

Healthy Volunteer Participant Information Sheet- Version 13 – 19 December 2023
IRAS ID: 55396
Study Number: 05424

Information for potential research participants - Healthy Volunteers

The development of an *in vitro* human skin explant safety assay for the detection of immunogenicity and hypersensitivity reactions to novel compounds and drugs.

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear to you or of you would like more information. Take time to decide whether or not you wish to take part. Thank you for considering to participate in this study.

Why have I been chosen?

We need samples of normal skin from healthy adults to test the safety of new drugs and compounds in order to predict and prevent adverse reactions. This will increase the number of drugs available to treat diseases such as autoimmune disease and inflammatory disorders. New tests would also reduce the need for extensive animal testing and will help in safety testing of new compounds. These tests can be used for a variety of uses including cosmeceuticals i.e. cosmetic compounds with biological activity. Alcyomics tests can also be used to test the safety of new cellular anti-viral therapies using your blood and skin samples. You are being approached because you have seen the poster about this research and would like further information.

What is the purpose of the study?

Research within a spin out company from the University and NHS Trust, Alcyomics, is looking at ways to predict the safety of new drugs and prevent adverse and/or hypersensitivity reactions. Some of these hypersensitivity reactions can also be caused by therapies using cells and Alcyomics technology can help to identify these.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form and complete a health questionnaire. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

If you give consent we will take a 70ml blood sample from you at your first clinic visit which will include screening for common viruses and HLA (Human Leucocyte Antigen) genotypes. The blood samples given will **not** be used for medical testing for assessment of your health. We will take two 4mm skin biopsies from the abdomen or buttocks either at the first or second visit. This is done with local anaesthetic and will require a small stitch and will leave a small scar after the skin biopsy. You will be requested to return to the clinic one week after the biopsy has been taken in order to have the stitch removed. We will do tests in the laboratory on these samples. We may also ask you if you have any known allergies, this information will be used to aid our research. No identifying information about you will be given to the researchers. You will have the option to agree to consent to provide further study samples at the sponsor's request. This is entirely voluntary. A maximum of 3 sets of skin punch biopsies (2 biopsies per set) and 3 further 70ml blood samples may be taken after a minimum of 7-14 days from the previous blood collection date.

What will happen to my samples if I take part in the study?

After the samples have been tested, they will normally be destroyed, or used for future research if you have given your permission for this, subject to relevant Ethical and Regulatory approvals. Tissue will be destroyed in accordance with the Newcastle Upon Tyne Hospitals NHS Foundation Trust Human Tissue Policy for Research and the Human Tissue Authority (HTA) Code of Practice and Standards.

What are the possible disadvantages and risks of taking part?

Taking the blood sample is uncomfortable but not harmful. There is always a small risk of bleeding or infection when we take the skin biopsy – similar to as if you cut yourself accidentally. It might be a little uncomfortable for a couple of days.

Healthy Volunteer Participant Information Sheet- Version 13 – 19 December 2023

IRAS ID: 55396

Study Number: 05424

What are the possible benefits of taking part?

We do hope that the study will develop innovative tests to aid in the reduction of animal testing; enable drugs to get to the clinic faster and safely and predict adverse reactions in patients.

In acknowledgement of your participation in the study, Alcyomics Ltd will issue participants with a gift/shopping as a thank you for their contribution to the study. A £25.00 voucher will be offered for blood samples only (when participants are not able to donate skin biopsy samples). A £50.00 voucher will be offered for skin biopsies (x2) and 1x blood sample.

Will my taking part in this study be kept confidential?

Yes all the Information collected will be kept confidential. If you decide to participate we will document this in your medical notes. Your confidentiality will be maintained by keeping the data you have provided on a secure password protected NHS database. Samples that we take will be labelled with a 'unique patient number' but without your personal details. The Laboratory staff and research team will not be given any identifying information about you.

What will happen to the results of the research study?

Alcyomics may publish the study in a scientific journal or it may be presented at a scientific meeting in a completely anonymous way. No-one will be able to identify anything about you from our reports.

Publications and or updates of the research will be available on the Alcyomics website (www.Alcyomics.com).

What happens if there is a commercial product developed from the study?

One aim of the study is to develop new patents and we hope that your samples will enable us to evaluate these new tests. Once evaluated, they may be made into commercial kits for use to the pharmaceutical industry. You will not have any rights over any commercial products that are developed as a result of the study.

Your samples may be used by Alcyomics in collaboration with a large pharmaceutical company (e.g. Pfizer) for industrial research purposes. Your samples will be used for commercial gain and may be sent to third parties (commercial).

Who is organising and funding the research?

The research is funded by Alcyomics Ltd and contracts from the pharmaceutical industry. Your doctor will not be paid for including you in this study.

Are there any GDPR issues for me to consider before I take part?

Yes. The information you provide through your questionnaire will be gathered by Alcyomics to check your eligibility for the study. The Alcyomics Privacy policy can be found [here](#). You can stop being part of the study at any time without giving a reason and the data that Alcyomics have on file will be removed however the NHS team will have to keep your information on file Please note that Alcyomics only has access to the information given by yourself at the time of signing up, they do not hold any medical information held on the NHS systems.

What personal data will be obtained in this study?

Alcyomics Ltd is the Data Controller for this study and will collect information from you that is required to check eligibility for the study. Alcyomics will not have any access to your personal medical records.. The Newcastle Hospitals NHS Foundation Trust (NuTH) will keep your name, NHS number and contact details address and telephone number. NuTH will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from regulatory organisations may look at your medical and research records to check the accuracy of the research study. When Alcyomics Ltd. Receive the sample from yourselves there will be nothing that can identify who it has come from.. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

NuTH will keep identifiable information about you from this study for 5 years after the study has finished.

Healthy Volunteer Participant Information Sheet- Version 13 – 19 December 2023
IRAS ID: 55396
Study Number: 05424

Dispute Resolution, Complaints and Contact for use of Personal Data

If you have any complaints or disputes about the study or your treatment, please contact the sponsor using the email address: anne.m.dickinson@alcyomics.com

If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:
Telephone: 0191 223 1382 or 0191 223 1454
Email: nuth.patient.relations@nhs.net
Address: Patient Relations Department
The Newcastle upon Tyne Hospitals NHS Foundation Trust
The Freeman Hospital
Newcastle upon Tyne
NE7 7DN

Who has reviewed this study?

The local Ethics Research Committee has reviewed and approved this study.

Contact for further information

Research nurse or a member of the clinical team Tel: (0191) 28 23568
Professor Anne Dickinson Tel: (0191) 5806157

You will be given a copy of the information sheet and a signed consent form which you may wish to keep. If you wish to have any further information about the study or Alcyomics please contact Anne Dickinson at anne.m.dickinson@alcyomics.com and or visit Alcyomics website, www.alcyomics.com