

The MELODY Study



Mass evaluation of lateral flow immunoassays (at home finger prick antibody tests) for the detection of SARS-CoV-2 antibody responses in immunosuppressed people

PRIVACY NOTICE FOR SOLID ORGAN TRANSPLANT RECIPIENTS

What is the purpose of this study?

This is an antibody research study. Antibodies are made by the immune system to fight infection. In this study, we aim to

1. Assess how many immunocompromised people have detectable antibodies against COVID-19 following at least 3 vaccines.
2. Investigate whether lack of detectable antibodies are associated with risk of infection over a 6-month period.
3. Investigate what factors are associated with lack of detectable antibodies in immunocompromised people, e.g. the type of immunosuppressant medication you receive.

At this time, antibody testing results should not be used to alter individual behaviour as there is still a lot to learn about this virus. A positive test does not mean that you are fully protected from getting COVID-19 or passing on the virus, and a negative test does not mean you do not have antibodies that may provide protection against COVID-19. Whatever your test result, it is important that you continue to follow the current Government advice on www.gov.uk.uk/coronavirus.

Why are we processing your personal data?

We process information to enable us to undertake research and development to improve patient outcomes. We will only collect information that is essential for the purpose of the research.

Who is included in this study?

The study involves two different groups – people who have received a solid organ transplant and people with either rare autoimmune diseases or a diagnosis of blood cancer. This privacy notice is an update for patients who have received a solid organ transplant only as no new data linkage is to be undertaken for patients with autoimmune disorders/ cancers.

How did you identify and contact me?

NHS Blood & Transplant (NHSBT) have a record of everyone in England who has received a solid organ transplant.

With permission from the Health Research Authority's Confidentiality Advisory Group, NHSBT transferred the NHS numbers of solid transplant recipients to NHS Digital (now NHS England).

Using the NHS numbers, NHS Digital were able to retrieve the names and addresses of organ transplant recipients and share them with Ipsos Mori– an independent research organisation. Ipsos Mori were not given any information about your health.

What data do you have about me?

We collected some details about you, including your name, age, gender, and ethnicity, we also asked for your address.

We asked for details of any vaccinations you may have had for COVID-19. We asked you about your home and work life, your health, your thoughts on COVID-19 and antibody testing. We also asked you specific questions about your medical condition(s) and treatments.

Confidentiality

It is extremely important to us that we maintain your confidentiality about taking part in this study. All information collected about you will be used and stored securely to protect and respect your identity. Your data (the information collected about you) will be given a unique study number to make sure you cannot be identified from your data. Only the Research Team at NHS Blood and Transplant or NHS Digital will be able to match your name to the unique study number, if it is necessary to do so.

Your name will not be shared outside the Research Team. We confirm that your personal data will never be available to the general public in any circumstances. The results of this research are likely to be published but will not contain any personal information which could identify you.

What will happen with the information I provide?

As a transplant patient, Imperial College London and NHS BT are joint data controllers throughout the study, which means that they are responsible for ensuring that the processing complies with the General Data Protection Regulation (GDPR).

If you consented to data linkage, NHS Blood and Transplant aim to link your data with NHS Digital and UKHSA using your NHS Number and date of birth to obtain information on COVID-19 infection, hospital admissions relating to COVID-19, and any COVID-19 therapeutics prescribed within 6 months of the antibody test undertaken for the study.

If you have had a transplant and you consented to being contacted for future research, and/or you agreed for the results of this study to be linked to other health

information that the NHS holds about you (e.g. GP health records), NHS Blood and Transplant may keep your data for up to 10 years in order to support this research.

Researchers who wish to access the data from this study and/or to contact participants about future research will need to have a legitimate reason to do so, the approval of a Research Ethics Committee and will have to apply to a data access committee composed of at least 3 of the study investigators (from NHS Blood and Transplant, NHS Digital and Imperial College London), and at least one public representative. For the data held in NHS Digital, data releases will be managed by the Data Access Request Service (DARS).

Legal Basis

We use personally identifiable information during this study to conduct research to improve health, care and services.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#).

Our legal basis for using your information under General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- performance of a task carried out in the public interest” (Article 6(1)(e) in the GDPR).
- Where special category personal information is involved, we rely on “scientific or historical research purposes or statistical purposes (Article 9(2)(j) in accordance with Article 89(1) in the GDPR”.

Data is shared by NHS Digital to NHS BT only if you have consented to data linkage in the survey, this data will be shared under your consent.

Do you share my information with others?

If you consent to be re-contacted, NHS Digital and NHS Blood and Transplant may share your personal data with certain researchers as outlined above. Any research study would require full ethical approval.

What are my choices about how my information is used?

You can stop taking part in the study at any time, without giving a reason, however once your data has been included with the rest of the study data and analysed, it is not possible to remove your specific data from the results.

There is also a National Data Opt-out, which means that you can opt out of your confidential patient information being shared by NHS Digital for purposes except your own care - either GP data, or other data we hold, such as hospital. Information about the National Data Opt-out can be found [here](https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/general-practice-data-for-planning-and-research/transparency-notice#where-we-store-patient-data): <https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/general-practice-data-for-planning-and-research/transparency-notice#where-we-store-patient-data>.

The National Data Opt-outs were applied to the MELODY study.

How do I know that my data is being kept safe by NHS Digital and NHS Blood and Transplant?

NHS Digital and NHS Blood and Transplant take their information security responsibilities seriously and apply various precautions to ensure your information is protected from loss, theft or misuse. Security precautions include appropriate physical security of offices and controlled and limited access to computer systems.

Where can I find out more about how my information is used?

You can find out more about how your information is used at www.hra.nhs.uk/information-about-patients

How to make a complaint

If you wish to raise a complaint on how we have handled your personal data, please contact:

Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on **020 7594 3502** and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

NHS Digital's Data Protection Officer, Kevin Willis via email nhsdigital.dpo@nhs.net

NHS Blood and Transplant's Data Protection Officer, Janet Kidd, via informationgovernanceteam@nhsbt.nhs.uk

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (Imperial College London) first before involving the regulator.

Thank you for taking part in this research.