a subgroup (group B) of the meningococcus germ. In the United Kingdom, babies are offered this vaccination at 2, 4 and 12 months.

We want to compare two different schedules of Men B vaccination, the standard schedule (at 2, 4 and 12 months) and the early schedule (at 2, 3 and 12 months). Receiving the first two doses of Men B vaccine by 3 months could provide infants earlier protection against Men B disease. This is what we are trying to find out through this study.

Why has my baby been chosen and does my baby have to take part?

We are approaching you because your baby was born in the last 2 months and has not yet received their first routine vaccinations. Your baby does not have to take part. If you decide to take part in the study, you will be asked to sign a consent form and we will give you a copy to keep. You would be able to withdraw your baby from the study at any time and without giving a reason. If you do not wish your child to take part in this study or withdraw your baby from the study before the end, their care will not be affected in any way and your baby would be offered vaccinations according to the routine UK schedule.

What happens if my baby takes part?

After you have signed the consent form, your baby will be randomly (like tossing a coin) assigned to one of two groups: one group (Group 2) will receive all recommended vaccines according to the standard UK schedule and the other (Group 1) will receive the vaccines with a slight adjustment to the order - the second dose of Men B vaccine at 3 instead of 4 months and the first dose of PCV13 at 4 instead of 3 months. Your baby will have a 50:50 chance of being in each group. There are no extra or new vaccines being used in the study.

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Visit Number	1	2	3	4	5	6
Age	2 months	3 months	4 months	5 months	12 months	13 months
Group 1 (early schedule)	**4CMenB** DTaP/IPV/Hib/HepB Rotavirus	**4CMenB** DTaP/IPV/Hib/HepB Rotavirus	**PCV13** DTaP/IPV/Hib/HepB		**4CMenB** PCV13 MCC-TT/Hib-TT MMR	
Blood tests			🩸		🩸	🩸
Group 2 (standard schedule)	**4CMenB** DTaP/IPV/Hib/HepB Rotavirus	**PCV13** DTaP/IPV/Hib/HepB Rotavirus	**4CMenB** DTaP/IPV/Hib/HepB		**4CMenB** PCV13 MCC-TT/Hib-TT MMR	
Blood tests				🩸	🩸	🩸

From January 2020, the United Kingdom have changed the childhood pneumococcal immunisation programme to a single 13-valent pneumococcal conjugate vaccine (PCV13) infant dose at 3 months of age followed by the 12-month booster. Since pneumococcal disease associated to PCV13 strains is so rare in infants across the United Kingdom, babies in Group 1 will receive PCV13 at 4 instead of 3 months. This will ensure that all infants will receive 2 injections at each primary immunisation visit (Visit 1, 2 and 3).

There will be no other differences in the vaccines received. The diagram below shows the schedule of vaccinations and blood tests for this study:

In this study, we want to compare the vaccine responses of infants who have received their vaccinations according to the two different schedules and to do this we will take a blood sample from the babies on three occasions. These time points have been chosen so that we can compare the response following the primary vaccinations and before and after the booster vaccination. A maximum of 3 mls will be taken on each occasion (about half a teaspoon) and the use of a local anaesthetic cream may be considered to make the blood test as comfortable as possible.

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What would I have to do?

If you agree for your baby to participate, you will be asked to sign a consent form. After every vaccination visit, you will be given a diary card to complete, which will be collected at the following visit. Your study doctor or nurse will explain how to fill in the diary. The diary card will be used to record daily temperatures and any redness or swelling that may occur around the injection site, for up to 7 days after each vaccination. A thermometer and a tape measure will be provided, along with a telephone number to contact the on-call doctor from our team at any time if you have concerns about your baby. We will also ask you to let us know by telephone if your baby has been unwell during the 28 days after immunisation, even if the illness seems unrelated to the vaccination. If you have to visit a doctor for the illness, we may contact them for further information. We will request your permission for study staff to ask your GP for your contact details if we lose contact with you during the study.

What are the risks with these vaccines?

Because the vaccines used in this study are exactly the same ones being used for routine immunisation of other babies in the UK, we do not expect the risk to be any different than with the routinely given vaccines. As with all vaccinations, however, there may occasionally be some redness and/or swelling at the injection site and fever. Fever is a side effect particularly associated with the Men B vaccination and we will give you advice about steps you can take to try to prevent this. Some babies have been reported to feed less, be more irritable and cry more than usual after vaccinations. Severe allergic reactions, such as anaphylaxis, are extremely rare but can occur with any vaccine. Your baby would be observed for 20 minutes following each immunisation and the study staff are specifically trained and equipped to deal with this in the extremely unlikely event that it did occur.

What are the other possible disadvantages of taking part?

Blood tests may be uncomfortable for infants, but we will try to minimise this by offering a local anaesthetic cream, if appropriate, to numb the skin before taking the blood sample.

It is anticipated that the immune response of the 2-3-month Men B schedule will be similar to that of the 2-4-month schedule, and similarly that the change of timing of the pneumococcal vaccine will have no impact on the protection offered by this vaccine. All participants will have their antibody levels checked following the 12-month vaccinations, which provides an opportunity to identify infants who have a suboptimal response. If this shows that your baby may have inadequate protection, your research team will contact you to discuss your options including the possibility of a booster dose of vaccine from your GP.

What coronavirus precautions are in place?

As you are most likely aware, due to the outbreak of Covid-19 (Coronavirus) Insert local site here like other hospitals, is treating Covid-19 patients. [**Delete if not applicable**] The research visits align with the current routine national immunisation schedule; therefore, you are not perceived to be at any additional risk of exposure to COVID-19. We are taking extra steps to ensure both staff and participants are kept safe at all times and to prevent any further spread.

As part of this, you will be asked to follow the hospital policy on social distancing and PPE if you attend hospital for your visit. [**Delete if not applicable**] Staff will be adhering to strict cleanliness guidelines and, in some cases, this may mean full PPE during home visits.

The Research Team will contact you ahead of scheduled study visits to check for COVID-19 symptoms and the symptom check will be repeated at the study visit. If a household member is currently experiencing any COVID-19 symptoms, please contact us to let us know so we can postpone your appointment.

If you have concerns, please don't hesitate to contact us (see below for details).

What are the possible benefits of taking part?

We will check the antibody response your baby makes to the Men B vaccine. You will have the choice of coming to [Insert local site] or for us to come to your home to give the vaccinations and take the blood samples **OR** All the visits will take place in your home **OR** All the visits will take place at [Insert site name]. If you attend at the local site, reasonable travel expenses will be covered. [**Delete if not applicable**] You will have 24 hour telephone access to a member of the study team if you have any concerns about your baby's vaccinations.

What blood test results will I receive?

At the end of the study you will receive a letter with the antibody response your baby developed to the Men B and PCV13 vaccines. The results will show whether your baby has adequate or inadequate protection against meningitis B and the pneumococcal serotypes included in the PCV 13 vaccine. If the protection is inadequate the research team will discuss with you whether your GP should provide your baby with a booster dose of either vaccine. In the unlikely scenario that the results are inconclusive, whether your baby requires another dose of the Men B or PCV vaccine will depend on the final trial results which the study team will discuss with you.

What happens when the research stops or if new information becomes available?

If new or relevant information becomes available during the course of the study, we will inform you as soon as possible and discuss with you whether you wish for your baby to continue in the study. If you decide that your baby will continue in the study, your research doctor may ask you to sign an agreement outlining the discussion.

What if there is a problem?

If you have any questions or concern about any aspect of this research study or wish to report a research related injury, you should first speak to your researchers who will do their best to answer your questions or take care of your concerns or research related injury. Please contact: [Insert local contact details]

St George's University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures your baby received during

the study. These special compensation arrangements apply where an injury is caused to your baby that would not have occurred if your baby was not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

What if I don't want my baby to carry on with this study?

If you decide to stop your child's participation in the study, we would like to keep the information collected already but would not collect any more. We would also like to keep the samples collected already.

What if you wish to complain about the trial?

If you wish to complain, or have any concerns about the way you have been treated during this study, then you can talk to the LION Men B research team who will do their best to answer your questions or concerns (contact details at the end of this leaflet). The National Health Service OR University [Delete as appropriate] complaints mechanisms are also available to you.

[Insert local information]

If you are still not satisfied with the response, you may contact:

The Sponsor Joint Research and Enterprise Services team at St George's: 0208 725 4986.

Would my baby's participation in the study be kept confidential?

Yes. We are bound by legislation and the NHS confidentiality code of practice to safeguard your confidentiality during and after the study. The following procedures are in place to ensure confidentiality:

- We will allocate your baby a study number. All information about your baby will be identified with this number, and not with your name or address.
- Information will be stored in files and on a computer database. These will be kept in locked offices in the medical school. The computer network is password protected.
- Results of this study will be kept on a database for at least 15 years.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised.

Personal data collected will include your baby's name, date of birth and address as well as your contact details and results of the blood tests and medical records. This information will be stored in a secure manner. Certain authorised individuals from SGUL, St George's University Hospitals NHS Foundation Trust and regulatory organisations may look at your baby's medical and research records to check the accuracy of the research study.
SGUL, as sponsor, will only receive information without any identifying information. The people who analyse the information will not be able to find out your baby's name, identifying information

or contact details. Anonymous data may be shared with the funder (GlaxoSmithKline) for safety reasons if applicable.
The data will only be used for the purposes of this study and any data released outside the above group will not contain any information that could be traced back to your baby. You have the right to obtain access to data relating to your child. If you wish to obtain any information, please contact us on the numbers listed below.

You can find out more about how we use your information here:
https://www.sgul.ac.uk/privacy
For general information on how the NHS uses research data please visit: https://www.hra.nhs.uk/information-about-patients/

What are your choices about how your baby's information is used?

If you decide to stop your child's participation in the study for any reason, we would like to keep already collected information about your baby. We need to manage your child's research information in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your baby.

Will my GP be informed of my involvement in the study?

Yes, we will be informing your GP that your baby is taking part in this study and we may share relevant medical information during the study if necessary for managing your child's health and safety. Infants enrolled in the study will receive the same vaccines from the research team as they would if they were in the routine infant programme. A letter will be sent to your GP after each vaccination and the relevant section of the red book will be completed.

What would happen to any samples from my baby?

We will test the blood samples to check your baby's level of immunity against the Men B and PCV13 vaccines and we may also test antibody levels against other diseases. At the end of the study any remaining blood samples will be destroyed unless you provide your specific permission on the consent form to allow us to use any of the extra samples for future ethically-approved research studies looking at how vaccines work. All extra samples will be anonymised so that it will not be possible to link the results of any extra tests back to your baby. Please remember that your baby's participation in this study does not depend on whether you allow or don't allow us to use the remaining blood sample.

What would happen to the results of the research study?

Your local study team will write to you at the end of the study to inform you of the study findings. This will be around 12 months after the end of the study. This may be some time after your participation in the study has ended. We will retain your contact details in a secure database at the site to enable us to contact you. We plan to publish the results in a medical journal so that

other healthcare professionals can learn about the findings of the study. If you wish, you can also be sent a copy of the published research.

Who is organising and funding the research?

The study is funded by GlaxoSmithKline (GSK) and is sponsored by St. George's, University of London. This study has been reviewed and approved by North East – Newcastle and North Tyneside 1 Research Ethics Committee and by the NHS Health Research Authority.

Further information

If you have any questions, or would like further information please contact:

[Insert local contact details]

We do hope that you and your family will take part in this study. Your contribution would be an important step towards the continual improvement of vaccine policy in the UK and would provide important information that should help us know what the best vaccination schedule should be for babies born in the future.

Thank you for reading this leaflet and thinking about taking part in the study.