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RATIONALE-15

caRriage to Assess proTectlon Of New pneumococccAL vaccinEs – PCV15

Consent Form

Study Code Site ID Code Participant identification number

RTN- 001 _ _ _ _ _

If you agree, please INITIAL box:

Section 1: Study Procedures	
1. I confirm that I have read and understood the participant information sheet Version: Dated:..... for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I have received detailed information about the study schedule and potential side effects and have discussed any potential questions.	
3. I understand that my participation is voluntary and that I am free to withdraw without giving any reason and without my medical care or legal rights being affected.	
Section 2: Personal Information	
4. I understand that relevant sections of my medical notes and data collected during the study including identifiable information may be looked at by individuals from the Oxford Vaccine Group, The University of Oxford (Sponsor), from regulatory authorities or monitors, from the NHS Trust(s), and authorised representatives appointed by the Sponsor, where it is relevant to my taking part in this research. I give permission for these people to access my records.	
5. I agree to my General Practitioner (GP) being informed of my participation in this study.	
6. I agree that my GP can provide the research team with information regarding my medical and vaccination history and study staff can access my NHS medical records either via my GP or electronic patient records system or and equivalent NHS database.	
7. I agree to provide my bank account details including my account name, sort code and account number for reimbursement purposes. I understand that my bank details will be stored electronically as described in the participant information sheet. I understand that my personal information will be shared to the extent required to process or verify eligibility of payments as described in the participant information sheet	
8. I understand TOPS is the Health Research Authority database that aims to prevent healthy volunteers from taking part in too many studies. I understand that only staff at the Oxford Vaccine Group and other research units can use the database and the study team will check volunteer details. I agree to my National Insurance (if UK citizen) and Passport number (for non-UK citizen) being used to register me on TOPS. I understand that it will be stored electronically for the duration of the study.	
9. I understand and agree that the study data, including identifiable information, will be held securely on a server at the University of Oxford	

Participant's number _____

10. I agree to provide my email address to set up the electronic symptom diary (eDiary) and receive the links for completion and reminders					
Section 3: Research samples and Data					
11. I agree to donate blood, saliva, throat swab and nasal samples (washings, swabs, cells and nasosorption). I consider these samples a gift to the University of Oxford and understand I will not gain any direct personal or financial benefit from them.					
12. I agree to results of HIV, Hepatitis B and Hepatitis C blood tests conducted as part of this study being reported to the United Kingdom Health Security Agency (UKHSA) as outlined in the participant information sheet if required.					
13. I agree that my samples, in a form that does not identify me, may be sent and stored within and outside of the United Kingdom for analysis by collaborating research groups and laboratories, including the study funder (Merck Sharp & Dohme (MSD) Inc.)					
14. I understand and agree that my samples will be used for DNA analysis as this research aims to understand the genetic influence of response to vaccination, and carriage with, the bacteria that causes pneumococcal pneumonia and that the results of these investigations will not have any implications for me personally.					
Section 4: Safety					
15. I agree to follow the recommendations regarding the antibiotic treatment.					
Section 5: Other					
16. Females of childbearing potential only: I confirm that I am not planning to conceive, and I will use effective contraception during the study.					
Section 6: SUMMARY					
17. I agree to take part in this study.					
Section 7: OPTIONAL. Please INITIAL box yes (Y) or no (N) accordingly:					
18. I agree to be contacted about other ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	<table border="1"> <tr> <td>Y</td> <td>N</td> </tr> <tr> <td></td> <td></td> </tr> </table>	Y	N		
Y	N				
19. I agree for my samples to be used, in a form that does not identify me, in future research in the UK or abroad, which has ethics approval. I understand this research may involve commercial organisations.	<table border="1"> <tr> <td>Y</td> <td>N</td> </tr> <tr> <td></td> <td></td> </tr> </table>	Y	N		
Y	N				

Name of participant (print)

Signature

__/__/____
Date (dd-mon-YYYY)

Name of person taking consent

Signature

__/__/____
Date (dd-mon-YYYY)

When completed: 1 copy for participant; 1 for researcher site file (original)