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RATIONALE-15

caRriage to Assess proTectIon Of New pneumococcAL vaccinEs – PCV15

Nasal Biopsy Group 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 nasal biopsy 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 Nasal Biopsy procedure and the study schedule, 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 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 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.	

Macedo BR, *et al. BMJ Open* 2025; 15:e106028. doi: 10.1136/bmjopen-2025-106028

Participant's number _____

9. I understand and agree that the study data, including identifiable information, will be held securely on a server at the University of Oxford.		
Section 3: Research samples and Data		
10. I agree to donate blood, saliva, throat swab and nasal samples (washings, swabs, cells, nasosorption and nasal biopsies). 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.		
11. 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.		
12. 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.).		
13. 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 that the results of these investigations will not have any implications for me personally.		
Section 4: Other		
14. **Females of childbearing potential only:** I confirm that I am not planning to conceive, and I will use effective contraception during the study.		
Section 5: Summary		
15. I voluntarily agree to take part in this study.		
Section 6: Optional: Please <u>INITIAL</u> box yes (Y) or no (N) accordingly:		
16. I agree to bebe 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.	Y	N
17. 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 and I understand this research may involve commercial organisations	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)

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