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**The Newcastle upon Tyne Hospitals**  
NHS Foundation Trust

## PARTICIPANT INFORMATION SHEET

### -KEY FACTS-

### The INSIGHT-AM trial

INhaled Sargramostim In Groups of Healthy and inTensive care unit participants to study Alveolar Macrophage function

Thank you for showing an interest in the INSIGHT-AM study. This document contains a very brief overview of the study and who is eligible to participate. To register your interest, please contact us on either email address below and we will send the full participant information sheet and answer any specific questions you may have.

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INSIGHT-AM is a research study looking at a unique aspect of lung immune function. We are studying an inhaled intervention that we believe can improve lung immunity, especially in the settings of ageing and critical illness.

The study involves includes both healthy volunteers and critically ill patients within hospitals. At different stages we will be looking for participants aged 18-30 and aged 60+. The following are essential requirements for participation:

- You **must** consider yourself to be in good health, without any risk factors that may cause diseases of the lungs.
- You **must not** have a history of significant cardiovascular diseases (heart attacks, strokes), diabetes or kidney impairment.
- You **must not** take regular medications other than the following: skin creams, hormone therapy (oral contraceptives, hormone replacement therapy), blood pressure medications (maximum of one drug for this purpose), drugs for constipation, aspirin, paracetamol, codeine, thyroid replacement, and PPIs for acid reflux (e.g. Omeprazole, Lansoprazole).

Your first hospital visit would be for a brief screening, to ensure you are fit to participate. Your participation would then be split over 2 separate weeks, at least a month apart. You would visit hospital on 3 consecutive days (typically Tuesday – Thursday); if you had your screening visit on a Monday these days could follow immediately thereafter. The first 2 visits would be brief (less than an hour) for you to receive a dose of an inhaled intervention. The third visit would involve spending a few hours in hospital to have a bronchoscopy. This is a medical procedure in which we examine inside the lungs with a small fibre-optic camera on a flexible telescope passed down the nose or mouth. It is a common and safe procedure which only takes around 15 minutes, though we observe you for a few hours afterwards.

The inhaled intervention is called GM-CSF. In order to determine its effectiveness, we also use an inhaled placebo (sterile water). For this reason, we plan to see all of our participants twice. On one week they would receive inhaled GM-CSF, and on the other week (after a gap of at least a month) they would receive a placebo. Neither you nor the researcher would know which intervention you are receiving.

We are extremely grateful for participants and the time they sacrifice to be part of research studies. We offer a small fee as a token of our appreciation (typically paid as a voucher however there may be an option for payment by bank transfer):

- Following your first week with the study we offer £150
- For completing your second week of the study we offer a further £200

The full participant information sheet contains expanded information on every aspect of the trial and will be provided to you should you wish to register your interest.