

Healthy Volunteer Consent Form- Version 12 – 21 December 2023

IRAS ID: 55396

Study Number: 05424

Participant Specific Identification Number:

CONSENT FORM- Healthy Volunteer

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

Chief Investigator: Anne Dickinson

Name of Researcher:

By signing below, I show that:

Please all initial boxes

1. I confirm that I have read the information sheet for <i>Healthy Volunteers</i> dated 03 July 2020 (version 12) for the above study. I have had the opportunity to consider the information, ask questions and these questions have been answered satisfactorily.	
2. I give permission for DNA samples, and therefore genetic studies and tissue obtained during the study, to be stored and used for future research. Future research will be subject to approval by a research ethics committee.	
3. I give permission for my samples to be used in other future related studies (given relevant approval) and I have read the information sheets concerned with these other related Projects.	
4. I give permission for my samples to be used by research collaborators outside of Newcastle.	
5. I give permission for my blood sample to be screened for commonly occurring Viruses and common HLA genotypes	
6. I understand that my participation is voluntary and that I am free to withdraw at any time and have my samples discarded, without giving any reason, without my medical care or legal rights being affected.	
7. I agree that my tissue may be transferred to other commercial companies who may use it in research for commercial gain, including a large pharmaceutical company (e.g. Pfizer), for industrial research.	
8. I understand that parts of my medical notes and information collected during the study may be looked at by responsible people. I give my permission for these people to have access to my medical records. This includes people from the study sponsor, regulatory authorities and local NHS Trust where it is relevant to my taking part in research.	
9. I agree to take part in the above study.	

Please check “Yes” or “No”. You may participate in this study regardless of your responses to the below statement.

I agree to be contacted in the future for the purpose of requesting consent for further clinical investigation and biological samples from me (up to a maximum of 3 skin biopsies and 3 further 70ml blood samples). I understand that this part of the study is entirely optional.

YES

NO

Name of Participant

Date

Signature

Name of Person
taking consent

Date

Signature

This section to only be completed in person at the time of procedure:

I confirm my voluntary participation in the Alcyomics study. I have reviewed the information previously provided, understand the nature of the study and willingly consent to continue my involvement.

Name of Participant

Date

Signature

Name of Person
taking consent

Date

Signature