University of Bristol Tobacco and Alcohol Research Group Standard Operating Procedures

SOP - 17

SCREENING FOR ASTHMA IN CARBON-DIOXIDE CHALLENGE STUDIES

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Definitions/Abbreviations					
RED	Research Enterprise and Development				
R&D	Research and Development				
IMP	Investigational Medicinal Product				
SAE	Serious Adverse Event				
UoB	University of Bristol				
SOP	Standard Operating Procedure				

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SOP - 17

SCREENING FOR ASTHMA IN CARBON-DIOXIDE CHALLENGE STUDIES

1. PURPOSE:

To establish eligibility on studies which have asthma as an exclusion criterion.

2. PERSONNEL REQUIRED AND LEVEL OF EXPERTISE:

• Investigator or research team.

3. MATERIALS AND EQUIPMENT REQUIRED:

Relevant reporting forms

4. PROCEDURE:

Always check your study protocol to determine specific instructions relating to exclusion on the basis of asthma.

Asthma is an exclusion criterion for carbon dioxide challenge studies.

If participants report having asthma or asthmatic symptoms at **any point** during adulthood, you should not test them. If they report having asthma or asthmatic symptoms during childhood, use the checklist below to establish eligibility:

- 1. Have you ever been medicated for asthma or asthma-like symptoms, including irregular use of inhalers, since the age of 18 years?
- 2. When you engage in physical activity (e.g., walking, working out, climbing stairs) do you ever experience any of the following: shortness of breath, wheezing, tightness in the chest, coughing?
- 3. In the evening or during the night do you ever experience any of the following: shortness of breath, wheezing, tightness in the chest, coughing?

If the participant answers YES to \underline{ANY} question, the participant should NOT be enrolled onto the CO₂ challenge studies.

5. TROUBLE SHOOTING:

Problem	Solution			
Any problems	TARG Laboratory phone: 07957334265			
	Prof Marcus Munafò			
	(0117) 954 6841 internal 46841			
	Marcus.Munafo@bristol.ac.uk			
	Dr Angela Attwood			
	(0117) 331 7450 internal 17450			
	Angela.Attwood@bristol.ac.uk			
Reporting guidance or advice	Mr Adam Taylor (Head of Research Governance)			
	(No phone number on website)			
	Adam.Taylor@bristol.ac.uk			
	RED Reception and General Enquires			
	(0117) 428 3065 internal 83065			
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