ALABAMA Trial Verbal CONSENT FORM

Trial Title:	**ALlergy AntiBiotics And Microbial resistAnce (ALABAMA)**: Penicillin allergy status and its effect on antibiotic prescribing, patient outcomes, and antimicrobial resistance.		
Participant ID:		**GP Practice Name:**	
REC No:	**19/LO/0176**	**Patient's name, Date of birth and GP surgery name confirmed?**	**Tick** ☐

Investigators: Dr Jonathan Sandoe, Prof Sue Pavitt

*Write **Yes** if confirmed*

1 Do you confirm that you have read and understood the ALABAMA Information Sheet version number _____ dated: __ __ / __ __ __ / __ __ __ __ and you have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐

2 Do you understand your participation is voluntary and that you are free to withdraw at any time, without giving any reason, and without your medical care or legal rights being affected and that you understand that data collected up to your time of withdrawal may still be used? ☐

3 Do you understand that you will be randomised to either usual clinical care, or penicillin-allergy assessment pathway (PAAP)? You will be told which trial group you are in. ☐

4 Do you understand if you are in the PAAP group you will attend an additional appointment at the immunology clinic, Do you understand this appointment will involve skin testing (ST) and /or taking syrup solution containing penicillin called oral challenge test (OCT). ☐

5 Do you understand that if your PAAP result shows no penicillin allergy, your medical records will be updated and for future infections that require antibiotic treatment you may be prescribed a penicillin based antibiotic. ☐

6 Do you understand that you will be required to provide information to the research team through electronic, paper and telephone questionnaires? Do you consent to the ALABAMA research team to access, transfer and store this paper and electronic data. ☐

7 Do you consent to being contacted by the research team for the purposes of trial follow up and you understand that this will require you to provide the research team with your name and contact details. Do you agree to the transfer and storage of this data for use in the ALABAMA trial? ☐

8 Do you understand that your medical records, including information about general medical history, penicillin allergy history, visits to hospital, other NHS resource use and antimicrobial prescriptions will be reviewed and data collected by the ALABAMA research team for ten years after trial has ended. Do you permit these individuals to have access to your electronic health records and paper health records and any records held by NHS Digital? ☐

9 Do you understand that your name, date of birth and NHS Number will be shared with NHS Digital to enable them to supply the trial team with additional data about you for ten years after trial has ended? This may include Hospital Episode Statistics data and Mortality data. The data supplied by NHS Digital is linked by the trial team to the data collected during your participation in the ALABAMA trial. You are free to withdraw your consent for data linkage with NHS Digital at any time and it will not affect your ongoing care. ☐

10 Do you give permission for your data collected for the trial and up to 10 years after the trial has ended, to be looked at by authorised individuals from the University of Leeds, University of Oxford, authorised collaborators within the ALABAMA Trial and regulatory authorities for research purposes? Do you understand that all information collected will be used for medical research only and that you will not be identified in any way in the analysis and reporting of the results? ☐

11 Do you consent to your GP being informed of your participation within the trial and the results of the PAAP testing (if applicable)? ☐

12 Do you give permission for secondary use of your data for further research studies after the end of the trial? ☐

13 Do you agree to take part in the ALABAMA trial? ☐

14 **OPTIONAL:** Do you agree to potentially be contacted to take part in a telephone interview to discuss your experience of taking part in the ALABAMA trial? ☐

Name of Person Taking Consent (Print)	Date	Signature
Name of Participant (Print)	Date	

No signature obtained from the participant as verbal consent taken by telephone.

Armitage KF, *et al. BMJ Open* 2024; 13:e072253. doi: 10.1136/bmjopen-2023-072253