ALABAMA Trial ADULT 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: | | | | | | | REC Number: 19/LO/0176

Chief Investigators: Dr Jonathan Sandoe, Prof Sue Pavitt

		PLEASE INITIAL
1.	I confirm I have read and understood the ALABAMA Participant Information Sheet version number _____ dated:__ __ / __ __ __ / __ __ __ __. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.	
2.	I understand my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that data collected up to my time of withdrawal may still be used.	
3.	I understand that I will be randomised to either usual clinical care, or penicillin-allergy assessment pathway (PAAP). I will be told which trial group I am in.	
4.	If I am in the PAAP group I will attend an additional appointment at the immunology clinic, I understand this appointment will involve skin testing (ST) and /or taking syrup solution containing penicillin called oral challenge test (OCT).	
5.	I understand that if my PAAP result shows no penicillin allergy, my medical records will be updated and for future infections that require antibiotic treatment I may be prescribed a penicillin based antibiotic by my GP.	
6.	I understand that I will be required to provide information to the research team through electronic, paper and telephone questionnaires. I consent to the ALABAMA research team to access, transfer and store this paper and electronic data.	
7.	I consent to being contacted by the research team for the purposes of trial follow up and I understand that this will require me to provide the research team with my name and contact details. I agree to the transfer and storage of this data for use in the ALABAMA trial.	
8.	I understand that my 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. I permit these individuals to have access to my electronic health records and paper health records and any records held by NHS Digital.	
9.	I understand that my 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 me 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 my participation in the ALABAMA trial. I am free to withdraw my consent for data linkage with NHS Digital at any time and it will not affect my ongoing care.	
10.	I give permission for my 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. I understand that all information collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results.	
11.	I consent to my GP being informed of my participation within the trial and the results of the PAAP testing (if applicable).	
12.	I give permission for secondary use of my data for further research studies after the end of the trial.	
13.	I agree to take part in the ALABAMA trial.	
14.	**OPTIONAL:** I agree to potentially be contacted to take part in a telephone interview to discuss my experience of taking part in the ALABAMA trial.	

Name of Person Taking Consent (Print)	Date	Signature

Name of Participant (Print)	Date	Signature

When completed, store top copy in Site File & scan into Medical Notes; give bottom copy to participant.