



The Newcastle upon Tyne Hospitals
NHS Foundation Trust



SUMMARY OF PARTICIPANT INFORMATION SHEET

**Immune response to Pneumococcal vaccination in older people
(ImmuneVac)**

Eligibility:

If you are a healthy individual aged 60 and above, you can participate in this study, either in Group 1 or Group 2.

Group 1: Vaccine + Blood only group

Visit 1:

Provide written consent and a blood sample.

Physical examination

Receive Pneumovax 23 vaccine.

Visit 2:

Around 7 days after your first visit.

Provide a blood sample.

Visit 3:

Around 28 days after your first visit.

Provide a blood sample.

Group 2: Vaccine + Blood + BAL group

Visit 1:

Provide written consent and a blood sample.

Physical examination

Visit 2:

Around 7 days after your first visit.

Provide a blood sample.

Have first Bronchoscopy (camera test) with lung washings (bronchoalveolar lavage, BAL)

Receive Pneumovax 23 vaccine.

Visit 3:

Around 7 days after your first Bronchoscopy.

Provide a blood sample.

Visit 4:

Around 28 days after your first Bronchoscopy.

Provide a blood sample.

Have second bronchoscopy with BAL

GDPR (General Data Protection Regulation) transparency

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data in case we need to check it **AND/OR** for future research.

We will make sure no one can work out who you are from the reports we write.

The information pack tells you more about this.

How will we use information about you?

- We will need to use information from you for this research project.
- This information will include your initials/ NHS number/ name/ contact details/ medical record number.
- People will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the sponsor of this research and is responsible for looking after your information.

We will share your information related to this research project with the following organisations:

- Oxford University
- University College London

The above-mentioned organisations would use your samples to run further laboratory tests, which are a part of this study.

We will keep all information about you safe and secure by:

- Ensuring all identifiable information is removed.
- Use a central portfolio management system to record the information.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

We will keep your study data for the minimum period required by this study and if you consent, for future studies. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records / your hospital / your GP. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to access, remove, change or delete data we hold about you for the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.
We will store your samples in dedicated temperature-controlled facilities in our lab and the biobank at Newcastle University. The data will be stored securely via an appropriate central portfolio management system.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by reading a leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to nuth.dpo@nhs.net