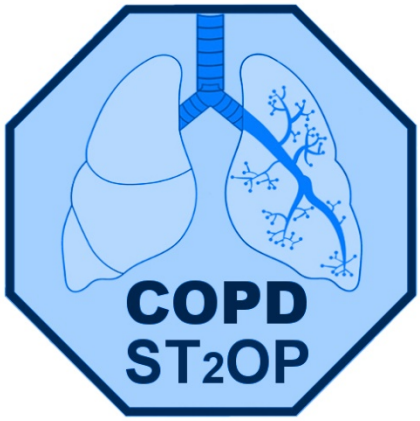
A randomised placebo-controlled trial of anti-ST2 in COPD (COPD-ST$_2$OP)



NCT03615040

Informed consent form

V2.1, 1st April 2019

CONSENT FORM

(Mandatory section)

Name of Chief Investigator: Professor C Brightling

Sponsor Reference: 0671 **Screening Number: SN** ☐☐☐

TITLE: A randomised placebo-controlled trial of anti-ST2 in COPD (COPD-ST$_2$OP)

Please initial box

1. I confirm that I have read and understand the participant information sheet (V2.2, 01/04/2019) for the above trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and 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 should I withdraw then the information collected so far will still be used in the trial analysis. ☐

3. I understand that relevant sections of my medical notes, GP records and/or trial data may be looked at by responsible individuals from the trial team, the sponsor, the Leicester Clinical Trials Unit (LCTU), NHS Trust, Host Organisation, Funder, GP Practice or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to access my records. ☐

4. I understand that I am consenting for my samples and anonymised data, including previous clinical data, to be used in research along with anonymised data by Glenfield Hospital, LCTU, academic and industry partners at routine visits and whilst in hospital. ☐

5. I understand and agree that my anonymised trial data may be shared with our research collaborators in other academic institutions, industry partners, LCTU and pharmaceutical companies and that this data may be used for other ethically approved research. ☐

6. I consent to the research team contacting my GP for additional information about my medical history, COPD exacerbations and medications if required. ☐

7. I agree to undergo the tests and investigations as described in the participant information sheet. The nature of the tests and investigations and any possible risks have been explained to me. ☐

8. I agree to my GP or any doctor treating me to be informed that I am taking part in this trial. ☐

9. I agree to take part in the above trial. ☐

THIS IS A DOUBLE SIDED DOCUMENT.
PLEASE TURN OVER TO SIGN AND FOR ADDITIONAL SECTION.

CONSENT FORM

(Optional section)

Name of Chief Investigator: Professor C Brightling

Sponsor Reference: 0671 **Screening Number: SN** ☐☐☐

TITLE: A randomised placebo-controlled trial of anti-ST2 in COPD (COPD-ST$_2$OP)

		Please indicate Yes	No
1.	I agree to being contacted with details of future research and for my contact details to be stored securely on a computer database by the local trial team.	☐	☐
2.	I agree for my postcode to be used for future studies that will link the outcomes of this trial with environmental exposure such as pollution and weather.	☐	☐
3.	I agree to being re-called for further tests based upon results of this trial, including but not restricted to, your genetics and response to therapy.	☐	☐
4.	I consent for a genetic sample (DNA) to be taken for the purpose of research into COPD and to be stored (at the Respiratory BRC Tissue Bank) for this trial and future studies.	☐	☐
5.	I agree for my health records in primary (GP) and secondary (hospital) to be linked to this study	☐	☐

_____	_____	_____
Name of Patient	**Date** (dd/mm/yyyy)	**Signature**
_____	_____	_____
Name of Person taking consent	**Date** (dd/mm/yyyy)	**Signature**