



**Title of Project:** A clinical challenge study to evaluate controlled human infection with BCG administered by the aerosol inhaled route in historically BCG-vaccinated healthy adult volunteers (TB044)

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**IRAS ref:** 276608

**Please Initial**

1. I confirm that I have read and understand the Participant Information Sheet version ____, dated ____, for the above study. I have had the opportunity to consider the information, ask questions and these have been answered satisfactorily.	
2. I understand that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. I understand that it may not be possible to destroy samples or research data previously gifted if they have already been used.	
3. I agree that relevant sections of my medical notes and data collected during the study can be reviewed by responsible individuals from the University of Oxford, the National Health Service, study monitors and regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree that my GP can be informed of my participation, and I permit my GP to share my medical history with the research team.	
5. I agree to have a chest x-ray as part of the screening for this study.	
6. I agree to have blood tests performed at regular intervals.	
7. I agree to have lung function tests performed at regular intervals.	
8. I agree to provide induced sputum samples if required	
9. I agree to be tested for COVID-19 infection if required. I understand that by law my result and personal data (including name, NHS number, contact details and postcode) may be shared with UK HSA.	
10. I understand that I will be given BCG by the aerosol-inhaled route in this study.	
11. I agree to wear an adapted mask at regular intervals to allow collection of aerosolised droplets and permit the involvement of external collaborators in the processing of these samples.	
12. I agree to undergo a bronchoscopy as part of the study, during which digital images/ photographs of my airways and lungs may be recorded and samples taken.	
13. I understand that the samples collected will be considered a gift to the University of Oxford, and I understand that I will not derive personal or financial benefit beyond the explained volunteer compensation amount.	
14. I agree to the genetic analysis of my samples, as detailed in the Participant Information Sheet. I understand the results will not have implications for me personally.	
15. I understand that I will be required to have pregnancy tests and I agree to use effective contraception ( <b>women of child bearing potential only</b> ).	



16. I agree to my registration on the confidential TOPS (The Over-Volunteering Prevention System) database to prevent entry into multiple clinical trials or studies at the same time.	
17. I consent to having my data stored securely as detailed in the Participant Information Sheet	
18. I agree to my pseudo-anonymised data being shared with study collaborators, both inside and outside of the European Economic Area (EEA).	
19. I agree to take part in this study.	
OPTIONAL - <b><i>The following are optional, answering "No" to any or all will not affect your ability to participate in the study.</i></b>	Yes No
20. To avoid repeated testing, I agree that if I am not enrolled into this study and apply to enter another study conducted by the Jenner Clinical Vaccine Trials Group, my screening results may be used in that study, where appropriate.	
21. I agree that my contact details may be stored so that I may be informed of opportunities to participate in future vaccine related research. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_ (in block letters) Volunteer number: \_\_\_\_\_

Signature of Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

Name of Investigator: \_\_\_\_\_ (in block letters)

*When completed, photocopy and provide 1 copy to the volunteer. Retain original for the research file.*