ISRCTN13109642 https://doi.org/10.1186/ISRCTN13109642

# Protocol for the donation of samples by volunteers for laboratory research

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 02/02/2023 | Recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 03/02/2023 | Ongoing | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 18/04/2024 | Other | [ ] Record updated in last year |

**Plain English summary of protocol**

Background and study aims
This study aims to obtain blood and/or urine, stool, skin, sputum, saliva, mucosal or nasal samples from healthy volunteers and patient volunteers for laboratory research, relating to the causes and treatment of disease, in order to identify markers of disease and drug effect or development of new laboratory methods.

Who can participate?
Men and women 18 years old or over

What does the study involve?
This study will involve ad hoc visits to the Medicines Evaluation Unit. After written informed consent is obtained, participants will be assessed for their eligibility to donate the samples required according to the specific procedure to be undertaken. Participants have one or more of the following samples taken at a single visit: sputum, blood, urine, nasal, stool or skin.

What are the possible benefits and risks of participating?
All sampling procedures are considered safe. There is a small risk of side effects such as bruising, bleeding and infection. This is laboratory research so there is no direct benefit to the participant.

Where is the study run from?
Medicines Evaluation Unit (UK)

When is the study starting and how long is it expected to run for?
November 2009 to December 2030

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Clinical Research Leader

## Contact information

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Public

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Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
149078

### Protocol serial number
DS-10-01, IRAS 149078, 46616

# Study information

### Scientific Title
Protocol for the donation of blood, urine, stool, dermatological, sputum and nasal samples by healthy volunteers and patient volunteers for laboratory research

### Study objectives
Identifying markers of disease and developing new assays

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 12/04/2010, North West Preston Research Ethics Committee (HRA Centre Manchester, Barlow House, 3rd Floor, 4 Minshull Street, Manchester M1 3DZ, UK; +44 (0) 2071048290; preston.rec@hra.nhs.uk), ref: 10/H1016/25

### Study design
Observational cross sectional study

### Primary study design
Observational

### Study type(s)
Diagnostic

### Health condition(s) or problem(s) studied
Healthy volunteers and patient volunteers of all conditions

### Interventions
Participants have one or more of the following samples taken at a single visit: sputum, blood, urine, nasal, stool or skin.

### Intervention Type
Other

### Primary outcome(s)
Sputum eosinophil counts in stable state measured using cytology at a single timepoint

### Key secondary outcome(s))

Sputum supernatant cytokines including IL-8 and TNF-α in stable state measured using immunoassay at a single timepoint

### Completion date
31/12/2030

## Eligibility

### Key inclusion criteria
1. Able to give written informed consent
2. Males and females aged over 18 years
3. Procedure specific criteria

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. History of anaemia or identified by haemocue test at screening or other clinically significant haematological disorders for blood donation
2. Current acute illness
3. Pregnancy or breastfeeding
4. History of Hepatitis B/C or HIV infection or a positive test at screen if required by the specific project
5. Volunteers who have donated to the blood transfusion service in the past 4 months, if applicable (applicable for blood donation or if specified for other procedures as per project-specific exclusion criteria)
6. Suspected use of drugs of abuse or positive drug screen, if required
7. Any contraindications for nasal sampling e.g. history of epistaxis, nasal defects, as assessed by the physician
8. Procedure-specific criteria and contraindications for performing the specific procedure
9. Any reason that the physician deems the subject not suitable to undertake the procedure(s)

### Date of first enrolment
07/05/2010

### Date of final enrolment
31/12/2029

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Medicines Evaluation Unit Limited**
The Langley Building
Southmoor Road
Wythenshawe
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# Sponsor information

**Organisation**
Medicines Evaluation Unit

**ROR**
https://ror.org/05e497m36

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are not expected to be made available due to the exploratory nature of the research and assays.

**IPD sharing plan summary**
Not expected to be made available